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Federal Register
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FEDERAL ELECTION COMMISSION

11 CFR Part 111

[Notice 2004–5]

Extension of Administrative Fines Program

AGENCY: Federal Election Commission.

ACTION: Final rule and transmittal of regulations to Congress.

SUMMARY: Section 639 of the Fiscal 2004 Omnibus Consolidated Appropriations Act ("2004 Appropriations Act") amended the Treasury and General Government Appropriations Act, 2000, by extending the expiration date in which the Federal Election Commission ("Commission") may assess civil monetary penalties for violations of the reporting requirements of section 434(a) of the Federal Election Campaign Act ("Act" or "FECA"). Accordingly, the Commission is extending the applicability of its rules and penalty schedules in implementing the administrative fines program ("AFP"). Further information is provided in the **SUPPLEMENTARY INFORMATION** that follows.

EFFECTIVE DATE: February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Mai T. Dinh, Acting Assistant General Counsel, or Mr. Daniel E. Pollner, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Explanation and Justification for 11 CFR 111.30

Section 640 of the Treasury and General Government Appropriations Act, 2000, Pub. L. No. 106–58, 106th Cong., 113 Stat. 430, 476–77 (1999), amended 2 U.S.C. 437g(a)(4) to provide for a modified enforcement process for violations of certain reporting requirements. Under 2 U.S.C. 437g(a)(4)(C), the Commission may assess a civil monetary penalty for violations of the reporting requirements of 2 U.S.C. 434(a). This authority, however, terminated on December 31, 2003. *See* Pub. L. No. 107–67, 107th Cong., 640(c). Recently, section 639 of the 2004 Appropriations Act amended the Treasury and General Government Appropriations Act, 2000, by extending the sunset date to include all reports that cover activity between July 14, 2000 and December 31, 2005. Accordingly, the Commission is issuing this final rule to amend section 11 CFR 111.30 to renew the applicability of the administrative fines regulations, 11 CFR part 111, subpart B, to include all violations relating to reports that cover the period between July 14, 2000 and December 31, 2003 and the period between the date that this final rule is published in the **Federal Register** and December 31, 2005.

Until the 2004 Appropriations Act was enacted, the Commission did not have the authority to extend the AFP beyond December 31, 2003. Consequently, there is a gap in the applicability of the AFP from January 1, 2004 to February 10, 2004. All reports covering reporting periods that began and ended during this gap and that are due before February 11, 2004, the effective date of this final rule, are not subject to the AFP. This includes certain 48-hour reports and pre-election reports. These reports are, however, subject to the Commission's enforcement procedures set forth at 11 CFR subpart A. *See* 11 CFR 111.31(a).

The Commission notes that Congress, in extending the Commission's AFP authority, provided for continuous applicability of the AFP through December 31, 2005. Moreover, the AFP is procedural; the underlying substantive reporting requirements have remained continuously in effect. Consequently, it is appropriate to apply the AFP to reports that are due after February 10, 2004 even though those reports may relate to reporting periods that include the gap.

The Commission is promulgating this final rule without notice or an opportunity for comment because it falls under the "good cause" exemption of the Administrative Procedures Act, 5 U.S.C. 553(b)(3)(B). This exemption allows agencies to dispense with notice and comment if the procedures are "impracticable, unnecessary, or contrary to public interest." *Id.* This final rule satisfies the "good cause" exemption because a notice and comment period is impracticable in that it would prevent this final rule from taking effect without an even larger gap in the applicability of the AFP. *See Administrative Procedures Act: Legislative History*, S. Doc. No. 248 200 (1946) (" 'Impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings"). In addition, this final rule merely extends the applicability of the AFP and does not change the substantive regulations themselves. Those regulations were already subject to notice and comment when they were proposed in March 2000, 65 FR 16534, and adopted in May 2000, 65 FR 31787, and again when substantive revisions to the AFP were proposed in April 2002, 67 FR 20461, and adopted in March 2003, 68 FR 12572. Thus, it is appropriate and necessary for the Commission to publish this final rule without providing a notice and comment period.

The Commission is making this final rule effective immediately upon publication in the **Federal Register** because it falls within the "good cause" exception to the thirty-day delayed effective date requirement set forth at section 553(d)(3) of the Administrative Procedures Act. *See* 5 U.S.C. 553(d)(3). The same reasons that justify the promulgation of this final rule without a notice and comment period, which are set forth above, also justify making this final rule effective without the thirty-day delay. Moreover, making this final rule effective immediately upon publication in the **Federal Register** is justified because a thirty-day delay of the effective date would increase the gap in the AFP.

The Commission is submitting this final rule to the Speaker of the House of Representatives and the President of the Senate pursuant to the Congressional Review of Agency Regulations Act, 5 U.S.C. 801(a)(1)(A), on February 6, 2004. Since this is a non-major rule, it is not subject to the delayed effective date provisions of 5 U.S.C. 801(a)(3).

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

The attached final rule will not have a significant impact on a substantial number of small entities. The basis for this certification is that this final rule merely extends the applicability of existing regulations for two more years. The existing regulations have already been certified as not having a significant economic impact on a substantial number of small entities. 65 FR 31793 (2000). Therefore, the extension of these existing regulations will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 11 CFR Part 111

Administrative practice and procedures, Elections, Law enforcement.

■ For the reasons set out in the preamble, subchapter A, chapter I of title 11 of the Code of Federal Regulations is amended as follows:

PART 111—COMPLIANCE PROCEDURES (2 U.S.C. 437g, 437d(a))

■ 1. The authority for part 111 continues to read as follows:

Authority: 2 U.S.C. 437g, 437d(a), 438(a)(8); 28 U.S.C. 2461 nt.

■ 2. 11 CFR 111.30 is revised to read as follows:

§ 111.30 When will subpart B apply?

Subpart B applies to violations of the reporting requirements of 2 U.S.C. 434(a) committed by political committees and their treasurers that relate to the reporting periods that begin on or after July 14, 2000 and end on or before December 31, 2005. This subpart, however, does not apply to reports that are due between January 1, 2004 and February 10, 2004 and that relate to reporting periods that begin and end between January 1, 2004 and February 10, 2004.

Dated: February 5, 2004.

Bradley A. Smith,

Chairman, Federal Election Commission.

[FR Doc. 04–2845 Filed 2–10–04; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 222

FEDERAL TRADE COMMISSION

16 CFR Part 602

[Regulation V; Docket Nos. R–1172 and R–1175; and Project No. PO44804]

RIN 3084–AA94

Effective Dates for the Fair and Accurate Credit Transactions Act of 2003

AGENCIES: Board of Governors of the Federal Reserve System (Board) and Federal Trade Commission (FTC).

ACTION: Joint final rules.

SUMMARY: The recently enacted Fair and Accurate Credit Transactions Act of 2003 (FACT Act or the Act) requires the Board and the FTC (the Agencies) jointly to adopt rules establishing the effective dates for provisions of the Act that do not contain specific effective dates. The Agencies are adopting joint final rules that establish a schedule of effective dates for many of the provisions of the FACT Act for which the Act itself does not specifically provide an effective date. The Agencies also are jointly making final rules that previously were adopted on an interim basis. Those rules establish December 31, 2003, as the effective date for provisions of the Act that determine the relationship between the Fair Credit Reporting Act (FCRA) and state laws and provisions that authorize rulemakings and other implementing action by various agencies.

EFFECTIVE DATE: Effective on March 12, 2004.

FOR FURTHER INFORMATION CONTACT:

Board: Thomas E. Scanlon, Counsel, Legal Division, (202) 452–3594; David A. Stein, Counsel, Minh-Duc T. Le, Ky Tran-Trong, Senior Attorneys, Krista P. DeLargy, Attorney, Division of Consumer and Community Affairs, (202) 452–3667 or (202) 452–2412; for users of Telecommunications Device for the Deaf ("TDD") only, contact (202) 263–4869.

FTC: Christopher Keller or Katherine Armstrong, Attorneys, Division of Financial Practices, (202) 326–3224.

SUPPLEMENTARY INFORMATION:

I. Background

The FACT Act became law on December 4, 2003. Pub. L. 108–159, 117 Stat. 1952. In general, the Act amends the FCRA to enhance the ability of consumers to combat identity theft, to increase the accuracy of consumer reports, and to allow consumers to exercise greater control regarding the type and amount of marketing solicitations they receive. The FACT Act also restricts the use and disclosure of sensitive medical information. To bolster efforts to improve financial literacy among consumers, title V of the Act (entitled the "Financial Literacy and Education Improvement Act") creates a new Financial Literacy and Education Commission empowered to take appropriate actions to improve the financial literacy and education programs, grants, and materials of the Federal government. Lastly, to promote increasingly efficient national credit markets, the FACT Act establishes uniform national standards in key areas of regulation.

The Act includes effective dates for many of its sections that vary to take account of the need for rulemaking, implementation efforts by industry, and other policy concerns. Section 3 of the FACT Act requires the Agencies to prescribe joint regulations establishing an effective date for each provision of the Act "[e]xcept as otherwise specifically provided in this Act and the amendments made by this Act." The FACT Act requires that the Agencies jointly adopt final rules establishing the effective dates within two months of the date of the enactment of the Act. Thus, by law, the Agencies must complete these rulemaking efforts by February 4, 2004. The Act also provides that each of the effective dates set by the Agencies must be "as early as possible, while allowing a reasonable time for the implementation" of that provision, but in no case later than ten months after the date of issuance of the Agencies' joint final rules establishing the effective dates for the Act. 117 Stat. 1953.

In mid-December of 2003, the Agencies took two related actions to comply with the requirement to establish effective dates for the Act. In the first action, the Agencies implemented joint interim final rules that establish December 31, 2003, as the effective date for sections 151(a)(2), 212(e), 214(c), 311(b), and 711 of the FACT Act, each of which determines the relationship of State laws to areas governed by the FCRA. *See* 68 FR 74467 (Dec. 24, 2003). In the second action, the Agencies proposed joint rules that would establish a schedule of effective dates for certain other provisions of the FACT Act for which the Act itself does not specifically provide an effective date. *See* 68 FR 74529 (Dec. 24, 2003). The Agencies sought comment on both of these related actions.

II. Overview of the Comments Received

The Agencies collectively received more than 50 comments in response to the joint interim final and proposed rules; many commenters sent copies of the same letter to each of the Agencies and submitted separate comments on both the joint interim final and proposed rules.[1] Most of the comments were submitted by financial institutions and associations that represent financial institutions. Other comments were submitted by the National Association of Attorneys General and by groups that represent consumers, including the Consumer Federation of America. Three members of Congress also submitted comments in response to the Agencies' joint interim and proposed rules.

Overall, commenters supported the Agencies' approach to establish effective dates in a bifurcated structure that distinguished the provisions that require immediate effective dates (primarily those that relate to state laws) from the other provisions of the FACT Act. The comments also expressed support for the Agencies' joint proposal to establish a schedule of effective dates that would make certain provisions effective as early as March 31, 2004, and others effective December 1, 2004. Commenters focused on two main issues: first, with respect to the Agencies' joint interim final rules, commenters raised concerns about establishing December 31, 2003, as the effective date for the preemption provisions of the FCRA, as amended by the FACT Act; and second, commenters raised concerns about establishing December 1, 2004, as the effective date for section 214(a) of the FACT Act, which relates to using information for making solicitations to a consumer. After reviewing the comments received, the Agencies have determined to make final the joint interim rules and have modified the joint proposed rules in certain respects, as discussed below.[2]

III. Section-by-Section Analysis

In the supplementary information to the joint interim final rules, the Agencies addressed the effective dates for certain provisions of the FACT Act that require one or more agencies to undertake an action or rulemaking within a specified period of time after enactment of the Act. 68 FR 74468. The Agencies determined that no joint regulations under section 3 of the FACT Act are required to make these provisions effective. The Agencies found that, in these cases, the date of enactment of the statute is specified as the lawful effective date because that is the predicate for mandating that an agency action be performed within a period of time after the date of enactment. The commenters addressing this determination supported the Agencies' finding and interpretation under section 3 with respect to these provisions of the Act. The Agencies have not established in these joint final rules the effective dates that apply to these provisions of the Act.

Section__.1(c)(1)(i): Provisions that relate to State laws

The Agencies received several comments on the joint interim final rules that establish December 31, 2003, as the effective date for the provisions of the FACT Act that make permanent the existing preemption provisions of the FCRA and add others.

Overall, commenters supported the Agencies' determination that a final rule should be prescribed immediately to implement December 31, 2003, as the effective date for paragraph (3) of section 711 of the FACT Act. That section eliminates the so-called sunset provision and thus makes permanent the current provisions preempting State laws in seven areas regulated under the FCRA.

Commenters presented several different views on the Agencies' joint interim final rule that also establishes December 31, 2003, as the effective date for paragraph (2) of section 711 of the Act. This sub-provision amends the FCRA by providing that no requirement or prohibition may be imposed by the laws of any State "with respect to the conduct required by the specific provisions of" nine sections of the FCRA, as amended by the FACT Act. Several commenters argued that the effective dates for the new preemption provisions added in paragraph (2) should be linked with the effective dates of the substantive provisions of the Act.[3] These commenters argued that, if the FACT Act provisions are read to preempt existing State laws prior to the time that the FACT Act provisions are actually implemented, then consumers who reside in several States may be deprived of the protections under State laws before the Federal protections become effective.

Other commenters argued in contrast that the Agencies should clarify that the FACT Act provisions preempt State laws immediately and without regard to when the underlying Federal provision becomes effective.[4] These commenters contended that it would be costly and confusing to delay the preemptive effect of the FACT Act provisions and thereby subject financial institutions, consumer reporting agencies, and others to State law requirements for the brief period of time until rules implementing the Federal provisions become effective.

The Agencies are required by section 3 of the FACT Act to establish effective dates for various provisions of the FACT Act, and to set those dates not later than 10 months after the issuance of the final joint rules. When and whether State laws are preempted by these provisions of the FACT Act is determined by each specific provision of the FACT Act and the provisions of the FCRA that the FACT Act amends. In establishing December 31, 2003, as the effective date for the provisions of the FACT Act that address the relation to State laws, the Agencies did not determine when or whether any particular State law was or would be preempted.

After review of the comments, the Agencies adopt section __.1(c)(1)(i) as set forth in the interim rules.

The Agencies note that section 711(2) of the FACT Act adds a new provision to the FCRA that bars any requirement or prohibition under any State laws "*with respect to the conduct required by* the specific provisions" of the FCRA, as amended by the FACT Act. The joint final rules are based on the Agencies' view that the specific protections afforded under the FCRA override State laws only when the referenced Federal provisions that require conduct by the affected persons are in effect because that is the time when conduct is required by those provisions of the FCRA. Similarly, section 151(a)(2) of the FACT Act adds a new provision to section 625(b)(1) of the FCRA that preempts any State law "*with respect to any subject matter regulated under*" that provision. Only when a Federal provision is in effect does the subject matter become regulated under that section and, consequently, State law preempted.[5] In both of these situations,

[1] Comments submitted to the Commission can be found at *http://www.ftc.gov/os/comments/factactcomments/index.html;* for the Board, *http://federalreserve.gov/generalinfo/foia/index.cfm?doc_id=R%2D1175&ShowAll=Yes* and *http://federalreserve.gov/generalinfo/foia/index.cfm?doc_id=R%2D1172&ShowAll=Yes*

[2] The Agencies note that the citations used in the discussion below refer to the subsections of their respective regulations, leaving citations to the part number used by each agency blank.

[3] *See* Nat'l Assoc. of Attorneys General, Consumer Federation of America, *et al.*, Privacy Rights Clearinghouse, Senators Paul S. Sarbanes and Dianne Feinstein, and Representative Barney Frank.

[4] *See, e.g.*, Bank of America, FleetBoston Financial Corp., Financial Services Roundtable, Visa USA, Inc., and Wells Fargo & Co.

[5] Identical language in the FCRA prefaces the preemption provisions established in sections 214(c) and 311(b) of the FACT Act, and similar

Continued

the Agencies believe that a requirement that applies under an existing State law will remain in effect until the applicable specific provision of the FCRA, as amended by the FACT Act, becomes effective. Consequently, because the substantive Federal provisions actually will become effective at different times, from six months to three years after the FACT Act was enacted, establishing December 31, 2003, as the effective date for the preemption provisions would allow the State law to continue in effect until the respective Federal protections underlying each of the Federal preemption provisions comes into effect.

Section ____.1(c)(1)(ii): Provisions relating to agency action

In the joint interim final rules, the Agencies determined that December 31, 2003, is the effective date for each of the provisions of the FACT Act that authorizes an agency to issue a regulation or to take other action to implement the applicable provision of the FACT Act or of the FCRA. This subsection of the joint interim final rules limited the immediate effective date only to an agency's authority to propose and adopt the implementing regulation or to take such other action. In reaching that determination, the Agencies explained that joint interim final rules would not affect the substantive provisions of the FACT Act implemented by an agency rule.

Commenters supported the Agencies' finding and determination to establish an immediate effective date for the provisions of the Act that relate to an agency's authority to issue a regulation or take other action. After review of the comments received and for the reasons set forth in the joint interim final rules, the Agencies adopt section __.1(c)(1)(ii) as set forth in the interim rules. The Agencies reassert the position that the substantive provisions of the Act become effective as provided in the Act, as provided in the Agencies' joint effective date rules, or as provided by the substantive rules promulgated by the agencies, as appropriate.

Section ____.1(c)(2): Provisions effective March 31, 2004

As the Agencies observed in the joint proposal, the FACT Act contains a number of provisions that clarify or address rights and requirements under the FCRA that are self-effectuating but that do not contain a specific effective date. These provisions are: Section 156 (statute of limitations); sections 312(d) (furnisher liability exception), (e) (liability and enforcement), and (f) (rule of construction); section 313(a) (action concerning complaints); section 611 (communications for certain employee investigations); and section 811 (clerical amendments). Section 111 (amendment to definitions) contains definitions that are self-effectuating but that do not contain specific effective dates. The Agencies proposed to establish March 31, 2004, as the effective date for each of the provisions of the Act listed above.

Overall, commenters supported the Agencies' proposal to establish March 31, 2004, as the effective date for these provisions. Many of the commenters specifically stated that the proposed effective date is appropriate for each of these provisions and would allow a reasonable period of time for affected entities to adjust or develop their systems to comply with the applicable requirements. For example, one financial institution observed that these provisions should not require significant changes to existing business practices conducted by financial institutions.[6]

One commenter argued that the Agencies should establish a later effective date for section 111 of the Act, which relates to certain definitions for the FCRA.[7] This commenter argued that section 111 designates a new type of consumer reporting agency, defined as a "reseller," that is specifically exempted from certain requirements that generally apply to all consumer reporting agencies. Under the Agencies' proposed rule, the definition of "reseller" would be effective earlier than the provisions that exempt a "reseller" from certain obligations, which would be effective on December 1, 2004. The commenter believed that, during that intervening period a "reseller" may be subject to certain requirements under the FCRA, but unable to avail itself of an exemption until the applicable statutory provision added by the FACT Act later becomes effective.

The Agencies have established March 31, 2004, as the effective date for section 111 as proposed. Establishing the effective date for section 111, which includes only definitions of terms used throughout the new provisions of the FCRA added by the FACT Act, does not impose any substantive obligation on a "reseller" or others referenced in that section. All the obligations, if any, are imposed by the substantive provisions of the FACT Act and FCRA, which become effective according to the terms of the applicable statutory provision, the Agencies' joint rules, or as provided by the substantive implementing regulation by an agency, as appropriate. The Agencies also believe that establishing a relatively early effective date for all of the definitions set forth in section 111 is appropriate because the new terms apply to a variety of statutory provisions and implementing regulations that become effective at various times.

One commenter urged the Agencies to adopt a later effective date for section 156 of the Act, which pertains to the statute of limitations.[8] Relative to the time periods that currently apply to actions involving violations of the FCRA, section 156 extends the statute of limitations to permit a plaintiff to bring an action in an appropriate court not later than the earlier of (1) two years after the date of discovery by the plaintiff of the violation or (2) five years after the date on which the violation that is the basis for such liability occurs. This commenter argued that the "extended statute of limitations for many causes of action will require users of consumer reports and others to reevaluate and alter their recordkeeping systems in order to retain the appropriate documents and other information that may be necessary for use in future causes of action."

The Agencies recognize that financial institutions and others undoubtedly will be affected by the amendment to the statute of limitations. Nevertheless, the Agencies find, upon review of all of the comments received on the proposal, that the potentially adverse effects that may arise due to a three-month implementation period (following the date of the Agencies' proposal) are minimal. In light of the mandate in section 3 of the Act to "establish effective dates that are as early as possible, while allowing a reasonable time for the implementation of the provisions of this Act," the Agencies have determined that March 31, 2004, is a reasonable effective date for section 156.

Upon review of the comments received on the other provisions of the Act subject to this part of the joint proposal, the Agencies believe that the "reasonable time to implement" standard of section 3 of the Act permits an early effective date because, in general, these provisions do not require significant changes to business procedures. Furthermore, the Agencies note that the commenters did not disagree with the Agencies' preliminary view that each of these provisions furnishes important benefits to consumers and affected businesses. The

language prefaces the preemption provision established in section 212(e).

[6] Capital One Financial Corp.

[7] Countrywide Financial Corp.

[8] MasterCard Int'l.

Agencies find that March 31, 2004, is an appropriate date that balances the statutory mandate to effectuate provisions of the Act "as early as possible" while allowing a reasonable time for the implementation of the provisions described in this part of the joint proposal.

Section ____.1(c)(3): Provisions effective December 1, 2004

In general, commenters supported the Agencies' proposal to establish December 1, 2004, as the effective date for provisions that require changes in systems, disclosure forms or practices, or implementing regulations to be administered effectively. With a few exceptions discussed below, the commenters stated that allowing the maximum time permitted under section 3 of the Act for these provisions to become effective is appropriate and would allow a reasonable period of time for affected entities to adjust or develop their systems to comply with the applicable requirements.

Many commenters expressed concerns about the Agencies' proposal to establish December 1, 2004, as the effective date for section 214(a) of the Act, which creates a new section 624 of the FCRA.[9] This new section sets forth a special rule that applies to the use of information by an affiliate for making solicitations to a consumer. Commenters argued, in general, that the Agencies' proposed effective date would be inconsistent with the time frame contemplated by the statute itself for implementing this provision. Commenters observed that section 214(b) of the FACT Act provides that regulations "*to implement* section 624 of the [FCRA]" must be prescribed no later than September 4, 2004, and those implementing regulations must become effective not later than six months thereafter. Commenters noted that aligning the effective date of the statutory provision with the time frame for prescribing the applicable regulations for that provision would, as a practical matter, assist companies to coordinate the notices to consumers required by this new law with their other notices, such as their privacy notices required by the Gramm-Leach-Bliley Act.[10]

Based on the comments received on the joint proposal, the Agencies have reconsidered whether it is necessary for the Agencies to establish an effective date for section 214(a) under section 3 of the FACT Act. Section 624(a)(5) of the FCRA, as added by section 214(a) of the FACT Act, restricts the use of customer information shared by a financial institution with its affiliate. That section also specifically provides that "[t]his subsection shall not prohibit the use of information to send a solicitation to a consumer if such information was received prior to the date on which persons are required to comply with regulations implementing this subsection." As noted above, subsection 214(b) establishes specific dates for the issuance and effectiveness of the implementing regulations for section 214(a). The Agencies believe that this "no-retroactivity" paragraph, which specifically references the date of the rules adopted under section 214(b), inextricably connects the underlying obligations imposed by section 214(a) with the effective date(s) specifically set by Congress in section 214(b). Read together, these provisions establish a specific effective date for the obligations in section 214(a).

Section 3 of the FACT Act mandates that the Agencies jointly establish effective dates for the provisions of the Act "[e]xcept as otherwise specifically provided in this Act and the amendments made by this Act." Because the obligations in section 214(a) are specifically referenced and directly connected to the rulemaking schedule specified in section 214(b), the Agencies believe Congress has established the effective date for section 214(a), which is the effective date of the rules implementing that section. Accordingly, the Agencies have determined that the Agencies are not required by section 3 of the FACT Act to establish an effective date for section 214(a) and that section becomes effective according to the schedule established by section 214(b).

The Agencies believe that the same analysis applies to sections 211(a) (concerning free consumer reports) and 216 (concerning the disposal of consumer report information and records). Each of these sections specifically references and depends upon the implementation of regulations that Congress has required be issued by specific dates.[11] Consequently, Congress has specified the effective dates of these sections to be the effective dates of the implementing rules, which must be completed by specific dates. For this reason, the Agencies believe that the Agencies are not required by section 3 of the FACT Act to set effective dates for section 211(a) or section 216. These sections will become effective on the dates that the implementing rules become effective. The FACT Act contains a number of other provisions without effective dates that would require changes in systems, disclosure forms or practices, or implementing regulations to be administered effectively. The Agencies have determined that December 1, 2004, is an appropriate effective date for all of the provisions included in subsection __.1(c)(3) of the joint proposed rules, except for sections 211(a), 214(a), and 216, as discussed above. Providing the full 10-month period permitted by the Act will allow industry and the various agencies a reasonable time to establish systems and rules to implement these sections effectively. Each of these sections is listed in the final joint rules.[12]

One commenter suggested that the Agencies should establish December 4, 2004, instead of December 1, 2004, as proposed, as the effective date for these provisions of the Act.[13] This commenter noted that December 1, 2004, falls on a Wednesday and contended that an effective date that falls during the middle of the week "could work a hardship on many companies." The commenter indicated that establishing December 4, 2004, as the effective date for these provisions may help to ensure that implementation processes proceed smoothly because companies would be provided with more time to implement and test new systems in place over that weekend. By contrast, other commenters stated that December 1, 2004, is consistent with the maximum 10-month period permitted under the statute and did not note any adverse consequences that could be posed by that particular day.

Section 3 of the FACT Act permits the Agencies to establish an effective date as late as 10 months following the effective date of the Agencies' joint final rules. This date was uncertain at the time the rules were proposed. The Agencies believed that adopting a date certain would reduce burden on all affected by the joint rules by removing uncertainty about the effective date. The Agencies proposed December 1, 2004, as a date that would both be within the 10-month statutory period and allow affected entities to begin implementation efforts

[9] *See, e.g.*, America's Community Bankers, Bank of America, MBNA America, FleetBoston Financial Corp., Capital One Financial Corp., Financial Services Roundtable, Household Automative Finance Corp., Household Bank, Visa USA, Inc., and Bank One Corp.

[10] 15 U.S.C. 6802–03.

[11] *See* sections 612(a)(1)(B), (C)(iii), and (C)(iv) of the FCRA, as added by section 211 of the FACT Act, and section 211(d) of the Act; section 628(a)(1) of the FCRA as added by section 216 of the FACT Act.

[12] The Agencies note that a portion of the amendment made by section 151(a)(1) (which adds section 609(e) to the FCRA) becomes effective 180 days after enactment of the Act.

[13] American Council of Life Insurers.

at the start of a new month. Based on all of the comments, the Agencies continue to believe that, on balance, December 1, 2004, is an appropriate effective date for the provisions of the statute described in section __.1(c)(3) of the joint rules because the first day of the month sharply demarcates the start date for these provisions of the new law and reduces burden on entities that use a monthly cycle.

Regulatory Analysis

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Agencies have reviewed the joint final rules. (The Board has done so under authority delegated to the Board by the Office of Management and Budget.) The joint final rules contain no collections of information pursuant to the Paperwork Reduction Act.

Regulatory Flexibility Act

In accordance with section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a)), the Agencies must publish a final regulatory flexibility analysis with these joint rules. The joint rules establish effective dates for several provisions of the FACT Act. Prior to the enactment of the FACT Act, the FCRA imposed various duties on parties that furnish information to consumer reporting agencies, on parties that use consumer reports, and on consumer reporting agencies themselves. The FACT Act modifies and extends some of these existing duties and imposes new duties on these respective parties. The schedule of effective dates established by the Agencies would make the newly-enacted statutory provisions applicable with respect to these parties.

Because the rules merely establish effective dates, the rules themselves impose no reporting, recordkeeping or other requirements, which would arise either from obligations imposed by the statute itself or as a result of rulemaking or other implementing actions that may be taken by agencies under the statute.

List of Subjects

12 CFR Part 222

Banks, banking, Holding companies, state member banks.

16 CFR Part 602

Consumer reports, Consumer reporting agencies, Credit, Trade practices.

Federal Reserve System

12 CFR Chapter II

Authority and Issuance

■ For the reasons set forth in the preamble, the Board amends 12 CFR part 222 as follows:

PART 222—FAIR CREDIT REPORTING (REGULATION V)

■ 1. The authority citation for 12 CFR part 222 continues to read as follows:

Authority: 15 U.S.C. 1681a; Sec. 3, Pub. L. 108–159; 117 Stat. 1953.

■ 2. In § 222.1, paragraphs (c)(2) and (c)(3) are added to read as follows:

Subpart A—General Provisions

§ 222.1 Purpose, scope, and effective dates.

* * * * *

(c) *Effective dates.* * * *

(2) *Provisions effective March 31, 2004.*

(i) Section 111, concerning the definitions;

(ii) Section 156, concerning the statute of limitations;

(iii) Sections 312(d), (e), and (f), concerning the furnisher liability exception, liability and enforcement, and rule of construction, respectively;

(iv) Section 313(a), concerning action regarding complaints;

(v) Section 611, concerning communications for certain employee investigations; and

(vi) Section 811, concerning clerical amendments.

(3) *Provisions effective December 1, 2004.*

(i) Section 112, concerning fraud alerts and active duty alerts;

(ii) Section 114, concerning procedures for the identification of possible instances of identity theft;

(iii) Section 115, concerning truncation of the social security number in a consumer report;

(iv) Section 151(a)(1), concerning the summary of rights of identity theft victims;

(v) Section 152, concerning blocking of information resulting from identity theft;

(vi) Section 153, concerning the coordination of identity theft complaint investigations;

(vii) Section 154, concerning the prevention of repollution of consumer reports;

(viii) Section 155, concerning notice by debt collectors with respect to fraudulent information;

(ix) Section 211(c), concerning a summary of rights of consumers;

(x) Section 212(a)–(d), concerning the disclosure of credit scores;

(xi) Section 213(c), concerning enhanced disclosure of the means available to opt out of prescreened lists;

(xii) Section 217(a), concerning the duty to provide notice to a consumer;

(xiii) Section 311(a), concerning the risk-based pricing notice;

(xiv) Section 312(a)–(c), concerning procedures to enhance the accuracy and integrity of information furnished to consumer reporting agencies;

(xv) Section 314, concerning improved disclosure of the results of reinvestigation;

(xvi) Section 315, concerning reconciling addresses;

(xvii) Section 316, concerning notice of dispute through reseller; and

(xviii) Section 317, concerning the duty to conduct a reasonable reinvestigation.

Federal Trade Commission

16 CFR Chapter 1

Authority and Issuance

■ For the reasons set forth in the preamble, the FTC amends 16 CFR part 602 as follows:

PART 602—FAIR CREDIT REPORTING

■ 1. The authority citation for 16 CFR part 602 continues to read as follows:

Authority: 15 U.S.C. 1681a; Sec. 3, Pub. L. 108–159; 117 Stat. 1953.

■ 2. In § 602.1, paragraphs (c)(2) and (c)(3) are added to read as follows:

Subpart A—General Provisions

§ 602.1 Purpose, scope, and effective dates.

* * * * *

(c) *Effective dates.* * * *

(2) *Provisions effective March 31, 2004.*

(i) Section 111, concerning the definitions;

(ii) Section 156, concerning the statute of limitations;

(iii) Sections 312(d), (e), and (f), concerning the furnisher liability exception, liability and enforcement, and rule of construction, respectively;

(iv) Section 313(a), concerning action regarding complaints;

(v) Section 611, concerning communications for certain employee investigations; and

(vi) Section 811, concerning clerical amendments.

(3) *Provisions effective December 1, 2004.*

(i) Section 112, concerning fraud alerts and active duty alerts;

(ii) Section 114, concerning procedures for the identification of possible instances of identity theft;

(iii) Section 115, concerning truncation of the social security number in a consumer report;

(iv) Section 151(a)(1), concerning the summary of rights of identity theft victims;

(v) Section 152, concerning blocking of information resulting from identity theft;

(vi) Section 153, concerning the coordination of identity theft complaint investigations;

(vii) Section 154, concerning the prevention of repollution of consumer reports;

(viii) Section 155, concerning notice by debt collectors with respect to fraudulent information;

(ix) Section 211(c), concerning a summary of rights of consumers;

(x) Section 212(a)–(d), concerning the disclosure of credit scores;

(xi) Section 213(c), concerning enhanced disclosure of the means available to opt out of prescreened lists;

(xii) Section 217(a), concerning the duty to provide notice to a consumer;

(xiii) Section 311(a), concerning the risk-based pricing notice;

(xiv) Section 312(a)–(c), concerning procedures to enhance the accuracy and integrity of information furnished to consumer reporting agencies;

(xv) Section 314, concerning improved disclosure of the results of reinvestigation;

(xvi) Section 315, concerning reconciling addresses;

(xvii) Section 316, concerning notice of dispute through reseller; and

(xviii) Section 317, concerning the duty to conduct a reasonable reinvestigation.

By order of the Board of Governors of the Federal Reserve System, February 5, 2004.

Jennifer J. Johnson,

Secretary of the Board.

Dated: February 5, 2004.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04–2913 Filed 2–10–04; 8:45 am]

BILLING CODES 6210–01; 6750–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 91, 121, 125, and 135

[Docket No. FAA–2003–14449; Amendment Nos. 1–52; 91–281; 121–303; 125–45; 135–93]

RIN 2120–AH78

Enhanced Flight Vision Systems; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects the preamble of the final rule on Enhanced Flight Vision Systems published in the **Federal Register** of Friday, January 9, 2004 (69 FR 1620). The correction removes an incomplete sentence that was inadvertently included.

DATES: The regulation is effective February 9, 2004.

FOR FURTHER INFORMATION CONTACT: Les Smith, (202) 385–4586.

SUPPLEMENTARY INFORMATION: On January 9, 2004, the FAA published a final rule amending its regulations for landing under instrument flight rules (69 FR 1620; Jan. 9, 2004). The rule allows aircraft to operate below certain specified altitudes during instrument approach procedures, even when the airport environment is not visible using natural vision, if the pilot uses certain FAA-certified enhanced flight vision systems. The preamble of the final rule contained an incomplete sentence that was inadvertently included. This correction removes that sentence in its entirety.

In FR Doc. 04–427 published on January 9, 2004, on page 1634, in the third column, in the fourth line from the top of the page, remove the partial sentence that reads "Other technology solutions for conducting low visibility approach and landing operations, such as SVS, would require a different operational."

Issued in Washington, DC on February 5, 2004.

Anthony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 04–2890 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21, 61, 91, 119, 125, 135, and 142

[Docket No. FAA–2001–10047; Amdt. Nos. 21–84, 61–109, 91–280, 119–7, 125–44, 135–91, 142–5]

RIN 2120–AH06

Regulation of Fractional Aircraft Ownership Programs and On-Demand Operations; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on September 17, 2003. That action updated and revised the regulations governing operations of aircraft in fractional ownership programs.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Katherine Hakala Perfetti, telephone (202) 267–3760.

Correction

■ In final rule FR Doc. 03–23021, published on September 17, 2003 (68 FR 54520), make the following corrections:

■ 1. On page 54520, in column 1 in the heading section, beginning on line five, correct "Amdt. Nos. 21–84, 61–109, 91–274, 119–7, 125–44, 135–82, 142–5" to read "Amdt. Nos. 21–84, 61–109, 91–280, 119–7, 125–44, 135–91, 142–5".

Issued in Washington, DC, on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2873 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21, 91, 121, 125, and 129

[Docket No. FAA–1999–6411; Amendment Nos. 21–83, 91–277, 121–295, 125–40, 129–35; Special Federal Aviation Regulation No. 88]

RIN 2120–AG62

Extension of Compliance Times for Fuel Tank System Safety Assessments, Correction; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the correction of the final rule published in the **Federal Register** on June 25, 2003. The first correction changed assigned amendment numbers. This action makes further corrections to assigned amendment numbers.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Mike Dosert, telephone (425) 227–2132.

Correction

■ In correction to the final rule FR Doc. 03–16001, published on June 25, 2003 (68 FR 37735), make the following corrections:

■ 1. On page 37735, at the bottom of column 2, in the heading section, beginning on line 4, correct "Amendment. Nos. 21–83, 91–272, 121–285, 125–40, 129–35; Special Federal Aviation Regulation No. 88" to read "Amendment. Nos. 21–83, 91–277, 121–295, 125–40, 129–35; Special Federal Aviation Regulation No. 88".

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2878 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 25, 91, 121, 125, and 135

[Docket No. FAA–2000–7909; Amdt. Nos. 25–110, 91–279, 121–301, 125–43, 135–90]

RIN 2120–AG91

Improved Flammability Standards for Thermal/Acoustic Insulation Materials Used in Transport Category Airplanes; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on July 31, 2003. That rule adopted upgraded flammability standards for thermal and acoustic insulation materials used in transport category airplanes.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Jeff Gardlin, (425) 227–2136.

Correction

■ In the final rule FR Doc. 03–18612 published on July 31, 2003, (68 FR 45046), make the following corrections:

■ 1. On page 45046, in column 1, in the heading section, beginning on line 4 correct "Amdt. Nos. 25–110, 91–275, 121–289, 125–43, 135–85" to read "Amdt. Nos. 25–110, 91–279, 121–301, 125–43, 135–90 ".

Issued in Washington, DC, on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2875 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–213–AD; Amendment 39–13465; AD 2004–03–21]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model 717–200 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas Model 717–200 airplanes, that requires inspection of the inboard ends of the outer skin panels of the horizontal stabilizer at Station Xh=±7.234 for material defects, and corrective action, if necessary. This action is necessary to detect material defects in the inboard ends of the outer skin panels of the horizontal stabilizer, which could lead to cracks and an associated loss of strength in the attachments, and consequent reduced structural integrity of the horizontal stabilizer. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Maureen Moreland, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5238; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model 717–200 airplanes was published in the **Federal Register** on September 18, 2003 (68 FR 54690). That action proposed to require inspection of the inboard ends of the outer skin panels of the horizontal stabilizer at Station Xh=±7.234 for material defects, and corrective action, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

There are approximately 56 airplanes of the affected design in the worldwide fleet. The FAA estimates that 41 airplanes of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per airplane to accomplish the required inspection, and that the average labor rate is $65 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $10,660, or $260 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include

incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. Manufacturer warranty remedies may be available for labor costs associated with this proposed AD. As a result, the costs attributable to the proposed AD may be less than stated above.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–21 McDonnell Douglas: Amendment 39–13465. Docket 2002–NM–213–AD.

Applicability: Model 717–200 airplanes, as listed in Boeing Service Bulletin 717–55–0005, dated June 27, 2002; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To detect material defects in the inboard ends of the outer skin panels of the horizontal stabilizer at Station Xh=±7.234, which could lead to cracks and an associated loss of strength in the attachments, and consequent reduced structural integrity of the horizontal stabilizer, accomplish the following:

Inspection

(a) Prior to the accumulation of 10,000 total flight cycles, or within 15 months after the effective date of this AD, whichever occurs later, do an ultrasonic inspection of the inboard ends of the outer skin panels of the horizontal stabilizer at Station Xh=±7.234 for material defects, per the Accomplishment Instructions of Boeing Service Bulletin 717–55–0005, dated June 27, 2002.

Corrective Action

(b) If any defects are found during the inspection required by paragraph (a) of this AD, and the service bulletin specifies contacting Boeing for appropriate action: Before further flight, repair per a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Los Angeles ACO, to make such findings. For a repair method to be approved, as required by this paragraph, the approval letter must specifically refer to this AD.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, Los Angeles ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(d) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Service Bulletin 717–55–0005, dated June 27, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(e) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 30, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2581 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–233–AD; Amendment 39–13466; AD 2004–03–22]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Falcon 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dassault Model Falcon 2000 series airplanes, that requires modification of the forward ribs of the left and right engine pylons to plug holes left open during production. This action is necessary to prevent fuel leakage into a "hot" section of the engine, and consequent propagation of an uncontained engine fire. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dassault Model Falcon 2000 series airplanes was

published in the **Federal Register** on December 4, 2003 (68 FR 67816). That action proposed to require modification of the forward ribs of the left and right engine pylons to plug holes left open during production.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

We have determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

We estimate that 119 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $65 per work hour. The cost of required parts is minimal. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $7,735, or $65 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–22 Dassault Aviation: Amendment 39–13466. Docket 2002–NM–233–AD.

Applicability: Model Falcon 2000 series airplanes on which Dassault Modification M2111 has not been installed, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel leakage into a "hot" section of the engine, and consequent propagation of an uncontained engine fire, accomplish the following:

Modification of the Engine Pylons

(a) Within 7 months after the effective date of this AD, modify the forward ribs of the left and right engine pylons by plugging the two 4-millimeter holes in each rib in accordance with the Accomplishment Instructions of Dassault Service Bulletin F2000–248, dated August 12, 2002. Although the service bulletin specifies to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(c) The actions shall be done in accordance with Dassault Service Bulletin F2000–248, dated August 12, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in French airworthiness directive 2002–413(B), dated August 7, 2002.

Effective Date

(d) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 30, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2580 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–267–AD; Amendment 39–13460; AD 2004–03–16]

RIN 2120–AA64

Airworthiness Directives; Dornier Model 328–300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dornier Model 328–300 series airplanes, that requires replacement of 3-switch and 4-switch overhead fire extinguisher control panels with new, improved panels. This action is necessary to prevent the inadvertent release of the fire switch pushbutton on the overhead fire extinguisher control panel with the switch guard closed, which could result in an uncommanded engine shutdown. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from AvCraft Aerospace GmbH, P.O. Box 1103, D–82230 Wessling, Germany. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of

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

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dornier Model 328–300 series airplanes was published in the **Federal Register** on November 17, 2003 (68 FR 64822). That action proposed to require replacement of 3-switch and 4-switch overhead fire extinguisher control panels with new, improved panels.

Comments

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

The commenter supports the proposed rule.

Conclusion

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

Cost Impact

The FAA estimates that 19 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the replacement of the overhead fire extinguisher control panel, and that the average labor rate is $65 per work hour. Required parts will be provided by the parts manufacturer at no cost to operators. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $1,235, or $65 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–16 Fairchild Dornier Gmbh (Formerly Dornier Luftfahrt GmbH): Amendment 39–13460. Docket 2002–NM–267–AD.

Applicability: Model 328–300 series airplanes as listed in Dornier Service Bulletins SB–328J–26–156 and SB–328J–26–161, both dated February 26, 2002; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent the inadvertent release of the fire switch pushbutton on the overhead fire extinguisher control panel with the switch guard closed, which could result in an uncommanded engine shutdown, accomplish the following:

Replacement of Overhead Fire Extinguisher Control Panel and Follow-on Actions

(a) Within 16 months after the effective date of this AD: Replace the overhead fire extinguisher control panels with new, improved fire extinguisher control panels, by accomplishing all of the actions specified in Paragraphs 2.A, 2.B(1) through (4) inclusive, and 2.C, of the Accomplishment Instructions of Dornier Service Bulletin SB–328J–26–156 or SB–328J–26–161, both dated February 26, 2002; as applicable.

Note 1: Dornier Service Bulletins SB–328J–26–156 and SB–328J–26–161 refer to Smiths Aerospace Service Bulletins 371–01 and 370–01, respectively, both dated February 20, 2002, as additional sources of service information for accomplishment of the required actions.

Parts Installation

(b) As of the effective date of this AD, no person may install fire extinguisher control panels manufactured by Smiths Aerospace having part numbers 715740–1 or 715355–1 on any airplane.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(d) The actions shall be done in accordance with Dornier Service Bulletin SB–328J–26–156, dated February 26, 2002; or Dornier Service Bulletin SB–328J–26–161, dated February 26, 2002; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from AvCraft Aerospace GmbH, P.O. Box 1103, D–82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 2: The subject of this AD is addressed in German airworthiness directives 2002–251, dated September 5, 2002; and 2002–335, dated October 17, 2002.

Effective Date

(e) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 29, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2579 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–84–AD; Amendment 39–13461; AD 2004–03–17]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR series airplanes, that requires a one-time inspection of each emergency evacuation slide or slide/raft to determine if a certain discrepant hose assembly is installed, and replacement of the hose assembly with a new or serviceable assembly if necessary. This action is necessary to prevent the failure of an emergency evacuation slide or slide/raft to fully inflate during an emergency situation, which could impede an evacuation and result in injury to passengers or airplane crewmembers. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from BFGoodrich Aircraft Evacuation Systems, 3414 S. Fifth Street, Phoenix, Arizona 85040. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Patrick Gillespie, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6429; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR series airplanes, was published in the **Federal Register** on July 9, 2003 (68 FR 40821). That action proposed to require a one-time inspection of each emergency evacuation slide or slide/raft to determine if a certain discrepant hose assembly is installed, and replacement of the hose assembly with a new or serviceable assembly if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received. One commenter concurs with the proposed rule.

Request to Revise Applicability

One commenter requests that the applicability in the proposed rule be revised to apply to "BFGoodrich slides or slide/rafts having part number 7A1238–()(), 7A1239–()(), 7A1248–()(), 7A1261–()(), 7A–1255–()(), 7A–1256–()(), or 7A–1257–()(), where "()()" represents any dash number of those part numbers, that may be installed on certain Model 747 series airplanes." The commenter states that the applicability of the proposed rule is misleading and could potentially cause compliance and/or record keeping errors because the slides are certified under a Technical Standard Order and may be removed, repaired, overhauled separately from the airplane, moved from airplane to airplane, or stored awaiting installation. Additionally, the commenter states that it is possible that the discrepant slides could be installed on airplane models not listed in the proposed applicability (*i.e.*, Model 747–400 series airplanes). Therefore, the commenter asserts that the proposed rule should be applicable to the component rather than the airplane model.

The FAA does not agree. According to general FAA policy, if an unsafe condition results from the installation of a particular component in only one particular make and model of airplane, the AD would apply to the airplane model, not the component. The reason for this is: If the AD applies to the airplane model equipped with the item, operators of those airplanes will be notified directly of the unsafe condition and the action required to correct it. While we assume that operators can identify the airplane models they operate, they may not be aware of specific items installed on the airplanes. Therefore, specifying the airplane models in the applicability as the subject of the AD prevents an operator's "unknowing failure to comply" with the AD. We recognize that an unsafe condition may exist in an item that is installed in many different airplanes. In that case, we consider it impractical to issue an AD against each airplane; in fact, many times, the exact models and numbers of airplanes on which the item is installed may be unknown. Therefore, in those situations, the AD would apply to the item and usually indicates that the item is known to be "installed on, but not limited to," various airplane models. In this case, the applicability extends only to those airplane models for which the discrepant escape slides are approved for installation on; the discrepant slides are not approved for installation on Model 747–400 series airplanes. No change to the final rule is necessary in this regard.

Request To Extend Compliance Time

Another commenter requests that the proposed compliance time be extended from 36 months to 54 months. The commenter states that its current overhaul interval for the affected slides is 54 months. The commenter points out that its maintenance program carries out the Goodrich slide component maintenance manual (CMM) inspections for hydrostatic testing of the hoses during slide overhaul and discards any hose not passing the test. During its 22 years of operating the affected slides on its Model 747 series airplanes, the commenter states that it has had no failed deployments (scheduled, unscheduled, or during shop inflation) due to hose failure. Therefore, the commenter suggests that a 54-month compliance time would provide an adequate level of safety.

We do not agree. In developing an appropriate compliance time for this action, we considered the safety implications, operators' normal maintenance schedules, and the compliance time recommended by the airplane manufacturer for the timely accomplishment of the required actions. In consideration of these items, we have determined that a 36-month compliance time will ensure an acceptable level of safety and is an appropriate interval of time wherein the required actions can be accomplished during scheduled maintenance intervals for the majority of affected operators. We have also determined that the CMM slide inspections are not an adequate means to address the failure mode of the affected slides. However, according to the provisions of paragraph (d) of this

final rule, we may approve requests to adjust the compliance time if the request includes data that justify that a different compliance time would provide an acceptable level of safety. No change to the final rule is necessary in this regard.

Conclusion

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

Cost Impact

There are approximately 333 airplanes of the affected design in the worldwide fleet. The FAA estimates that 88 airplanes of U.S. registry will be affected by this AD.

It will take approximately 1 work hour per airplane to accomplish the required inspection, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the required inspection on U.S. operators is estimated to be $5,720, or $65 per airplane.

Should an operator be required to accomplish the replacement of a hose assembly, it will take approximately 12 work hours per hose assembly, at an average labor rate of $65 per work hour. Required parts will cost between $795 and $1,169 per hose assembly. Based on these figures, the cost impact of the required replacement is estimated to be between $1,575 and $1,949 per hose assembly.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–17 Boeing: Amendment 39–13461. Docket 2003–NM–84–AD

Applicability: All Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR series airplanes; certificated in any category; and equipped with BFGoodrich slides or slide/rafts having part number 7A1238–()(), 7A1239–()(), 7A1248–()(), 7A1261–()(), 7A–1255–()(), 7A–1256–()(), or 7A–1257–()(), where "()()" represents any dash number of those part numbers.

Compliance: Required as indicated, unless accomplished previously.

To prevent the failure of an emergency slide or slide/raft to fully inflate during an emergency situation, which could impede an evacuation and result in injury to passengers or airplane crewmembers, accomplish the following:

Inspection To Determine Manufacturing Date

(a) Within 36 months after the effective date of this AD, perform a one-time inspection of the part number information label on each inflation hose assembly on each emergency evacuation slide or slide/raft to determine the manufacturing/test date of the inflation hose assembly. Do this inspection per BFGoodrich Service Bulletin 25–241, dated September 30, 1991. If the manufacturing/test date is May 30, 1983, or later, no further action is required for that inflation hose assembly.

Replacement of Inflation Hose Assembly

(b) For any inflation hose assembly having a manufacturing/test date before May 30, 1983, or on which the manufacturing/test date cannot be determined: Before further flight, replace the subject inflation hose assembly with a new or serviceable hose assembly having a manufacturing/test date on or after May 30, 1983, per BFGoodrich Service Bulletin 25–241, dated September 30, 1991.

Parts Installation

(c) As of the effective date of this AD, no person shall install an inflation hose assembly having a manufacturing/test date before May 30, 1983, or on which the manufacturing/test date cannot be determined, on an emergency evacuation slide or slide/raft on any airplane.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, Seattle Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with BFGoodrich Service Bulletin 25–241, dated September 30, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from BFGoodrich Aircraft Evacuation Systems, 3414 S. Fifth Street, Phoenix, Arizona 85040. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(f) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 29, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2578 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–139–AD; Amendment 39–13457; AD 2004–03–13]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–215–1A10 and CL–215–6B11 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Bombardier Model CL–215–1A10 and CL–215–6B11 series airplanes, that currently requires repetitive inspections to detect cracking of main landing gear (MLG) axles that have been reworked by chromium plating, and replacement of cracked axles with serviceable axles. This amendment requires a dimensional check and follow-on corrective actions, mandates terminating action for certain airplanes, and adds three airplanes to the applicability in the existing AD. The actions specified by this AD are intended to prevent cracking of the inner bearing surface of the MLG axles, which could result in failure of an axle, subsequent separation of the wheel from the airplane, and consequent reduced controllability of the airplane during takeoff or landing. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of a certain publication, as listed in the regulations, is approved by the Director of the Federal Register as of March 17, 2004.

The incorporation by reference of a certain other publication, as listed in the regulations, was approved previously by the Director of the Federal Register as of November 8, 1995 (60 FR 54421, October 24, 1995).

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: David Lawson, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York 11581; telephone (516) 228–7300; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 95–22–04, amendment 39–9411 (60 FR 54421, October 24, 1995), which is applicable to certain Canadair Model CL–215–1A10 and CL–215–6B11 series airplanes, was published in the **Federal Register** on December 5, 2003 (68 FR 67971). The action proposed to require inspections to detect cracking of main landing gear (MLG) axles that have been reworked by chromium plating, and replacement of cracked axles with serviceable axles. That action also proposed to add a dimensional check and follow-on corrective actions, mandate terminating action for certain airplanes, and add three airplanes to the applicability in the existing AD.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

There are approximately 3 airplanes of U.S. registry that will be affected by this AD.

The inspections that are currently required by AD 95–22–04 take about 2 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the currently required inspections on U.S. operators is estimated to be $390, or $130 per airplane, per inspection cycle.

The dimensional check and ultrasonic inspection required by this AD action will take about 2 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of these checks and inspections on U.S. operators is estimated to be $390, or $130 per airplane, per cycle.

The replacement required by this AD action, if done, will take about 8 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Required parts will cost approximately $13,000 per assembly (two per airplane). Based on these figures, the cost impact of the replacement required by this AD on U.S. operators is estimated to be $26,520 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing amendment 39–9411 (60 FR 54421, October 24, 1995), and by adding a new airworthiness directive (AD), amendment 39–13457, to read as follows:

2004–03–13 Bombardier, Inc. (Formerly Canadair): Amendment 39–13457. Docket 2003–NM–139–AD. Supersedes AD 95–22–04, Amendment 39–9411.

Applicability: Model CL–215–1A10 (piston) and CL–215–6B11 (turboprop) series airplanes, having serial numbers 1001 through 1125 inclusive, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent cracking in the inner bearing surface of the main landing gear (MLG) axles, which could result in failure of an axle, subsequent separation of the wheel from the airplane, and consequent reduced controllability of the airplane during takeoff or landing, accomplish the following:

Restatement of Certain Requirements of AD 95–22–04

Repetitive Inspections/Corrective Action

(a) Within 60 days after November 8, 1995 (the effective date of AD 95–22–04, amendment 39–9411), perform either an eddy current inspection or a chemical inspection of the inner bearing surface area of the left and right MLG axles to determine if they have been reworked using chromium plating, in accordance with Canadair Alert Service Bulletin 215–A462, dated June 2, 1993; or Bombardier Alert Service Bulletin 215–A462, Revision 3, dated January 17, 2000. If the inner bearing surface of the MLG axle has not been reworked using chromium plating, no further action is required by this paragraph for that axle only.

(b) If the inner bearing surface of the MLG axle has been reworked using chromium plating, prior to further flight, perform an ultrasonic inspection to detect cracking in the axle, in accordance with Canadair Alert Service Bulletin 215–A462, dated June 2, 1993; or Bombardier Alert Service Bulletin 215–A462, Revision 3, dated January 17, 2000.

(1) If no crack is detected during this inspection, repeat the ultrasonic inspection at intervals not to exceed 150 landings.

(2) If any crack is detected during this inspection, prior to further flight, remove the cracked axle and replace it with a serviceable axle that does not have an inner bearing surface that has been reworked using chromium plating, in accordance with the service bulletin.

New Requirements of This AD

Dimensional Check/Follow-on Corrective Actions

(c) Within 150 landings after the effective date of this AD: Do a dimensional check by measuring the diameter of the left and right MLG axles to determine if they have been reworked outside the dimensions specified in Canadair CL–215 Overhaul Manual PSP 298, or if the axle has unknown rework dimensions or the service life of that axle cannot be determined, in accordance with Bombardier Alert Service Bulletin 215–A462, Revision 3, dated January 17, 2000.

(1) If any axle has been reworked outside the specified dimensions, or has unknown rework dimensions, or if the service life of that axle cannot be determined: Prior to further flight, do an ultrasonic inspection to detect cracking of the axle, in accordance with the alert service bulletin, and replace the axle with a serviceable axle before the accumulation of 1,050 total landings, in accordance with the alert service bulletin. Such replacement ends the repetitive inspections for that axle only.

(i) If no cracking is detected during the inspection required by paragraph (c)(1) of this AD, repeat the inspection at intervals not to exceed 150 landings, and replace with a serviceable axle before the accumulation of 1,050 total landings, in accordance with the alert service bulletin.

(ii) If any cracking is detected during the inspection required by paragraph (c)(1) of this AD, prior to further flight, replace the axle with a serviceable axle in accordance with the alert service bulletin.

(2) If the service life of the axle is known, and the axle has not been reworked outside the specified dimensions, no further action is required by this AD for that axle only.

Actions Done per Previous Issues of Service Bulletin

(d) Inspections and replacements done before the effective date of this AD in accordance with Canadair Alert Service Bulletin 215–A462, dated June 2, 1993; or Bombardier Alert Service Bulletin 215–A462, Revision 1, dated August 26, 1996; or Revision 2, dated March 3, 1999; are considered acceptable for compliance with the applicable actions specified in this AD.

Alternative Methods of Compliance

(e) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(f) The actions shall be done in accordance with Canadair Alert Service Bulletin 215–A462, dated June 2, 1993; and Bombardier Alert Service Bulletin 215–A462, Revision 3, dated January 17, 2000; as applicable.

(1) The incorporation by reference of Bombardier Alert Service Bulletin 215–A462, Revision 3, dated January 17, 2000; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Canadair Alert Service Bulletin 215–A462, dated June 2, 1993; was approved previously by the Director of the Federal Register as of November 8, 1995 (60 FR 54421, October 24, 1995).

(3) Copies may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in Canadian airworthiness directive CF–1993–08R3, dated March 30, 2000.

Effective Date

(g) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 29, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2577 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–116–AD; Amendment 39–13462; AD 2004–03–18]

RIN 2120–AA64

Airworthiness Directives; Aerospatiale Model ATR42 and ATR72 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42 and ATR72 series airplanes, that requires replacement of the swinging lever spacers in the left and right leg assemblies of the main landing gear with new, improved spacers. This action is necessary to prevent propagation of fatigue cracking, which could result in failure of the spacer base and could affect the symmetrical functioning of the braking system. Asymmetrical braking could result in the airplane overrunning the runway during takeoff or landing. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the

regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tony Jopling, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2190; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR42 and ATR72 series airplanes was published in the **Federal Register** on December 17, 2003 (68 FR 70208). That action proposed to require replacement of the swinging lever spacers in the left and right leg assemblies of the main landing gear with new, improved spacers.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 133 airplanes of U.S. registry will be affected by this AD, that it will take about 16 work hours per airplane to accomplish the replacement, and that the average labor rate is $65 per work hour. Required parts will cost between $921 and $4,272 per airplane. Based on these figures, the cost impact of the replacement on U.S. operators is estimated to be between $1,961 and $5,312 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–18 Aerospatiale: Amendment 39–13462. Docket 2002–NM–116–AD.

Applicability: Model ATR42–200, –300, –320, and –500 series airplanes on which ATR Modification 5338 has not been done; and Model ATR72–101, –102, –201, –202, –211, –212, and –212A series airplanes on which ATR Modification 5337 has not been done; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the spacer base of the swinging lever spacers in the left and right leg assemblies of the main landing gear (MLG) and consequent asymmetrical braking, which could result in the airplane overrunning the runway during takeoff or landing, accomplish the following:

Replacement

(a) Replace the swinging lever spacers in the left and right leg assemblies of the MLG with new, improved spacers, per Avions de Transport Regional Service Bulletin ATR42–32–0094 or ATR72–32–1042, both dated November 26, 2001, as applicable. Do the replacement at the applicable time specified in paragraph (a)(1) or (a)(2) of this AD.

(1) For Model ATR42–200, –300, and –320, and Model ATR72–101, –102, –201, –202, –211, –212, and –212A series airplanes: Do the replacement at the later of the times specified in paragraphs (a)(1)(i) and (a)(1)(ii) of this AD.

(i) Before the accumulation of 15,000 total landings or 8 years in-service on new or overhauled swinging lever spacers, whichever is first.

(ii) Within 3,000 landings after the effective date of this AD.

(2) For Model ATR42–500 series airplanes: Do the replacement before the accumulation of 18,000 total landings or 9 years in-service on new or overhauled swinging lever spacers, whichever is first.

(b) Messier-Dowty Service Bulletin 631–32–166, dated November 28, 2001 (for Model ATR42 series airplanes); or 631–32–165, dated November 27, 2001 (for Model ATR72 series airplanes), may be used for accomplishment of the replacement required by paragraph (a) of this AD.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(d) Unless otherwise specified in this AD, the actions shall be done in accordance with Avions de Transport Regional Service Bulletin ATR42–32–0094, dated November 26, 2001; or Avions de Transport Regional Service Bulletin ATR72–32–1042, dated November 26, 2001; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in French airworthiness directives 2001–614–089(B) and 2001–615–062(B), both dated December 26, 2001.

Effective Date

(e) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 30, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2574 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–333–AD; Amendment 39–13464; AD 2004–03–20]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes, that requires repetitive general visual inspections, lubrication, and tests of the release mechanism for the service/emergency door; and corrective actions if necessary. This AD also provides an optional terminating action for the repetitive inspections and lubrication. This action is necessary to prevent failure of the release mechanism on the service/emergency door, which could result in the inability to open the service/emergency door during an emergency evacuation. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes was published in the **Federal Register** on December 5, 2003 (68 FR 67981). That action proposed to require repetitive general visual inspections, lubrication, and tests of the release mechanism for the service/emergency door; and corrective actions if necessary. That action also proposed an optional terminating action for the repetitive inspections and lubrication.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

We have determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

We estimate that 6 airplanes of U.S. registry will be affected by this AD, that it will take approximately 15 work hours per airplane to accomplish the required actions, and that the average labor rate is $65 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $5,850, or $975 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–20 Fokker Services B.V: Amendment 39–13464. Docket 2001–NM–333–AD.

Applicability: Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes; as listed in the effectivity of Fokker Service Bulletin F28/52–118, dated June 25, 2001; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the release mechanism on the service/emergency door, which could result in the inability to open the service/emergency door during an emergency evacuation, accomplish the following:

Inspection, Lubrication, Testing, and Corrective Actions

(a) Within 12 months after the effective date of this AD: Do a general visual inspection (including measurement of the torque for the actuating mechanism torsion spring), lubricate, and test to verify proper

operation of the emergency release mechanism of the service/emergency door by accomplishing all of the actions specified in paragraphs A. through R. of the Accomplishment Instructions of Fokker Service Bulletin F28/52–118, dated June 25, 2001.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(1) If no discrepant or corroded part is found during the inspection required by paragraph (a) of this AD: Repeat the actions specified in paragraph (a) of this AD thereafter at intervals not to exceed 1,500 flight hours or 18 months, whichever occurs first.

(2) If any discrepancy (including a torque value that exceeds the limits specified in the applicable service bulletin, an improperly installed part, or a damaged part) is found, or if a corroded part is found, during any inspection required by paragraph (a) of this AD: Before further flight, do the applicable corrective action in accordance with the Accomplishment Instructions of the service bulletin. Repeat the actions specified in paragraph (a) of this AD thereafter at intervals not to exceed 1,500 flight hours or 18 months, whichever occurs first.

Optional Terminating Action and Concurrent Service Bulletin

(b) Replacement of the Bowden cable-operated service/emergency door with a push-pull rod-operated service/emergency door, in accordance with Fokker Service Bulletin F28/52–89, dated October 31, 1983, constitutes terminating action only for the repetitive inspections and lubrication required by paragraph (a) of this AD.

(c) For airplanes with serial numbers 11003 to 11051 inclusive, 11991, and 11992: Prior to or concurrent with paragraph (b) of this AD, accomplish the modification specified in part VII of Fokker Service Bulletin F28/52–55, Revision 1, dated February 28, 1977.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Fokker Service Bulletin F28/52–118, dated June 25, 2001. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

Note 2: The subject of this AD is addressed in Dutch airworthiness directive 2001–094, dated July 31, 2001.

Effective Date

(f) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 30, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2573 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–238–AD; Amendment 39–13453; AD 2004–03–09]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes. This AD requires repetitive inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, and repair if necessary. This AD also provides for an optional modification that, if accomplished, terminates the repetitive inspection requirement, but would necessitate eventual post-modification inspections. This action is necessary to find and fix fatigue cracking of structure near and common to the upper chord and splice fittings of the rear spar of the wing, which could result in loss of structural integrity of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Nick Kusz, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6432; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes was published in the **Federal Register** on June 18, 2003 (68 FR 36506). That action proposed to require repetitive inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, and repair if necessary. That action also proposed to provide for an optional modification that, if accomplished, would terminate the repetitive inspection requirement, but would necessitate eventual post-modification inspections.

Comments

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

Request To Change Paragraph (c) of the Proposed AD

One commenter, the manufacturer, requests a change to paragraph (c) of the proposed AD to state, "If any cracking, corrosion, or damage is found * * *" rather than "If any cracking is found * * *". The commenter states that corrosion is often present in bolt holes vacated by alloy steel bolts, and that damage can occur during removal and installation of bolts. The commenter also requests that paragraph (c) be changed to reference "Part 3—Inspection and Repair," of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003 (which is

referenced in the proposed AD as the appropriate source of service information for the required actions) for the proposed repair for cracked, corroded, and damaged fastener holes.

The FAA agrees. The comments clarify the types of discrepancies for operators to look for and point out which part of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, contains the necessary instructions for repair. We have revised paragraph (c) of the final rule to include the requested changes. For the same reason, we have added reference to paragraph (d) of the final rule and Part 4 of the service bulletin.

Request To Change Paragraph (d) of the Proposed AD

The same commenter requests a change to paragraph (d) of the proposed AD to include a reference to the installation of new bushings, as required. The request is intended to make the wording in the proposed AD consistent with the wording in Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003.

The FAA agrees. The comments clarify the type of modification that is allowed in Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. We have revised paragraph (d) of the final rule to include the requested change.

Request To Change Paragraph (e) of the Proposed AD to Reference H–11 Bolts

The same commenter requests that paragraph (e) of the proposed AD include a reference to an ultrasonic or magnetic particle inspection of removed H–11 bolts, and a reference to a detailed inspection of other non H–11 removed bolts for cracking, corrosion, or damage. The commenter states that a visual inspection of H–11 steel bolts is not adequate for finding cracks in these bolts because H–11 bolts are susceptible to stress corrosion cracking. The commenter further states that it is necessary to find small cracks by non-destructive test (NDT) methods before the cracks grow long enough to fracture the H–11 bolts and cause the loss of shear load capability in the splices. The commenter adds that a detailed visual inspection is adequate for finding damage to titanium or Inconel bolts because these bolts are not susceptible to stress corrosion cracking.

The FAA does not agree with the proposed changes to paragraph (e) of the AD. Paragraph (e) requires inspections only after the modification per paragraph (d) has been accomplished. Once the optional modification in paragraph (d) of the AD is accomplished, all H–11 bolts will have been replaced with updated Inconel bolts, thereby eliminating the need for inspections of H–11 bolts. Therefore, we have determined that no instructions referring to H–11 bolts in the post-modification instructions are necessary. No change to the final rule is necessary on this issue.

Request To Change Paragraph (e)(2) of the Proposed AD to Refer to Part 5 of the Service Bulletin

The same commenter requests a change to paragraph (e)(2) of the proposed AD to include a reference to Part 5 of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, which contains instructions for repairing cracked holes found during post modification inspections.

The FAA agrees. The comments clarify where to find the repair instructions in the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. We have revised paragraph (e)(2) of the final rule to include the requested change.

Request To Change Paragraph (f) of the Proposed AD

The same commenter requests that the FAA change paragraph (f) of the proposed AD to include a reference to the original release of Boeing Alert Service Bulletin 747–57A2314, dated June 28, 2001. The purpose of the change would be to ensure that operators are aware that inspections, repairs, or modifications accomplished before the effective date of the proposed AD, per the original release or Revision 1 of the service bulletin are acceptable methods of compliance.

While the FAA agrees with the intent of the comment, we find that paragraph (f) of the AD already provides for acceptable use of the original release of the service bulletin. In addition, the AD implies that actions accomplished previously per Revision 1 of the service bulletin are acceptable because the proposed AD is written to address the actions required by Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, which was inadvertently listed by the commenter as having a date of June 28, 2001. Operators are given credit for work previously performed by the means of the phrase in the "Compliance" section of the AD that states, "Required as indicated, unless accomplished previously." Therefore, in the case of this AD, if the required inspections, repairs, or modifications have been accomplished before the effective date of this AD, this AD does not require that they be repeated. No change to the final rule is necessary on this issue.

Request To Change Paragraph (j) of the Proposed AD

The same commenter requests that the FAA include paragraph (e) of the proposed AD in the list in paragraph (j) of the proposed AD. Paragraph (j) of the proposed AD contains a list of paragraphs that are excepted from the restriction on the installation of any alloy steel bolt in any location specified in the proposed AD on any airplane listed in the applicability of the proposed AD. The commenter states that both paragraph (e) of the proposed AD and Figure 2, Table 3 of Boeing Service Bulletin 747–57A2314, Revision 1, allow for re-installation of alloy steel bolts provided that they have been inspected by ultrasonic or magnetic particle inspection and found to be free of cracks, corrosion, or damage. The commenter states that the requirement to replace undamaged H–11 alloy steel bolts will result in unnecessary cost to the operators and will conflict with the service bulletin. The commenter further states that airplanes may be unnecessarily grounded by the lack of replacement Inconel bolts, which are difficult to procure, and that the requirement would place an economic burden on the manufacturer to maintain a large inventory of replacement bolts.

In addition, the commenter states that the manufacturer has received no reports of multiple H–11 bolt fractures in the splice at the rear spar upper chord side of the body splice and upper surface stringer 1. As a result, the commenter states, flight safety is provided by existing maintenance. The commenter further states that Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, requires ultrasonic or magnetic particle inspection of the alloy steel bolts during each repeat inspection of the bolt holes, and that the bolts must be free of cracks before they can be re-installed in the holes. According to the commenter, the repeat inspections every 6,000 to 13,000 flight cycles, and the replacement of the alloy steel bolts with Inconel bolts during splice modification provide an additional level of safety.

The FAA does not agree with this request to add paragraph (e) of the proposed AD to the list of paragraphs that are excepted from the restriction on the installation of any alloy steel bolt in paragraph (j) of the proposed AD. In reaching this conclusion, we considered that paragraph (e) does not allow for the re-installation of alloy steel (H–11) bolts because, in order for the post-

modification inspections of paragraph (e) to be necessary, the optional modification of paragraph (d) must have been previously accomplished. If the operators chooses to accomplish the optional modification of paragraph (d), all alloy steel (H–11) bolts are required to be replaced with Inconel bolts. Also, it is important that once the Inconel bolts are installed as part of the modification, they are not replaced by alloy steel (H–11) bolts in the future. No change to the final rule is necessary on this issue.

Explanation of Change Made to the Proposed AD

The FAA has changed all references to a "Boeing Alert Service Bulletin 747–57A2314, Revision 1" in the proposed AD to "Boeing Service Bulletin 747–57A2314, Revision 1" in this final rule. We have also changed the paragraph (j) to refer to the H–11 bolt for clarity.

Conclusion

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

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Change to Labor Rate Estimate

We have reviewed the figures we have used over the past several years to calculate AD costs to operators. To account for various inflationary costs in the airline industry, we find it necessary to increase the labor rate used in these calculations from $60 to $65 per work hours. The cost impact information, below, reflects this increase in the specified hourly labor rate.

Cost Impact

There are approximately 593 airplanes of the affected design in the worldwide fleet. The FAA estimates that 176 airplanes of U.S. registry are affected by this AD.

It will take approximately 8 work hours per airplane to accomplish the required inspection, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the required inspection on U.S. operators is estimated to be $91,520, or $520 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Should an operator elect to accomplish the optional terminating action that is provided by this AD action, it will take approximately 22 work hours to accomplish it, at an average labor rate of $65 per work hour. The cost of required parts will be approximately $10,700 per airplane. Based on these figures, the cost impact of the optional terminating action will be approximately $12,130 per airplane.

If the optional terminating action provided by this AD action is accomplished, an eventual post-modification inspection is necessary. That inspection will take approximately 8 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the post modification inspections would be approximately $250 per airplane, per inspection cycle.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–09 Boeing: Amendment 39–13453. Docket 2001–NM–238–AD.

Applicability: All Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200F, 747–200C, 747–300, 747SR, and 747SP series airplanes; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To find and fix fatigue cracking of structure near and common to the upper chord and splice fittings of the rear spar of the wing, which could result in loss of structural integrity of the airplane, accomplish the following:

Initial Inspections

(a) Perform inspections for discrepancies of the structure near and common to the upper chord and splice fittings of the rear spar of the wing, per Part 2 of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. The inspection procedures include removing existing bolts; performing an ultrasonic or

magnetic particle inspection for cracking of removed H–11 bolts; performing a detailed inspection of all other removed bolts for cracking, corrosion, or damage; replacing cracked, corroded, or damaged bolts with new improved bolts; removing any installed repair bushings; performing an open-hole high frequency eddy current (HFEC) inspection for cracking of the bolt holes; installing new bushings, if necessary; reinstalling bolts that are not cracked, corroded, or damaged; torquing the nuts; performing a detailed inspection of the shim between the kick fitting and bulkhead strap for cracking or migration; and replacing the shim with a new shim if necessary, except as provided by paragraph (h) of this AD. Do the initial inspection at the time specified in paragraph (a)(1) or (a)(2) of this AD, whichever is later.

(1) Inspect at the earlier of the applicable times specified in the "Flights" and "Hours" columns under the heading "Initial Inspection Threshold" in Table 1 of Figure 1 of the service bulletin. Where the "Initial Inspection Threshold" column of Table 1 of Figure 1 of the service bulletin specifies "flights" and "hours," for the purposes of this paragraph the numbers in that column are considered to be the airplane's total flight cycles and total flight hours.

(2) Inspect within 18 months after the effective date of this AD.

Note 2: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Repetitive Inspections

(b) Repeat the inspection required by paragraph (a) of this AD at intervals not to exceed the earlier of the times specified in the "Flights" and "Hours" columns under the heading "Repeat Inspection Intervals" in Table 1 of Figure 1 of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, until paragraph (d) of this AD is accomplished. Where the "Repeat Inspection Intervals" column of Table 1 of Figure 1 of the service bulletin specifies "flights" and "hours," for the purposes of this paragraph, the figures in that column are considered to be the number of flight cycles and flight hours from the time of the most recent inspection per paragraph (a) or (b) of this AD, except as provided by paragraph (g) of this AD.

Repair

(c) If any cracking, corrosion, or damage is found during any inspection required by paragraph (a), (b) or (d) of this AD, before further flight, repair per Part 3 or 4 (as applicable) of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, except as provided by paragraph (h) of this AD.

Optional Modification

(d) Accomplishment of the modification specified in Part 4 of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, constitutes terminating action for the initial inspections required by paragraph (a) of this AD and the repetitive inspections required by paragraph (b) of this AD, provided that the repetitive post-modification inspections required by paragraph (e) of this AD are initiated at the applicable time. The modification procedures include removing installed repair bushings, performing an open-hole HFEC inspection for cracking of the bolt holes, repairing any cracking that is found, oversizing bolt holes, and installing new bushings as required, and new improved bolts.

Post-Modification Inspections

(e) For airplanes on which the optional modification specified in paragraph (d) of this AD is accomplished: At the earlier of the times specified in the "Flights" and "Hours" columns under the heading "Post Modification Threshold" in Table 2 of Figure 1 of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, perform a post-modification inspection per Part 5 of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. The inspection procedures include removing existing bolts; performing a detailed inspection of removed bolts for cracking, corrosion, or damage; replacing cracked, corroded, or damaged bolts with new bolts; removing any installed repair bushings; performing an open-hole HFEC inspection for cracking of the bolt holes; installing new bushings if necessary; reinstalling bolts that are not cracked, corroded, or damaged; torquing the nuts; performing a detailed inspection of the shim between the kick fitting and bulkhead strap for cracking or migration; and replacing the shim with a new shim if necessary; except as provided by paragraph (h) of this AD. Where the "Post Modification Inspection Threshold" column of Table 2 of Figure 1 of the service bulletin specifies "flights" and "hours," for the purposes of this paragraph, the numbers in that column are considered to be the flight cycles and flight hours after accomplishment of the modification specified in paragraph (d) of this AD.

(1) Repeat the inspection at intervals not to exceed the earlier of the times specified in the "Flights" and "Hours" columns under the heading "Post Modification Repeat Inspection Intervals" in Table 2 of Figure 1 of the service bulletin. Where the "Post Modification Repeat Inspection Intervals" column of Table 2 of Figure 1 of the service bulletin specifies "flights" and "hours," for the purposes of this paragraph, the numbers in that column are considered to be the flight cycles and flight hours since the most recent inspection per paragraph (e) or (e)(1) of this AD.

(2) If any cracking is found during any inspection required by paragraph (e) or (e)(1) of this AD, before further flight, repair per Part 5 of the Accomplishment Instructions of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, except as provided by paragraph (h) of this AD.

Actions Accomplished per Previous Issue of Service Bulletin

(f) Inspections, repairs, or modifications accomplished before the effective date of this AD per Boeing Alert Service Bulletin 747–57A2314, including Appendix A and B, dated June 28, 2001, are considered acceptable for compliance with the corresponding action specified in this AD, except as provided by paragraph (h) of this AD.

(g) As specified in Flag Note 1 of the logic diagram in Figure 1 of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003: An inspection accomplished before the effective date of this AD per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110, Revision 6, dated November 21, 1991; or Revision 7, dated April 23, 1998; is considered acceptable, as applicable, for compliance with the initial inspection required by paragraph (a) of this AD. An inspection accomplished before the effective date of this AD per Figure 4, Step 9, of Boeing Service Bulletin 747–57–2110, Revision 3, dated February 19, 1987; Revision 4, dated May 26, 1988; and Revision 5, dated October 26, 1989; is also considered acceptable, as applicable, for compliance with the initial inspection required by paragraph (a) of this AD. The first repeat inspection per paragraph (b) of this AD must be accomplished at the applicable interval established in paragraph (b) of this AD after the most recent inspection per Figure 4, Step 14, of Boeing Service Bulletin 747–57–2110, Revision 6 or 7; or Figure 4, Step 9, of Boeing Service Bulletin 747–57–2110, Revision 3, 4, or 5.

Exception to Instructions in Service Bulletin

(h) Where Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, specifies to contact Boeing for appropriate action, before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

(i) Although Appendix B of Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003, refers to a reporting requirement, such reporting is not required by this AD.

Parts Installation

(j) Except as provided by paragraphs (a) and (b) of this AD, as of the effective date of this AD, no person may install any alloy steel (H–11) bolt in any location specified in this AD on any airplane listed in the applicability of this AD.

Alternative Methods of Compliance

(k) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add

comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

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

Incorporation by Reference

(m) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Service Bulletin 747–57A2314, Revision 1, dated January 9, 2003. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(n) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on January 29, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2571 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–79–AD; Amendment 39–13472; AD 2004–03–28]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 airplanes, that requires a one-time inspection to determine the serial numbers of the elevator and aileron servos of the drive assemblies of the automatic flight control system, and follow-on corrective actions if necessary. This action is necessary to prevent separation of the screws from the autopilot clutch assembly of the SM–300 servo, which could result in uncommanded engagement of the autopilot servo and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ezra Sasson, Aerospace Engineer, Systems and Flight Test Branch, ANE–172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York 11581; telephone (516) 228–7300; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Bombardier Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 airplanes was published in the **Federal Register** on December 11, 2003 (68 FR 69057). That action proposed to require a one-time inspection to determine the serial numbers of the elevator and aileron servos of the drive assemblies of the automatic flight control system, and follow-on corrective actions if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

We estimate that 200 airplanes of U.S. registry will be affected by this AD. It will take approximately 1 work hour per airplane to accomplish the inspection, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the inspection on U.S. operators is estimated to be $13,000, or $65 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator,

the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–28 Bombardier, Inc. (Formerly de Havilland, Inc.): Amendment 39–13472. Docket 2002–NM–79–AD.

Applicability: Model DHC–8–102, –103, –106, –201, –202, –301, –311, and –315 airplanes; serial numbers 003 through 580 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent separation of the screws in the autopilot clutch assembly of the SM–300 servo, which could result in uncommanded engagement of the autopilot servo and consequent reduced controllability of the airplane, accomplish the following:

One-Time Inspection/Follow-on Corrective Action, if Necessary

(a) Within 12 months after the effective date of this AD: Do a general visual inspection to determine the serial numbers of the elevator and aileron servo drive assemblies of the automatic flight control system per paragraphs III.1. and III.2. of the Accomplishment Instructions of Bombardier Alert Service Bulletin A8–22–18, Revision 'B', dated November 19, 2001.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(1) If any elevator or aileron servo, part number (P/N) 7002260–922, or any aileron servo, P/N 7002260–923, with serial numbers 4826 through 5935 inclusive, is found: Before further flight, do all the follow-on actions per paragraphs III.3. and III.4. of the Accomplishment Instructions of Bombardier Alert Service Bulletin A8–22–18, Revision "B", dated November 19, 2001; and per paragraphs 3.A. through 3.F. of the Honeywell Accomplishment Instructions specified on pages 14 through 17 of the Bombardier service bulletin.

(2) If no serial number specified in paragraph (a)(1) of this AD is found, no further action is required by this paragraph.

Part Installation

(b) As of the effective date of this AD, no person may install an elevator or aileron servo, P/N 7002260–922, or an aileron servo, P/N 7002260–923, with serial numbers 4826 through 5935 inclusive, on any airplane.

Note 2: Although Bombardier Alert Service Bulletin A8–22–18, Revision "B", dated November 19, 2001, specifies accomplishment of concurrent requirements, this AD does not include those requirements.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(d) The actions shall be done in accordance with Bombardier Alert Service Bulletin A8–22–18, Revision 'B', dated November 19, 2001. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Westbury, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF–2001–40, dated November 9, 2001.

Effective Date

(e) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on February 3, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2681 Filed 2–11–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–284–AD; Amendment 39–13469; AD 2004–03–25]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330 and A340–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Airbus Model A330 and A340–200 and –300 series airplanes, that requires repetitive inspections for proper installation of the parachute pins located in the escape slides/rafts at the door 3 Type I emergency exits on the left and right sides of the airplane; a one-time inspection of the associated electrical harnesses for the escape slides/rafts for proper routing and installation; and corrective actions if necessary. This AD also requires adjustment of the speed lacing for the soft covers of the escape slides/rafts, which will terminate the repetitive inspections. This action is necessary to prevent failure of the escape slides/rafts to deploy correctly at door 3 Type I emergency exits, which could result in the escape slides/rafts being unusable during an emergency evacuation, and consequent injury to passengers or crew members. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Airbus Model A330 and A340–200 and –300 series airplanes was published in the **Federal Register** on December 5, 2003 (68 FR 67984). That action proposed to require repetitive inspections for proper installation of the parachute pins located in the escape slides/rafts at the door 3 Type I emergency exits on the left and right sides of the airplane; a one-time inspection of the associated electrical harnesses for the escape slides/rafts for proper routing and

installation; and corrective actions if necessary. That action also proposed to require adjustment of the speed lacing for the soft covers of the escape slides/rafts, which would terminate the repetitive inspections.

Comments

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

Request To Clarify Paragraph (c), Parts Installation

The commenter states that the affected slide part numbers and serial number range are listed in the Applicability section of the proposed AD, but only the affected part numbers are listed in paragraph (c), Parts Installation, of the proposed AD. The commenter requests that the serial number range be included in paragraph (c) to coincide with the Applicability section. The commenter states that this change would clarify that slide/raft assemblies with serial numbers later than those in the applicability section are not affected by the AD.

The FAA concurs with the commenter's request to add the serial number range which appears in the Applicability section of this final rule to paragraph (c). We find that this change will clarify that slide/raft assemblies with serial numbers later than those listed in paragraph (c) are not affected by this final rule. We have clarified paragraph (c) of this final rule accordingly.

Conclusion

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

Cost Impact

We estimate that 14 Model A330 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required inspections, and that the average labor rate is $65 per work hour. Based on these figures, the cost impact on U.S. operators of the inspections required by this AD is estimated to be $910, or $65 per airplane.

It will take approximately 3 work hours per airplane to adjust the speed lacing for the escape slide/raft soft cover at an average labor rate of $65 per work hour. Based on these figures, the cost impact on U.S. operators for the adjustment of the speed lacing for the escape slide/raft soft cover required by this AD is estimated to be $2,730, or $195 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Currently, there are no Model A340 series airplanes on the U.S. Register. However, should an affected airplane be imported and placed on the U.S. Register in the future, it will require 1 work hour per airplane to accomplish the inspections and 3 work hours per airplane to accomplish the adjustment of the speed lacing for the escape slide/raft soft cover, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the AD for Model A340 operators would be $260 per airplane.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–25 Airbus: Amendment 39–13469. Docket 2001–NM–284–AD.

Applicability: Model A330 and A340–200 and –300 series airplanes equipped with an escape slide/raft having any part number (P/N) 7A1509–101 through 7A1509–117 inclusive, and any serial number AD001 through AD0855 inclusive, at door 3 Type I emergency exits; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the escape slides/rafts to deploy correctly at door 3 Type I emergency exits, which could result in the escape slides/rafts being unusable during an emergency evacuation, and consequent injury to passengers or crew members, accomplish the following:

Inspections

(a) Within 550 flight hours after the effective date of this AD: Do a detailed inspection of the escape slides/rafts located at door 3 Type I emergency exits, on the left and right sides of the airplane, for correct installation of the parachute pins, and a one-time detailed inspection of the associated electrical harnesses for correct installation of the quick-disconnect connector, in accordance with paragraphs 4.1 and 4.2 of Airbus All Operator Telex (AOT) A330–25A3154 (for Model A330 series airplanes) or A340–25A4172 (for Model A340–200 and –300 series airplanes), both dated July 26, 2001; as applicable. If any parachute pin or quick disconnect connector is incorrectly installed, before further flight, do the corrective actions per the applicable AOT. Repeat the inspections of the parachute pins thereafter at intervals not to exceed 1,000 flight hours until accomplishment of paragraph (b) of this AD.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by

the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Note 2: Repetitive inspections of the electrical harnesses are not required.

Terminating Action for Repetitive Inspections

(b) Within 18 months after the effective date of this AD: Adjust the speed lacing for the soft covers of the escape slides/rafts located at door 3 Type I emergency exits, in accordance with paragraph 4.3 of Airbus AOT A330–25A3154 (for Model A330 series airplanes) or A340–25A4172 (for Model A340–200 and –300 series airplanes), both dated July 26, 2001; as applicable. This adjustment terminates the repetitive inspections of the parachute pins required by paragraph (a) of this AD.

Note 3: The AOTs reference Goodrich Aircraft Evacuation Systems Alert Service Bulletin 7A1509–25A324, dated July 16, 2001, as an additional source of service information for adjusting the speed lacing.

Parts Installation

(c) As of the effective date of this AD, no person may install on any airplane an escape slide/raft having any P/N 7A1509–101 through 7A1509–117 inclusive, and any serial number AD001 through AD0855 inclusive, unless the parachute pin has been inspected and the speed lacing has been adjusted in accordance with paragraphs (a) and (b) of this AD.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Airbus All Operator's Telex A330–25A3154, dated July 26, 2001; or Airbus All Operator's Telex A340–25A4172, dated July 26, 2001; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directives 2001–359(B) R3, dated October 30, 2002, and 2001–360(B) R1, dated February 6, 2002.

Effective Date

(f) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on February 3, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2682 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–223–AD; Amendment 39–13468; AD 2004–03–24]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200, A330–300, A340–200, and A340–300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to all Airbus Model A330–200, A330–300, A340–200, and A340–300 series airplanes. This action requires a revision of the airplane flight manual to include procedures for a pre-flight elevator check before each flight, repetitive inspections for cracks of the attachment lugs of the mode selector valve position transducers on the elevator servocontrols, and corrective actions if necessary. This action is intended to advise the flightcrew of the potential for an undetected inoperative elevator, and of the action they must take to avoid this hazard. This action is necessary to ensure proper functioning of the elevator surfaces, and to detect and correct cracking of the attachment lugs, which could result in partial loss of elevator function and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective February 26, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 26, 2004.

Comments for inclusion in the Rules Docket must be received on or before March 11, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–223–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-iarcomment@faa.gov*. Comments sent via the Internet must contain "Docket No. 2003–NM–223–AD" in the subject line and need not be submitted in triplicate. Comments sent via fax or the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in this AD may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on all Airbus Model A330–200, A330–300, A340–200, and A340–300 series airplanes. Each elevator on these airplanes is equipped with two servocontrols having three operating modes. A selector valve installed in each servocontrol enables the servocontrol to change between operating modes; the selector valve's position is transmitted to the flight control computers by a transducer. The DGAC advises that several cracks of the transducer body at its attachment lugs have been detected. The affected transducers were installed at the damping positions 3CS1 and 3CS2. The cracks resulted in displacement of the transducer and consequent leakage of the hydraulic fluid into the affected servocontrol. In two cases the displacement of the transducer resulted in the elevator becoming inoperative (it dropped into a full down position), with no electronic centralized aircraft monitor (ECAM) warning provided to the flightcrew. Without an ECAM warning, this inoperative condition can be identified only if no elevator surface movement is detected during a pre-flight elevator check. Loss of elevator function, if not corrected, could result

in reduced controllability of the airplane.

Explanation of Relevant Service Information

Airbus has issued Service Bulletins A330–27A3115 and A340–27A4119, both Revision 02, dated December 30, 2003. The service bulletins describe procedures for repetitive dye penetrant inspections for cracks of the attachment lugs of the mode selector valve position transducer on each elevator servocontrol installed at damping positions 3CS1 and 3CS2. The service bulletins also provide procedures for replacing a cracked transducer with a new part and torqueing the bolts when the transducer is reinstalled. The DGAC classified the service bulletins as mandatory and issued French airworthiness directive F–2003–460, dated December 24, 2003, to ensure the continued airworthiness of these airplanes in France.

The Airbus service bulletins refer to Goodrich Actuation Systems Inspection Service Bulletin SC4800–27–13 as an additional source of service information for the inspection.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. We have examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to ensure proper functioning of the elevator surfaces, and to detect and correct cracking of the attachment lugs of the mode selector valve position transducers on the elevator servocontrols, which could result in partial loss of elevator function and consequent reduced controllability of the airplane. This AD requires a revision of the airplane flight manual (AFM) to include procedures for a pre-flight elevator check, repetitive inspections for cracks of the attachment lugs, and corrective action if necessary. The actions are required to be accomplished in accordance with the Airbus service bulletins described previously, except as discussed under "Differences Between This AD and French Airworthiness Directive."

This AD also requires that operators report crack findings to Airbus. Because the cause of the cracking is not known, these required inspection reports will help determine the extent of the cracking in the affected fleet. Based on the results of these reports, we may determine that additional rulemaking is warranted.

Differences Between This AD and the French Airworthiness Directive

The FAA and DGAC airworthiness directives differ in their compliance times for the first repetitive inspection interval for airplanes already inspected in accordance with Revision 01 of the service bulletin. The DGAC allows up to 700 flight cycles or 1,350 total flight cycles (whichever occurs later) for this interval, but this AD requires that all inspections be done within intervals of 350 flight cycles. French airworthiness directive 2003–371—which was replaced by the existing French airworthiness directive 2003–460—required that the inspection be done only one time. Therefore, for operators that had complied with 2003–371, the additional time following the initial inspection could provide the necessary time to schedule the subsequent repetitive inspections. Since we have not previously required the subject inspection, this AD does not provide for any extension of the first-repeated inspection interval. However, we may approve requests to adjust that interval, according to the provisions of paragraph (g) of this AD, if the request includes data that prove that the first repetitive interval would provide an acceptable level of safety.

Also, the DGAC airworthiness directive mandates a change to the flight crew operating manual (FCOM) to include an additional elevator pre-flight check. We agree with the need to check for proper functioning of the elevators before takeoff, but we have determined that the appropriate location for the procedure is in the AFM, in the Limitations section. We base this determination on the following considerations:

1. The FCOM does not require FAA approval; therefore, FCOM changes cannot be mandated by an AD.

2. It is possible that later changes to the FCOM made by an operator could result in removal of the necessary pre-flight check.

3. An ECAM warning to the flightcrew would not be provided following an elevator failure.

4. An elevator failure could result in reduced controllability of the airplane.

The DGAC airworthiness directive specifies that the FCOM be amended "for one or both damping servo controls above 1000 FC since new." However, this AD requires that the parallel change to the AFM—which applies across airplane model/series—be incorporated within 30 days.

Interim Action

We consider this AD interim action. The manufacturer is considering developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, we may consider additional rulemaking.

Determination of Rule's Effective Date

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

Comments Invited

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

Submit comments using the following format:

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2003–NM–223–AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–24 Airbus: Amendment 39–13468. Docket 2003–NM–223–AD.

Applicability: All Model A330–200, A330–300, A340–200, and A340–300 series airplanes; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To ensure proper functioning of the elevator surfaces, and to detect and correct cracking of the attachment lugs of the mode selector valve position transducers on the elevator servocontrols, which could result in partial loss of elevator function and consequent reduced controllability of the airplane, accomplish the following:

AFM Revision

(a) Within 30 days after the effective date of this AD, revise the Limitations section of the airplane flight manual (AFM) to include a pre-flight elevator check, by including the following language. This may be done by inserting a copy of this AD into the applicable AFM. Thereafter perform the pre-flight check before every flight in accordance with the procedure.

Prior or During Taxi:

"FLIGHT CONTROLS CHECK

1. AT A CONVENIENT STAGE, PRIOR TO OR DURING TAXI, AND BEFORE ARMING THE AUTOBRAKE, THE PF SILENTLY APPLIES FULL LONGITUDINAL AND LATERAL SIDESTICK DEFLECTION. ON THE F/CTL PAGE, THE PNF CHECKS FULL TRAVEL OF ALL ELEVATORS AND ALL AILERONS, AND THE CORRECT DEFLECTION AND RETRACTION OF ALL SPOILERS. THE PNF CALLS OUT "FULL UP," "FULL DOWN," "NEUTRAL," "FULL LEFT," "FULL RIGHT," "NEUTRAL," AS EACH FULL TRAVEL/NEUTRAL POSITION IS REACHED. THE PF SILENTLY CHECKS THAT THE PNF CALLS ARE IN ACCORDANCE WITH THE SIDESTICK ORDER.

NOTE: IN ORDER TO REACH FULL TRAVEL, FULL SIDESTICK MUST BE HELD FOR A SUFFICIENT PERIOD OF TIME.

2. THE PF PRESSES THE PEDAL DISC PUSHBUTTON ON THE NOSEWHEEL TILLER, AND SILENTLY APPLIES FULL LEFT RUDDER, FULL RIGHT RUDDER, AND NEUTRAL. THE PNF CALLS OUT "FULL LEFT," "FULL RIGHT," "NEUTRAL," AS EACH FULL TRAVEL/NEUTRAL POSITION IS REACHED.

3. THE PNF APPLIES FULL LONGITUDINAL AND LATERAL SIDESTICK DEFLECTION, AND SILENTLY CHECKS FULL TRAVEL AND CORRECT SENSE OF ALL ELEVATORS AND ALL AILERONS, AND CORRECT DEFLECTION AND RETRACTION OF ALL SPOILERS, ON THE ECAM F/CTL PAGE."

Note 1: Full and complete elevator travel (position commanded) can be verified on the ECAM Flight Control Page. A determination of "correct sense" should include verification that there is complete and full motion of the sidesticks without binding.

(b) If any pre-flight check required by paragraph (a) of this AD reveals improper function of the elevator: Before further flight, perform the inspections required by paragraph (c) of this AD.

Inspections

(c) At the applicable time specified in paragraph (c)(1) or (c)(2) of this AD, except as required by paragraph (b) of this AD: Perform a dye penetrant inspection of the attachment lugs of the mode selector valve position transducers on each elevator servocontrol installed at damping positions 3CS1 and 3CS2. Do the inspection in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–27A3115 or A340–27A4119, both Revision 02, both dated December 30, 2003, as applicable (hereafter "the service bulletin"). An inspection that is done before the effective date of this AD is acceptable for compliance with the initial inspection requirement of this paragraph, if the inspection is done in accordance with any of the following Airbus All Operators Telexes (AOTs): AOT A330–27A3115 or A340–27A4119, dated September 11, 2003, or Revision 01 of each AOT dated September 25, 2003; as applicable. Repeat the inspection thereafter at intervals not to exceed 350 flight cycles.

(1) If the age of the servocontrol from the date of its first installation on the airplane can be positively determined: Do the inspection before the accumulation of 1,000 total flight cycles on the elevator servocontrol, or within 350 flight cycles on the servocontrol after the effective date of this AD, whichever occurs later.

(2) If the age of the servocontrol from the date of its first installation on the airplane cannot be positively determined, do the inspection within 350 flight cycles on the servocontrol after the effective date of this AD.

Note 2: The service bulletin refers to Goodrich Actuation Systems Inspection Service Bulletin SC4800–27–13 as an additional source of service information for the inspection.

Corrective Actions

(d) If any crack is found during any inspection required by paragraph (c) of this AD: Before further flight, replace either the transducer or servocontrol with a new part, in accordance with the service bulletin.

Reporting Requirement

(e) If any crack is found during any inspection required by paragraph (c) of this AD: Submit a report in accordance with the service bulletin at the applicable time(s) specified in paragraphs (e)(1) and (e)(2) of this AD: Submit reports to Airbus Customer

Services, Engineering and Technical Support, Attention: J. Laurent, SEE53, fax +33/(0)5.61.93.44.25, Sita Code TLSBQ7X. Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

(1) For an initial inspection done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(2) For an inspection done after the effective date of this AD: Submit the report within 30 days after the inspection.

Parts Installation

(f) As of the effective date of this AD, no person may install the following part on any airplane: a transducer, or a transducer fitted on an elevator servocontrol, in the operator's inventory before September 25, 2003, unless that transducer has been inspected in accordance with the service bulletin and is crack-free.

Alternative Methods of Compliance

(g) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(h) Unless otherwise specified in this AD, the actions must be done in accordance with Airbus Service Bulletin A330–27A3115, Revision 02, including Appendix 01, dated December 30, 2003; or Airbus Service Bulletin A340–27A4119, Revision 02, including Appendix 01, dated December 30, 2003; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive F–2003–460, dated December 24, 2003.

Effective Date

(i) This amendment becomes effective on February 26, 2004.

Issued in Renton, Washington, on February 2, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2683 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–283–AD; Amendment 39–13470; AD 2004–03–26]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Falcon 900EX Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dassault Model Falcon 900EX series airplanes, that requires modification of the front attachment area of the No. 2 engine. This action is necessary to prevent failure of the fail-safe lugs of the hoisting plate of the forward engine mount, and subsequent cracking of the pick-up folded sheet of the pylon forward rib. Such cracking could rupture the mast case box, which could result in loss of the two forward engine mounts and consequent separation of the engine from the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective March 17, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 17, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Dassault Falcon Jet, PO Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dassault Model Falcon 900EX series airplanes was published in the **Federal Register** on October 9, 2003 (68 FR 58285). That action proposed to require modification of the front attachment area of the No. 2 engine.

Comment

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

Request To Add Revised Service Information

The commenter asks that the proposed AD be changed to cite only Dassault Service Bulletin F900EX–103, Revision 1, dated October 16, 2002, as the appropriate source of service information for accomplishment of the modification. (The original issue of the service bulletin was cited as the appropriate source of service information for accomplishment of the modification in the proposed AD.) The commenter states that there are some build differences on airplanes with serial numbers 1 through 4 inclusive, that do not exist on other airplanes specified in the applicability of the original issue of the service bulletin; therefore, the original issue cannot be used for airplanes with those serial numbers. Revision 1 describes additional procedures for the modification of airplanes with serial numbers 1 through 4. The commenter adds that the Direction Générale de l'Aviation Civile, which is the airworthiness authority for France, has been informed of this change and has agreed not to issue a revision to French airworthiness directive 2001–160–027(B), dated May 2, 2001 (referenced in the proposed AD), due to inclusion of the phrase "original issue or further approved revisions" in that airworthiness directive.

The FAA agrees with the commenter. We have added Revision 1 of the service bulletin, and we have changed all service bulletin references in this final rule to specify Revision 1.

Conclusion

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

Cost Impact

We estimate that 36 airplanes of U.S. registry will be affected by this AD, that it will take about 85 work hours per airplane to accomplish the modification,

and that the average labor rate is $65 per work hour. Required parts will cost about $14,479 per airplane. Based on these figures, the cost impact of the modification on U.S. operators is estimated to be $720,144, or $20,004 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2004–03–26 Dassault Aviation: Amendment 39–13470. Docket 2001–NM–283–AD.

Applicability: Model Falcon 900EX series airplanes, serial numbers 1 through 60 inclusive; certificated in any category; except those on which Dassault Modifications M2754 and M2925, identified in Dassault Service Bulletin F900EX–103, Revision 1, dated October 16, 2002, have been accomplished.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the fail-safe lugs of the forward engine mount, and consequent cracking of the pick-up folded sheet of the pylon forward rib, which could rupture the mast case box and result in loss of the two forward engine mounts and consequent separation of the engine from the airplane, accomplish the following:

Modification

(a) Prior to the accumulation of 3,750 flight cycles since the date of issuance of the original Airworthiness Certificate or the date of issuance of the Export Certificate of Airworthiness, whichever occurs first: Modify the front attachment area of the No. 2 engine by doing all the actions per Paragraphs 2.A. through 2.D. of the Accomplishment Instructions of Dassault Service Bulletin F900EX–103, Revision 1, dated October 16, 2002.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(c) The actions shall be done in accordance with Dassault Service Bulletin F900EX–103, Revision 1, dated October 16, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in French airworthiness directive 2001–160–027(B), dated May 2, 2001.

Effective Date

(d) This amendment becomes effective on March 17, 2004.

Issued in Renton, Washington, on February 3, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2684 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–CE–38–AD; Amendment 39–13473; AD 2004–03–29]

RIN 2120–AA64

Airworthiness Directives; Pacific Aerospace Corporation, Ltd. Models FU24–954 and FU24A–954 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA adopts a new airworthiness directive (AD) for all Pacific Aerospace Corporation, Ltd. Models FU24–954 and FU24A–954 airplanes. This AD requires you to perform repetitive detailed visual inspections of the forward vertical fin base for cracks. If any cracks or discrepancies are found, you must repair the structure before further flight and notify the FAA. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for New Zealand. We are issuing this AD to detect and correct cracks in the vertical fin base, which could result in loss of the fin and loss of aircraft control.

DATES: This AD becomes effective on April 19, 2004.

ADDRESSES: You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–38–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, Small Airplane Directorate, 901 Locust, Room 302, Kansas City, MO 64106; telephone: 816–329–4146; facsimile: 816–329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Civil Aviation Authority (CAA), which is the airworthiness authority for New Zealand, notified the FAA of an unsafe condition that may exist on all

Pacific Aerospace Corporation, Ltd. Models FU24–954 and FU24A–954 airplanes. The CAA reports a recent fatal accident where the aircraft's fin separated in flight. Initial investigation of this accident indicates that the forward fin structure failed from fatigue cracks that were concealed beneath the rubber abrasion protection fitted to the fin.

What is the potential impact if FAA took no action? Failure to detect cracks in the vertical fin base could result in loss of the fin and loss of aircraft control.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to all Pacific Aerospace Corporation, Ltd. Models FU24–954 and FU24A–954 airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 30, 2003 (68 FR 61766). The NPRM proposed to require you to perform repetitive detailed visual inspections of the forward vertical fin base for cracks. If any cracks or discrepancies are found, you must repair the structure before further flight and notify the FAA.

Comments

Was the public invited to comment? We provided the public the opportunity to participate in the development of this AD. We received no comments on the proposal or on the determination of the cost to the public.

Conclusion

What is FAA's final determination on this issue? We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed except for the changes discussed above and minor editorial corrections. We have determined that these changes and minor corrections:

—are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and

—do not add any additional burden upon the public than was already proposed in the NPRM.

Changes to 14 CFR Part 39—Effect on the AD

How does the revision to 14 CFR part 39 affect this AD? On July 10, 2002, the FAA published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

How many airplanes does this AD impact? We estimate that this AD affects 2 airplanes in the U.S. registry.

What is the cost impact of this AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
8 workhours est. $60 per hour = $480	No parts needed for inspection	$480	$960

The FAA has no method of determining the number of repairs each owner/operator will incur over the life of each of the affected airplanes based on the results of the inspections. We have no way of determining the number of airplanes that may need such repair. The extent of damage may vary on each airplane.

Regulatory Findings

Will this AD impact various entities? We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Will this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this AD:

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

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

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

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 2003–CE–38–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. FAA amends § 39.13 by adding a new AD to read as follows:

2004–03–29 Pacific Aerospace Corporation, Ltd.: Amendment 39–13473; Docket No. 2003–CE–38–AD.

When Does This AD Become Effective?

(a) This AD becomes effective on April 19, 2004.

What Other ADs Are Affected by This Action?

(b) None.

What Airplanes Are Affected by This AD?

(c) This AD affects Models FU24–954 and FU24A–954 airplanes, all serial numbers, that are certificated in any category.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of a recent fatal accident where the aircraft's fin separated in flight. The actions specified in this AD are intended to detect and correct cracks in the vertical fin base, which could result in loss of the fin or loss of control of the aircraft.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) Perform visual inspection of the forward area at the base of the fin for cracks.	Initially inspect within the next 50 hours time-in-service (TIS) after April 19, 2004 (the effective date of this AD). Repetitively inspect every 100 hours TIS thereafter.	Inspect from the bottom of the fin up to the first external strap, paying particular attention to the skin in the area of the rivets that join the fin skin to the bulkhead, part number (P/N) 242305, and aft to the first vertical lap joint. To do this inspection, remove any rubber abrasion protection that is fitted in this area, including any sealant. You must also remove the fin leading edge fairing, P/N 242321.
(2) Repair any cracks that are found during the inspection.	Prior to further flight after doing any inspection required in paragraph (e)(1) of this AD.	Obtain an FAA-approved repair scheme from Pacific Aerospace Corporation, Ltd., Airport Road, Hamilton Airport, Hamilton, New Zealand and notify the FAA at the address and phone number in paragraph (f) of this AD.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, FAA, Small Airplane Directorate. For information on any already approved alternative methods of compliance, contact Karl Schletzbaum, Aerospace Engineer, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, MO 64106; telephone: (816) 329–4146; facsimile: (816) 329–4090.

Is There Other Information That Relates to This Subject?

(g) CAA airworthiness directive DCA/FU24/173, dated April 23, 2002, also addresses the subject of this AD.

Issued in Kansas City, Missouri, on February 4, 2004.

Dorenda D. Baker,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2953 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91 and 93

[Docket No. FAA–2002–13235; Amendment Nos. 91–278, 93–82]

RIN 2120–AH57

Special Air Traffic Rules; Flight Restrictions in the Vicinity of Niagara Falls; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on February 28, 2003. That action codified flight restrictions for aircraft operating in U.S. airspace in the vicinity of Niagara Falls, NY.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Terry Brown, telephone (202) 267–9193.

Correction

■ In final rule FR Doc. 03–4638, published on February 28, 2003 (68 FR 9792), make the following corrections:

■ 1. On page 9792, in column 1, in the heading section, beginning on line 4, correct "Amendment Nos. 91–273 and 93–82" to read "Amendment Nos. 91–278 and, 93–82".

Issued in Washington, DC on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2880 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 119, 121 and 135

[Docket No. FAA–2003–15571; Amdt. Nos. 119–8, 121–298 and 135–88]

RIN 2120–AI00

DOD Commercial Air Carrier Evaluators; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on July 10, 2003. That rule clarified existing regulations as they apply to Department of Defense (DOD) commercial air carrier evaluators.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Lt. Col. Tom Barrale, USAF, Department of Defense Air Mobility Command Liaison Officer to FAA Flight Standards Service, (202) 267–7088.

Correction

In the final rule FR Doc. 03–17459 published on July 10, 2003, (68 FR 41214), make the following corrections:

■ 1. On page 41214, in column 3, in the heading section of the rule at the bottom of the page, beginning on line 4 of the heading, correct "Amdt Nos. 119–8, 121–286, and 135–83" to read "Amdt Nos. 119–8, 121–298, and 135–88".

Issued in Washington, DC, on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2874 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 119, 121, 129, 135, and 183

[Docket No. FAA–1999–5401; Amdt. Nos 119–6, 121–296, 129–34, 135–87, and 183–11]

RIN 2120–AE42

Aging Airplane Safety; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Interim final rule; correction.

SUMMARY: This document corrects amendment numbers in the final rule published in the **Federal Register** on February 4, 2003. That action extended the comment period for the interim final rule which deals with inspections and records reviews required on aircraft

with more than fourteen years in service.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Frederick Sobeck, telephone (202) 267–7355.

Correction

■ In final rule FR Doc. 03–2679, published on February 4, 2003 (68 FR 5782), make the following corrections:
■ 1. On page 5782, in column 1 of the heading section, beginning on line five, correct "Amdt. Nos. 119–6, 121–284, 129–34, 135–81, and 183–11" to read "Amdt. Nos. 119–6, 121–296, 129–34, 135–87, and 183–11".

Issued in Washington, DC on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2879 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125, and 129

[Docket No. FAA–2001–10910; Amendment Nos. 121–297, 125–41, and 129–37]

RIN 2120–AG90

Collision Avoidance Systems; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on April 1, 2003. That action revised the applicability of certain collision avoidance system requirements for airplanes.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Alberta Brown, telephone (202) 267–8321.

Correction

■ In the final rule FR Doc. 03–7653, published on April 1, 2003 (68 FR 15884), make the following correction:
■ 1. On page 15884, in column 1 in the heading section, beginning on line 4, correct "Amendment Nos. 121–286, 125–41, and 129–37" to read "Amendment Nos. 121–297, 125–41, and 129–37".

Issued in Washington, DC on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2881 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125, and 135

[Docket No. FAA–2003–15682; Amendment Nos. 121–300 125–42, 135–89]

RIN 2120–AH89

Digital Flight Data Recorder Requirements—Changes to Recording Specifications and Additional Exceptions; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects amendment numbers assigned in the final rule published in the **Federal Register** on July 18, 2003. That action amended the flight data recorder regulations by expanding the recording specifications of certain data parameters for specified airplanes, and by adding aircraft models to the lists of aircraft excepted from the 1997 regulations.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Gary Davis, telephone (202) 267–8166.

Correction

■ In the correction to the final rule FR Doc. 03–18269, published on July 18, 2003 (68 FR 42932), make the following correction:

■ 1. On page 42932 in column one, in the heading section beginning on line 4, correct "Amendment Nos. 121–288, 125–42, 135–84" to read "Amendment Nos. 121–300, 125–42, 135–89".

Issued in Washington, DC on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2876 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 129

[Docket No. FAA–2003–15653; Amendment Nos. 121–299 and 129–38]

RIN 2120–AH96

Flightdeck Security on Large Cargo Airplanes; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to the amendment numbers in the final rule published in the **Federal Register** on July 18, 2003. That rule provided an alternative means of compliance to operators of all-cargo airplanes that are required to have a reinforced security flightdeck door.

EFFECTIVE DATE: This correction is effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Joe Keenan, (202) 267–9579.

Correction

In the final rule FR Doc. 03–18075 published on July 18, 2003, (68 FR 42874), make the following corrections:

■ 1. On page 42874, in column 1, in the heading section, beginning on line 4 correct "Amendment Nos. 121–287 and 129–37" to read "Amendment Nos. 121–299 and 129–38".

Issued in Washington, DC, on January 30, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 04–2877 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 529 and 556

Certain Other Dosage Form New Animal Drugs; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for use of oxytetracycline hydrochloride soluble

powder for skeletal marking of finfish fry and fingerlings by immersion.

DATES: This rule is effective February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (301) 827–7571, e-mail: *jgotthar@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 130–435 that provides for use of OXYMARINE (oxytetracycline hydrochloride) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667 which were compiled under National Research Support Project 7 (NRSP–7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. The supplemental NADA is approved as of December 24, 2003, and the regulations are amended in 21 CFR part 529 by adding § 529.1660 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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

FDA has determined under 21 CFR 25.33(d)(4) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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

List of Subjects

21 CFR Part 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 529 and 556 are amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Section 529.1660 is added to read as follows:

§ 529.1660 Oxytetracycline.

(a) *Specifications.* Each gram of powder contains 366 milligrams (mg) of oxytetracycline hydrochloride.

(b) *Sponsor. See* No. 046573 in § 510.600 of this chapter.

(c) *Related tolerances. See* § 556.500 of this chapter.

(d) *Conditions of use in finfish*—(1) *Amount.* Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.

(2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.500 [Amended]

■ 4. Section 556.500 *Oxytetracycline* is amended in paragraph (b) by removing "*catfish, lobster, and salmonids*" and by adding in its place "*finfish, and lobster*".

Dated: January 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–2894 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for revised labeling for the use of single-ingredient monensin Type A medicated articles to make Type C medicated feeds used for the prevention and control of coccidiosis in feedlot cattle. The regulations are being amended to remove a redundant entry for use of monensin in Type C medicated cattle feeds.

DATES: This rule is effective February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *jmessenh@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 for use of RUMENSIN 80 (monensin sodium) Type A medicated article. The supplemental NADA provides revised labeling for Type C medicated feeds containing 10 to 30 grams per ton (g/ton) of monensin used for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in feedlot cattle. This revised labeling replaces labeling approved in 1998 for this indication (64 FR 5158, February 3, 1999). The supplemental application is approved as of December 12, 2003, and the regulations are amended in 21 CFR 558.355(f)(3)(vii) to remove indications for improved feed efficiency in cattle feeds containing 10 to 30 g/ton of monensin. This indication for use is already codified in 21 CFR 558.355(f)(3)(i) for cattle feeds containing 5 to 30 g of monensin per ton.

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

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor environmental impact statement is required.

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

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

■ 2. Section 558.355 *Monensin* is amended in paragraph (f)(3)(vii)(*a*) by removing "improved feed efficiency; for"; and in paragraph (f)(3)(vii)(*b*) by removing "feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis,".

Dated: January 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–2893 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD13–04–004]

Drawbridge Operation Regulations; Snake River, Burbank, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Burlington Northern Santa Fe Railroad Drawbridge across the Snake River, mile 1.5, at Burbank, Washington. This deviation allows the vertical lift span to be temporarily closed during two periods while wire ropes are replaced. The deviation is necessary to facilitate this essential maintenance.

DATES: This deviation is effective from 8 a.m. March 8 through 5 p.m. March 12, 2004, and from 8 a.m. March 15 through 5 p.m. March 16, 2004.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (oan), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174–1067 between 7:45 a.m. and 4:15 p.m., Monday through Friday, except Federal holidays. The telephone number is (206) 220–7270. The Bridge Section of the Aids to Navigation and Waterways Management Branch maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Austin Pratt, Chief, Bridge Section, Aids to Navigation and Waterways Management Branch, (206) 220–7282.

SUPPLEMENTARY INFORMATION: The Burlington Northern Santa Fe Railroad (BNSF) requested this deviation from normal operations to facilitate the replacement of wire ropes on the lift span and its supporting towers. This project is occurring during the annual lock maintenance closure on the Snake River. During lock closure commercial traffic will be much reduced so that few, if any, vessels will be hindered by this bridge maintenance project. Currently, this drawbridge is maintained in the open position except for the passage of trains.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: February 3, 2004.

Jeffrey M. Garrett,

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

[FR Doc. 04–2989 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–04–019]

Drawbridge Operation Regulations; Loxahatchee River, Palm Beach County, FL

AGENCY: U.S. Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Florida East Coast Railway bridge across the Loxahatchee River, mile 1.2, Jupiter, Florida. This deviation allows the bridge to remain in the closed position from 8 a.m. to 12:30 p.m. and 1 p.m. to 5 p.m. Monday through Friday from February 10 until March 12, 2004, for repairs.

DATES: This deviation is effective from 8 a.m. on February 10 until 5 p.m. on March 12, 2004.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket [CGD07–04–019] will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Miami, Florida 33131–3050 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch at (305) 415–6744.

SUPPLEMENTARY INFORMATION: The Florida East Coast Railway bridge across the Loxahatchee River, Jupiter, Florida, is a single leaf bascule bridge with a vertical clearance of 4 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 40 feet. The current operating regulation in 33 CFR 117.300 requires that: (a) The bridge is not constantly tended; (b) The draw is normally in the fully open position, displaying flashing green lights to indicate that vessels may pass; (c) When a train approaches, the lights go to flashing red and a horn starts four blasts, pauses, and then continues four blasts. After an eight minute delay, the draw lowers and locks, providing the scanning equipment reveals nothing under the draw. The draw remains down for a period of eight minutes or while the approach track circuit is occupied; (d) After the train has cleared, the draw opens and the lights return to flashing green.

On January 12, 2004, the bridge owner, Florida East Coast Railroad, requested a deviation from the current operating regulations to allow the owner and operator to keep this bridge in the closed position during certain times each day to facilitate repairs. The Commander, Seventh Coast Guard District has granted a temporary

deviation from the operating requirements listed in 33 CFR 117.300 to complete repairs to the bridge. Under this deviation the Florida East Coast Railway bridge, across the Loxahatchee River, mile 1.2, Jupiter, Florida, need not open from 8 a.m. to 12:30 p.m. and 1 p,m. to 5 p.m. Monday through Friday from February 10 until March 12, 2004.

Dated: February 3, 2004.

Greg Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 04–2990 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–03–205]

RIN 1625–AA00

Security Zone; Military Ocean Terminal Sunny Point and Lower Cape Fear River, Brunswick County, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone at Military Ocean Terminal Sunny Point (MOTSU), North Carolina. Entry into or movement within the security zone will be prohibited without authorization from the Captain of the Port (COTP). This action is necessary to safeguard the vessels and the facility from sabotage, subversive acts, or other threats.

DATES: This rule is in effect from 12:01 a.m. e.s.t. on January 13, 2004 to 12:01 a.m. e.d.t. on June 13, 2004.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–03–205 and are available for inspection or copying at Coast Guard Marine Safety Office, 721 Medical Center Drive, Suite 100, Wilmington, North Carolina 28401, between 7:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Chuck Roskam, Chief Port Operations (910) 772–2200 or toll free (877) 229–0770.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. The Coast Guard is promulgating this security zone regulation to protect Military Ocean Terminal Sunny Point, NC, and the surrounding vicinity from threats to national security. Accordingly, based on the military function exception set forth in the Administrative Procedure Act, 5 U.S.C. 553(a)(1), notice and comment rule-making and advance publication, pursuant to 5 U.S.C. 553(b) and (c), are not required for this regulation.

Background and Purpose

Vessels frequenting the security zone at Military Ocean Terminal Sunny Point (MOTSU) facility serve as a vital link in the transportation of military munitions and explosives in support of Department of Defense missions at home and abroad. This vital transportation link is potentially at risk to acts of terrorism, sabotage and other criminal acts. Munitions and explosives laden vessels also pose a unique threat to the safety and security of the MOTSU facility, vessel crews, and others in the maritime community and the surrounding community should the vessels be subject to acts of terrorism or sabotage, or other criminal acts. The ability to control waterside access to munitions and explosives laden vessels moored to the MOTSU facility is critical to national defense and security, as well as to the safety and security of the MOTSU facility, vessel crews, and others in the maritime community and the surrounding community. Therefore, the Coast Guard is establishing this security zone to safeguard human life, vessels and facilities from sabotage, terrorist acts or other criminal acts.

Discussion of Rule

The security zone is necessary to protect MOTSU and vessels moored at the facility, their crews, others in the maritime community and the surrounding communities from subversive or terrorist attack that could cause serious negative impact to vessels, the port, or the environment, and result in numerous casualties. The security zone contains the area and waters encompassed by a line connecting the northern tip of the security zone is at 34°02.03′ N, 077°56.60′ W, near Cape Fear River Channel Lighted Buoy 9 (LLNR 30355); extending south along the shore to 34°00.00′ N, 077°57.25′ W, proceeding to the southern most tip of the zone at 33°59.16′ N, 077°50.00′ W, at then proceeding north to 34°00.65′ N, 077°56.41′ W, at Cape Fear River Channel Lighted Buoy 31 (LLNR 30670 & 39905); then back to the point of origin at 34°02.03′ N, 077°56.60′ W.

No person or vessel may enter or remain in the security zone at any time without the permission of the Captain of the Port, Wilmington. Each person or vessel operating within the security zone must obey any direction or order of the Captain of the Port. The Captain of the Port may take possession and control of any vessel in a security zone and/or remove any person, vessel, article or thing from this security zone.

Regulatory Evaluation

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

Although this regulation restricts access to the security zone, the effect of this regulation will not be significant because: (i) The COTP or his or her representative may authorize access to the security zone; (ii) the security zone will be enforced for limited duration; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners and operators of vessels intending to transit or anchor in the vicinity of Military Ocean Terminal Sunny Point. This includes owners and operators of vessels desiring to enter the security zone.

This security zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The security zone is not located in an area that would impede commercial or recreational traffic.

Assistance for Small Entities

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

Small businesses may send comments on the actions of federal employees who enforce, or otherwise determine compliance with, federal regulations to the Small Business and Agriculture Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

Federalism

A rule has implications for Federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that order and have determined that it does not have implications for Federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T05–205 to read as follow:

§ 165.T05–205 Security Zone: Military Ocean Terminal Sunny Point and Lower Cape Fear River, NC.

(a) *Location.* The following area is a security zone: The area and waters encompassed by a line connecting the following points: the northern tip of the security zone is at 34°02.03′ N 077°56.60′ W near Cape Fear River Channel Lighted Buoy 9 (LLNR 30355); extending south along the shore to 34°00.00′ N, 077°57.25′ W proceeding to the southern most tip of the Zone at 33°59.16′ N, 077°57.00′ W then proceeding north to 34°00.65′ N, 077°56.41′ W, at Cape Fear River Channel Lighted Buoy 31(LLNR 30670 & 39905); then back to the point of origin at 34°02.03′ N, 077°56.60′ W.

(b) *Captain of the Port. Captain of the Port* means the Commanding Officer of the Marine Safety Office Wilmington, NC, or any Coast Guard commissioned, warrant, or petty officer who has been authorized to act on his or her behalf.

(c) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones in 33 CFR 165.33.

(2) Persons or vessels with a need to enter into or get passage within the security zone, must first request authorization from the Captain of the Port. The Captain of the Port's representative enforcing the Zone can be contacted on VHF marine band radio, channel 16. The Captain of the Port can be contacted at (910) 772–2000 or toll free (877) 229–0770.

(3) The operator of any vessel within or in the immediate vicinity of this security zone while it is being enforced must:

(i) Stop the vessel immediately upon being directed to do so by the Captain of the Port or his or her designated representative.

(ii) Proceed as directed by the Captain of the Port or his or her designated representative.

(d) *Effective period.* This section is in effect from 12:01 a.m. e.s.t., on January 13, 2004, to 12:01 a.m. e.d.t., on June 13, 2004.

Dated: January 13, 2004.

Jane M. Hartley,

Captain, U.S. Coast Guard, Captain of the Port, Wilmington, North Carolina.

[FR Doc. 04–2986 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0344; FRL–7338–3]

Aldicarb, Atrazine, Cacodylic Acid, Carbofuran, et al.; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule revokes specific meat, milk, poultry, and egg (MMPE) tolerances for residues of the insecticides aldicarb, carbofuran, diazinon, and dimethoate; herbicides atrazine, metolachlor, and sodium acifluorfen; fungicides fenarimol, propiconazole, and thiophanate-methyl; and the defoliant cacodylic acid. EPA determined that there are no reasonable expectations of finite residues in or on meat, milk, poultry, or eggs for the aforementioned pesticide active ingredients and that these tolerances are no longer needed. Also, this document modifies specific fenarimol tolerances. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. Because all the tolerances were previously reassessed, no reassessments are counted here toward the August, 2006 review deadline.

DATES: This regulation is effective February 11, 2004. Objections and requests for hearings, identified by docket ID number OPP–2003–0344, must be received on or before April 12, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8037; e-mail address: *nevola.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0344. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/,* a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background

A. What Action Is the Agency Taking?

In this final rule, EPA is revoking 105 specific MMPE tolerances for residues of the insecticides aldicarb, carbofuran, diazinon, and dimethoate; herbicides atrazine, metolachlor, and sodium acifluorfen; fungicides fenarimol, propiconazole, and thiophanate-methyl; and the defoliant cacodylic acid because the Agency has concluded that there is no reasonable expectation of finite residues in or on the commodities associated with those tolerances, and therefore these tolerances are no longer needed. Also, EPA is modifying other specific fenarimol tolerances.

The determinations that there are no reasonable expectations of finite residues for the tolerances listed in this document were made based on feeding studies submitted since the time that the tolerances were originally established. These feeding studies used exaggerated amounts of the compound and did not show measurable residues of the pesticides tested. The Agency originally made these determinations in memoranda of March 6, 2002; March 25, 2002; April 21, 2002; July 1, 2002; and July 23, 2002. Because there was no expectation of finite residues, in subsequent memoranda of May 3, 2002; June 3, 2002; July 11, 2002; and July 23, 2002, respectively, the Agency declared these tolerances as safe and counted

these tolerances toward meeting the tolerance reassessment requirements listed in FFDCA section 408(q). Copies of these memoranda can be found in the public docket for the proposed rule which published in the **Federal Register** of July 16, 2003 (68 FR 41989) (FRL–7301–5), under docket number OPP–2003–0092. Because EPA determined that there is no reasonable expectation of finite residues, under 40 CFR 180.6 the tolerances are no longer needed under the FFDCA, and they can therefore be revoked.

Generally, EPA will proceed with the revocation of these tolerances on the grounds discussed in Unit II.A., if one of these conditions applies, as follows:

1. Prior to EPA's issuance of a FFDCA section 408(f) order requesting additional data or issuance of a FFDCA section 408(d) or (e) order revoking the tolerances on other grounds, commenters retract the comment identifying a need for the tolerance to be retained.

2. EPA independently verifies that the tolerance is no longer needed.

3. The tolerance is not supported by data that demonstrate that the tolerance meets the requirements under FQPA.

This final rule does not revoke those tolerances for which EPA received comments stating a need for the tolerance to be retained. In the **Federal Register** of July 16, 2003 (68 FR 41989), EPA issued a proposed rule to revoke specific MMPE tolerances for residues of the insecticides aldicarb, carbofuran, diazinon, and dimethoate; herbicides atrazine, metolachlor, and sodium acifluorfen; fungicides fenarimol, propiconazole, and thiophanate-methyl; and the defoliant cacodylic acid; and to modify specific fenarimol tolerances. Also, the July 16, 2003, proposal provided a 60–day comment period which invited public comment for consideration and for support of tolerance retention under the FFDCA standards. In response to the proposal published in the **Federal Register** of July 16, 2003 (68 FR 41989), EPA received two comments as follows:

- *Comments.* An individual from Michigan requested that the MMPE tolerances proposed for revocation not be revoked. Another individual from New Jersey requested that the aldicarb, cacodylic acid, and fenarimol MMPE tolerances proposed for revocation not be revoked. Both individuals expressed concern with pesticide use in general.

In addition, Syngenta Crop Protection objected to the revocation of poultry and egg tolerances for propiconazole. The Syngenta comment expressed a concern that the reregistration process for propiconazole might result in a requirement that new studies be conducted and that if new studies happen to show propiconazole residues of concern in/on these poultry and egg commodities, then tolerances might be needed.

- *Agency response.* None of the comments addressed any of the available feeding studies that EPA reviewed in making its determinations that there are no reasonable expectations of finite residues for the MMPE tolerances in question. Nor did the comments take issue with the Agency's conclusion that the tolerances were no longer needed under 40 CFR 180.6. When EPA establishes tolerances for pesticide residues in or on raw agricultural commodities, consideration must be given to the possible residues of those active ingredients in MMPE commodities produced by animals that are fed agricultural products (for example, grain or hay) containing pesticide residues (40 CFR 180.6). When considering this possibility, EPA can conclude that there is a reasonable expectation that finite residues will not exist. Based on the available data, EPA made such a determination and believes that the tolerances revoked in this final rule are no longer needed.

Should future data be made available to EPA that shows pesticide residues of concern in or on the specific MMPE commodities associated with the tolerances revoked herein, then the Agency will evaluate all the available data, including the availability of a practicable analytical method to determine the pesticide residue. The Agency may conclude from such new data that finite residues will actually be incurred, or that it is not possible to establish with certainty whether finite residues will be incurred, but that there is a reasonable expectation of finite residues or no reasonable expectation of finite residues (40 CFR 180.6). Should EPA determine that a tolerance is needed, the Agency will take appropriate action to establish the tolerance.

1. *Aldicarb.* Based on available ruminant feeding and storage stability data, EPA determined that there is no reasonable expectation of finite residues of aldicarb and its carbamate metabolites in milk and livestock commodities. The associated tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.269 for the combined residues of the insecticide and nematocide aldicarb (2-methyl-2-(methylthio)propionaldehyde O-(methylcarbamoyl) oxime and its cholinesterase-inhibiting metabolites 2-methyl 2-(methylsulfinyl) propionaldehyde O-(methylcarbamoyl) oxime and 2-methyl-2-(methylsulfonyl) propionaldehyde O-(methylcarbamoyl) oxime in or on the following: Cattle, fat; cattle, meat; cattle, meat byproducts; goat, fat; goat, meat; goat, meat byproducts; hog, fat; hog, meat; hog, meat byproducts; horse, fat; horse, meat; horse, meat byproducts; sheep, fat; sheep, meat; sheep, meat byproducts; and milk.

2. *Atrazine.* Based on available ruminant and poultry feeding data, EPA determined that there is no reasonable expectation of finite residues of atrazine in fat, meat, and meat byproducts of hogs and poultry; and eggs. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.220 for residues of the herbicide atrazine in or on hog, fat; hog, meat; hog, meat byproducts; poultry, fat; poultry, meat; poultry, meat byproducts; and egg.

3. *Cacodylic acid (dimethylarsinic acid).* Arsenic is ubiquitous and abundant in the environment. Studies show that arsenicals are methylated in animals to potentially significant levels of dimethyl arsonate (cacodylate). Also, available data show that background levels of cacodylate found in beef tissues and milk may substantially exceed those incurred from the maximum theoretical dietary burden from ingestion of feed stuffs derived from raw agricultural commodities treated with cacodylic acid at the maximum supported use rates. Based on all these data, EPA determined that tolerances for residues of cacodylic acid in beef tissues and milk are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.311 for residues of the defoliant cacodylic acid (dimethylarsinic acid), expressed as As2O3, in or on cattle, fat; cattle, kidney; cattle, liver; cattle, meat; cattle meat byproducts, except kidney; and cattle meat byproducts, except liver.

In the **Federal Register** of July 16, 2003 (68 FR 41989), EPA issued a rule which proposed the tolerance revocations made in this final rule. The July 16, 2003 document proposed to revoke 105 tolerances. The proposal was signed on June 17, 2003. Later, in the **Federal Register** of July 1, 2003 (68 FR 39435) (FRL–7316–9), EPA made terminology revisions in 40 CFR 180.311 for cacodylic acid which created two tolerances for meat byproducts of cattle (cattle, meat byproducts, except kidney and cattle, meat byproducts, except liver, both at 0.7 ppm). This specific terminology revision was in error. The Agency

considers the preferred terminology to be one tolerance; i.e. cattle, meat byproducts, except kidney and liver. While EPA is revoking both tolerances, the Agency will count them as one revocation in a total of 105 revocations in this final rule.

In the **Federal Register** of July 1, 2003 (68 FR 39435), EPA issued a final rule that revised specific tolerance nomenclatures, including the terminology for "cottonseed" to "cotton, undelinted seed" in 40 CFR 180.311, making the proposal in the **Federal Register** of July 16, 2003 (68 FR 41989) to revise cottonseed in 40 CFR 180.311 no longer needed.

4. *Carbofuran.* Based on available dairy cattle feeding data, EPA determined that there is no reasonable expectation of finite residues of carbofuran and its metabolites in fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.254 for the combined residues of the insecticide carbofuran (2,3-dihydro-2,2-dimethyl-7-benzofuranyl-*N*-methylcarbamate), its carbamate metabolite (2,3-dihydro-2,2-dimethyl-3-hydroxy-7-benzofuranyl-*N*-methylcarbamate), and its phenolic metabolites (2,3-dihydro-2,2-dimethyl-7-benzofuranol, 2,3-dihydro-2,2-dimethyl-3,-oxo-7-benzofuranol and 2,3-dihydro-2,2-dimethyl-3,7-benzofurandiol) in or on the following commodities: Cattle, fat (of which no more than 0.02 parts per million (ppm) is carbamates); cattle, meat (of which no more than 0.02 ppm is carbamates); cattle, meat byproducts (of which no more than 0.02 ppm is carbamates); goat, fat (of which no more than 0.02 ppm is carbamates); goat, meat (of which no more than 0.02 ppm is carbamates); goat, meat byproducts (of which no more than 0.02 ppm is carbamates); hog, fat (of which no more than 0.02 ppm is carbamates); hog, meat (of which no more than 0.02 ppm is carbamates); hog, meat byproducts (of which no more than 0.02 ppm is carbamates); horse, fat (of which no more than 0.02 ppm is carbamates); horse, meat (of which no more than 0.02 ppm is carbamates); horse, meat byproducts (of which no more than 0.02 ppm is carbamates); sheep, fat (of which no more than 0.02 ppm is carbamates); sheep, meat (of which no more than 0.02 ppm is carbamates); and sheep, meat byproducts (of which no more than 0.02 ppm is carbamates).

5. *Diazinon.* Based on available cattle dermal treatment and feeding data, EPA determined that there is no reasonable expectation of finite residues in or on meat and meat byproducts from the registered uses of cattle ear tags or from consumption of diazinon treated feed items by cattle. These tolerances are no longer needed under 40 CFR 180.6(a)(3). A tolerance for milk is not required as long as the ear tag labels maintain that use is for beef cattle and non-lactating dairy cattle, only. Therefore, EPA is revoking the tolerances in 40 CFR 180.153 for residues of the insecticide diazinon in or on cattle, meat (fat basis) and cattle, meat byproducts (fat basis).

6. *Dimethoate.* Metabolism and feeding studies in ruminants and poultry showed no detectable residues of dimethoate in muscle, fat, kidney, liver, milk, and egg samples. However, residues of omethoate, its oxygen analog, were found in liver and egg whites samples and residues of dimethoate carboxylic acid were found in liver, egg whites, and milk samples. Based on these available ruminant and poultry metabolism and feeding data, EPA determined that there is no reasonable expectation of finite residues of concern in meat, fat, and kidney of livestock (ruminants and poultry) from ingestion of dimethoate treated crop and feed items. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.204 for total residues of the insecticide dimethoate (*O,O*-dimethyl S-(*N*-methylcarbamoylmethyl) phosphorodithioate) including its oxygen analog (*O,O*-dimethyl S-(*N*-methylcarbamoylmethyl) phosphorothioate) in or on the following commodities: Cattle, fat; cattle, meat; goat, fat; goat, meat; hog, fat; hog, meat; horse, fat; horse, meat; poultry, fat; poultry, meat; sheep, fat; and sheep, meat. Use of dimethoate on other commodities, including food and feed commodities, will be addressed in the "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision" (IRED), which EPA will complete in the near future.

Also, in 40 CFR 180.204, EPA is removing the "(N)" designation from all entries to conform to current Agency administrative practice ("(N)" designation means negligible residues).

7. *Fenarimol.* Fenarimol tolerances were reassessed according to the FQPA standard in the August 2002 "Report of the FQPA Tolerance Reassessment Progress and Risk Management Decision (TRED) for Fenarimol." The Agency extrapolated data from a 28–day ruminant feeding study of exaggerated dietary burdens to the 1x feeding rate, and examined the expected impact of the average theoretical dietary burden from wet apple pomace (calculated using Food and Drug Administration monitoring data for apples). Of the currently registered uses of fenarimol, wet apple pomace is the only commodity considered a livestock feed item. (Dry apple pomace is no longer considered a significant feed item). For cattle, goats, horses, and sheep, the Agency concluded from monitoring, feeding, and metabolism data that tolerances for liver should be effectively decreased from 0.1 to 0.05 ppm and tolerances for meat byproducts should be increased from 0.01 to 0.05 ppm based on the highest residue found on an organ tissue; i.e., liver. Because both liver and meat byproduct tolerances were reassessed at the same level (0.05 ppm) for cattle, goats, horses, and sheep, the Agency recommended covering residues in liver by the reassessed tolerances for meat byproducts, revising each commodity terminology to "meat byproducts, except kidney," and revoking existing liver tolerances at 0.1 ppm since they are no longer needed. EPA issued a finding in this TRED that these revised tolerances are safe, as required by section 408 of FFDCA.

Therefore, EPA is revoking the separate tolerances in 40 CFR 180.421 for residues of the fungicide fenarimol in or on cattle, liver; goat, liver; horse, liver; and sheep, liver. Also in 40 CFR 180.421, EPA is increasing the tolerances for the meat byproducts of cattle, goats, horses, and sheep, each from 0.01 to 0.05 ppm, respectively, and revising their commodity terminologies to cattle, meat byproducts, except kidney; goat, meat byproducts, except kidney; horse, meat byproducts, except kidney; and sheep, meat byproducts, except kidney, respectively.

Expected fenarimol residues in muscle, fat, and kidney are calculated from the 28–day data to be less than or near the enforcement method's limit of detection (0.003 ppm). Therefore, the Agency concluded that for muscle, fat, and kidney of ruminants it is not possible to establish with certainty whether finite residues will be incurred, but there is a reasonable expectation of finite residues under 40 CFR 180.6(a)(2). While EPA reassessed fenarimol tolerances for cattle, goats, horses, and sheep in the TRED, including meat, kidney, and fat tolerances at 0.01 ppm, the method limit of quantitation, the Agency will address them in a **Federal Register** document to be published in the near future.

In addition, the fenarimol tolerance for milk (0.003 ppm) should be revoked because residues in milk for dairy cattle are predicted to be significantly less than the enforcement method's limit of

detection (0.001 ppm). Based on the available data, EPA determined that there is no reasonable expectation of finite residues of fenarimol in milk and that the tolerance is no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerance in 40 CFR 180.421 for residues of the fungicide fenarimol in milk.

Moreover, EPA determined that there is no reasonable expectation of residue transfer to livestock commodities via consumption of fenarimol treated crop and feed items because no feed items for poultry and hogs are associated with active fenarimol registrations. The tolerances for eggs, poultry, and hogs are no longer needed and should be revoked. Therefore, EPA is revoking the tolerances in 40 CFR 180.421 for residues of the fungicide fenarimol in or on the following commodities: Egg; hog, fat; hog, kidney; hog, liver; hog, meat; hog, meat byproducts; poultry, fat; poultry, meat; and poultry, meat byproducts.

Furthermore, in order to conform to current Agency practice, in 40 CFR 180.421, EPA is revising the tolerance commodity terminology for "pecans" to "pecan."

8. *Metolachlor.* Based on available ruminant feeding data and the maximum theoretical dietary burden for swine, EPA determined that there is no reasonable expectation of finite residues of metolachlor and its metabolites in fat, kidney, liver, meat, and meat byproducts of hogs. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.368 for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on hog, fat; hog, kidney; hog, liver; hog, meat; and hog, meat byproducts, except kidney and liver.

9. *Propiconazole.* Based on available poultry metabolism and feeding data, EPA determined that there is no reasonable expectation of finite residues of propiconazole and its metabolites (determined as 2,4-dichlorobenzoic acid) in poultry muscle, liver, fat, and egg samples from hens fed 10X the maximum theoretical dietary burden for poultry. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking tolerances in 40 CFR 180.434 for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on egg; poultry, fat; poultry, kidney; poultry, liver; poultry, meat; and poultry, meat byproducts, except kidney and liver.

10. *Sodium acifluorfen.* Label restrictions prohibit use of sodium acifluorfen treated peanut and soybean forage or hay for feed and grazing livestock on these treated crops. As noted in a memorandum dated April 21, 2002, available under docket ID number OPP–2003–0092, EPA evaluated available ruminant and poultry metabolism data and determined that there is no reasonable expectation of residues being transferred to livestock commodities via consumption of feed items derived from crops treated with sodium acifluorfen according to current use directions. Based on the registered food/feed use patterns and metabolism data, EPA determined that there is no reasonable expectation of finite residues of sodium acifluorfen and its metabolites in eggs; kidney and liver of cattle, goats, hogs, horses, and sheep; fat, meat, and meat byproducts of poultry; and milk. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.383 for combined residues of the herbicide sodium salt of acifluorfen (sodium 5-[2-chloro-4-trifluoromethyl) phenoxy]-2-nitrobenzoic acid) and its metabolites (the corresponding acid, methyl ester, and amino analogues) in or on the following commodities: Cattle, kidney; cattle, liver; egg; goat, kidney; goat, liver; hog, kidney; hog, liver; horse, kidney; horse, liver; milk; poultry, fat; poultry, meat; poultry, meat byproducts; sheep, kidney; and sheep, liver.

11. *Thiophanate-methyl.* Based on available ruminant and poultry feeding data, EPA determined that there is no reasonable expectation of finite residues of thiophanate-methyl, its oxygen analogue, and benzimidazole metabolites in fat, liver, meat, and meat byproducts of hogs and poultry. These tolerances are no longer needed under 40 CFR 180.6(a)(3). Therefore, EPA is revoking the tolerances in 40 CFR 180.371 for residues of the fungicide thiophanate-methyl (dimethyl[(1,2-phenylene)-bis(iminocarbonothioyl)] bis [carbamate]), its oxygen analogue dimethyl-4,4-o-phenylene bis(allophonate), and its benzimidazole-containing metabolites (calculated as thiophanate-methyl) in or on hog, fat; hog, liver; hog, meat; hog, meat byproducts, except liver; poultry, fat; poultry, liver; poultry, meat; and poultry, meat byproducts, except liver.

B. What Is the Agency's Authority for Taking This Action?

When EPA establishes tolerances for pesticide residues in or on raw agricultural commodities, the Agency gives consideration to possible pesticide residues in meat, milk, poultry, and/or eggs produced by animals that are fed agricultural products (for example, grain or hay) containing pesticide residues (40 CFR 180.6). When considering this possibility, EPA can conclude that:

1. Finite residues will exist in meat, milk, poultry and/or eggs, or

2. There is a reasonable expectation that finite residues will exist, or

3. There is a reasonable expectation that finite residues will not exist.

If there is no reasonable expectation of finite pesticide residues in or on meat, milk, poultry, or eggs, then tolerances do not need to be established for these commodities (40 CFR 180.6(b) and 40 CFR 180.6(c)). EPA has evaluated specific meat, milk, poultry, and egg tolerances in this final rule, concluded that there is no reasonable expectation of finite residues of the listed pesticide active ingredients in or on those commodities, and is revoking them.

Regarding the modification of specific fenarimol tolerances, EPA is required to determine whether each of the amended tolerances meets the safety standards under the FQPA. A safety finding determination is found in detail in the August 2002 TRED for fenarimol. An electronic copy of the TRED for fenarimol is available on EPA's website at *http://www.epa.gov/pesticides/reregistration/status.htm.*

C. When Do These Actions Become Effective?

These actions become effective on February 11, 2004. The Agency has determined that this revocation date allows users to continue utilizing existing pesticide stocks and that commodities treated with these pesticides in a manner that is lawful under FIFRA will continue to clear the channels of trade since there is no reasonable expectation of finite residues. Also, while certain individual liver tolerances for fenarimol are revoked, residues in/on liver of cattle, goat, horse, and sheep are covered by revised "meat byproduct, except kidney" tolerances.

In addition, because the modifications to specific fenarimol tolerances increased herein are safe, as required by section 408 of FFDCA, the Agency has

determined that these modifications are effective on February 11, 2004.

D. What Is the Contribution to Tolerance Reassessment?

By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. As of January 27, 2004, EPA has reassessed 6,628 tolerances. In this final rule, EPA is revoking 105 tolerances. These tolerances were previously reassessed and counted as described in Unit II.A.

In the July 1, 2003 version of 40 CFR 180.311, there are two cattle meat byproducts tolerances in the table in paragraph (a). However, when converting the text in 40 CFR 180.311 to tabular form, the tolerance for meat, fat, and meat byproducts, except kidney and liver, of cattle was erroneously published as two seperate entries. Therefore, for tolerance reassessment counting purposes, the meat byproducts tolerance for cattle was previously counted as one reassessment; i.e., cattle, meat byproducts, except kidney and liver.

III. Are There Any International Trade Issues Raised by This Final Action?

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual REDs. The EPA has developed guidance concerning submissions for import tolerance support (65 FR 35069, June 1, 2000) (FRL–6559–3). This guidance will be made available to interested persons. Electronic copies are available on the internet at *http://www.epa.gov/*. On the Home Page select "Laws, Regulations and Dockets," then select "Regulations and Proposed Rules" and then look up the entry for this document under "**Federal Register**—Environmental Documents." You can also go directly to the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*.

IV. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0344 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 12, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IV.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0344, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and

hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

V. Statutory and Executive Order Reviews

This final rule revokes and modifies tolerances established under section 408 of FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions (i.e., modification of a tolerance and tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether raising of tolerance levels or revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses were published on May 4, 1981 (46 FR 24950) and on December 17, 1997 (62 FR 66020), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account these analyses, and the fact that there is no reasonable expectation that residues of the pesticides listed in this final rule will be found on the commodities discussed in this final rule (so that the lack of the tolerance could not prevent sale of the commodity), I certify that this action will not have a significant economic impact on a substantial number of small entities. Furthermore, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). 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." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments. 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 21, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.153 [Amended]

■ 2. Section 180.153 is amended by removing the entries for cattle, meat (fat basis) and cattle, meat byproducts (fat basis) from the table in paragraph (a)(1).

§ 180.204 [Amended]

■ 3. Section 180.204 is amended by removing the entries for cattle, fat; cattle, meat; goat, fat; goat, meat; hog, fat; hog, meat; horse, fat; horse, meat; poultry, fat; poultry, meat; sheep, fat; and sheep, meat; from the table in paragraph (a), and by also removing from the table in paragraph (a) the "(N)" designation from any entry where it appears.

§ 180.220 [Amended]

■ 4. Section 180.220 is amended by removing the entries for egg; hog, fat; hog, meat byproducts; hog, meat; poultry, fat; poultry, meat byproducts; and poultry, meat from the table in paragraph (a)(1).

§ 180.254 [Amended]

■ 5. Section 180.254 is amended by removing the entries for cattle, fat (of which no more than 0.02 ppm is carbamates); cattle, meat (of which no more than 0.02 ppm is carbamates); cattle, meat byproducts (of which no more than 0.02 ppm is carbamates); goat, fat (of which no more than 0.02 ppm is carbamates); goat, meat (of which no more than 0.02 ppm is carbamates); goat, meat byproducts (of which no more than 0.02 ppm is carbamates); hog, fat (of which no more than 0.02 ppm is carbamates); hog, meat (of which no more than 0.02 ppm is carbamates); hog, meat byproducts (of which no more than 0.02 ppm is carbamates); horse, fat (of which no more than 0.02 ppm is carbamates); horse, meat (of which no more than 0.02 ppm is carbamates); horse, meat byproducts (of which no more than 0.02 ppm is carbamates); sheep, fat (of which no more than 0.02 ppm is carbamates); sheep, meat (of which no more than 0.02 ppm is carbamates); and sheep, meat byproducts (of which no more than 0.02 ppm is carbamates) from the table in paragraph (a).

§ 180.269 [Amended]

■ 6. Section 180.269 is amended by removing the entries for cattle, fat; cattle, meat byproducts; cattle, meat; goat, fat; goat, meat byproducts; goat, meat; hog, fat; hog, meat byproducts; hog, meat; horse, fat; horse, meat byproducts; horse, meat; milk; sheep, fat; sheep, meat byproducts; and sheep, meat from the table in paragraph (a).

■ 7. Section 180.311 is revised to read as follows:

§ 180.311 Cacodylic acid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the defoliant cacodylic acid (dimethylarsinic acid), expressed as As2O3, in or on the following raw agricultural commodity as follows:

Commodity	Parts per million
Cotton, undelinted seed	2.8

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

§ 180.368 [Amended]

■ 8. Section 180.368 is amended by removing the entries for hog, fat; hog, kidney; hog, liver; hog, meat; and hog, meat byproducts, except kidney and liver from the table in paragraph (a)(1).

§ 180.371 [Amended]

■ 9. Section 180.371 is amended by removing the entries for hog, fat; hog, liver; hog, meat byproducts, except liver; hog, meat; poultry, fat; poultry, liver; poultry, meat byproducts, except liver; and poultry, meat from the table in paragraph (a).

■ 10. Section 180.383 is amended by revising the table in paragraph (a) to read as follows:

§ 180.383 Sodium salt of acifluorfen; tolerances for residues.

(a) * * *

Commodity	Parts per million
Peanut	0.1
Rice, grain	0.1
Rice, straw	0.1
Soybean	0.1
Strawberry	0.05

* * * * *

■ 11. Section 180.421 is amended by revising the table in paragraph (a)(1) to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Apple	0.1
Apple, dry pomace	2.0
Apple, wet pomace	2.0
Cattle, fat	0.1
Cattle, kidney	0.1
Cattle, meat	0.01
Cattle, meat byproducts, except kidney	0.05
Goat, fat	0.1
Goat, kidney	0.1
Goat, meat	0.01
Goat, meat byproducts, except kidney	0.05
Horse, fat	0.1
Horse, kidney	0.1
Horse, meat	0.01
Horse, meat byproducts, except kidney	0.05
Pear	0.1
Pecan	0.1
Sheep, fat	0.1
Sheep, kidney	0.1
Sheep, meat	0.01
Sheep, meat byproducts, except kidney	0.05

* * * * *

§ 180.434 [Amended]

■ 12. Section 180.434 is amended by removing the entries for egg; poultry, fat; poultry, kidney; poultry, liver; poultry, meat byproducts, except kidney and liver; and poultry, meat; from the table in paragraph (a).

[FR Doc. 04–2956 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

[RCRA–2003–0025; FRL–7620–2]

Land Disposal Restrictions: Site-Specific Treatment Variances for Heritage Environmental Services LLC and Chemical Waste Management Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is today granting three site-specific treatment variances from the Land Disposal Restrictions (LDR) treatment standards for selenium-bearing hazardous wastes generated by the glass manufacturing industry. EPA is granting these variances because the chemical properties of the wastes differ significantly from those from the waste used to establish the current LDR standard for selenium (5.7 mg/L, as measured by the Toxicity Characteristic Leaching Procedure (TCLP)), and the petitions have adequately demonstrated that the wastes cannot be treated to meet this treatment standard.

In the first action, EPA is granting a variance to Heritage Environmental Services LLC (Heritage) to stabilize a selenium-bearing hazardous waste generated by Guardian Industries Corp. (Guardian) at their RCRA permitted facility in Indianapolis, Indiana. With

promulgation of this final rule, Heritage may treat the Guardian waste to an alternate treatment standard of 39.4 mg/L, as measured by the TCLP. Heritage may dispose of the treated waste in a RCRA Subtitle C landfill, provided they meet the applicable LDR treatment standards for the other hazardous constituents in the waste.

In the second and third actions, EPA is permanently establishing two site-specific variances from the Land Disposal Restrictions treatment standards for Chemical Waste Management Inc. (CWM), at their Kettleman Hills facility in Kettleman City, California, for two selenium-bearing hazardous wastes. EPA previously granted treatment variances to these wastes on a temporary basis. CWM will continue to be required to treat these two specific wastes to alternative treatment standards of 51 mg/L, as measured by the TCLP, for the Owens-Brockway waste, and 25 mg/L, as measured by the TCLP, for the St. Gobain (formerly Ball Foster) waste. CWM may dispose of the treated wastes in a RCRA Subtitle C landfill provided they meet the applicable LDR treatment standards for the other hazardous constituents in the wastes.

DATES: This final rule is effective on March 29, 2004 without further notice, unless EPA receives adverse comment by March 12, 2004. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be submitted by mail to: EPA Docket Center—OSWER Docket, Environmental Protection Agency, Mailcode: 5305 T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. RCRA–2003–0025. Comments may also be submitted electronically, or through hand delivery/courier. Follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703 412–9810 or TDD 703 412–3323. For more detailed information on specific aspects of this rulemaking, contact Juan Parra at (703) 308–0478 or *parra.juan@epa.gov*, Office of Solid Waste (MC 5302 W), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: EPA is publishing this rule without prior proposal because we view it as a noncontroversial action. We anticipate no significant adverse comments because, to our knowledge, no new treatment options have become available to treat these high concentration selenium wastes more effectively, and in the case of the two selenium-bearing hazardous wastes treated by CWM, we are making permanent a variance that is already in effect, and which has already been the subject of notice and opportunity for comment. Having said this, in the "Proposed Rules" section of today's **Federal Register** publication, we are publishing a separate document that could serve as a proposal to grant these variances to Heritage and CWM if significant adverse comments are filed. See the **SUPPLEMENTARY INFORMATION** section on how to submit comments.

This direct final rule will be effective on March 29, 2004 without further notice unless we receive adverse comment on the proposed rule by March 12, 2004. If we receive adverse comment on the direct final rule, we will withdraw the direct final action and the treatment variance for Heritage and restore the terms and conditions of the three year site-specific selenium treatment variance to CWM. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting on this direct final rule must do so at this time.

A. How Can I Get Copies of This Variance Proposal ?

1. Docket. EPA has established an official public docket for this action under Docket ID No. RCRA–2003–0025. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the OSWER 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 Public Reading Room is (202) 566–1744, and the telephone number for the OSWER Docket is (202) 566–0272. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

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J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act

I. Background

A. What Is the Basis for LDR Treatment Variances?

Under section 3004(m) of the Resource Conservation and Recovery Act (RCRA), EPA is required to set "levels or methods of treatment, if any, which substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized." EPA interprets this language to authorize treatment standards based on the performance of best demonstrated available technology (BDAT). This interpretation was upheld by the DC Circuit in *Hazardous Waste Treatment Council* v. *EPA*, 886 F.2d 355 (DC Cir. 1989).

The Agency recognizes that there may be wastes that cannot be treated to levels specified in the regulations because an individual waste can be substantially more difficult to treat than those wastes the Agency evaluated in establishing the treatment standard. For such wastes, EPA has a process by which a generator or treater may seek a treatment variance (*see* 40 CFR 268.44). If granted, the terms of the variance establish an alternative treatment standard for the particular waste at issue.

B. What Is the Basis of the Current Selenium Treatment Standard?

The current treatment standard for wastes exhibiting the toxicity characteristic for selenium is based upon the performance of stabilization treatment technology. When the Agency developed these treatment standards for selenium, EPA believed that wastes containing high concentrations of selenium were rarely generated and land disposed (62 FR 26041, May 12, 1997). The Agency also stated that it believed that, for most waste containing high concentrations of selenium, recovery of the selenium was feasible using recovery technologies currently employed by copper smelters and copper refining operations (Id.). The Agency further stated that it did not have any performance data for selenium recovery, but available information indicated that recovery of elemental selenium out of certain types of scrap material and other types of waste was practiced in the United States.

The Agency used performance data from the stabilization of a selenium characteristically hazardous mineral processing waste (waste code D010) to set the national treatment standard for selenium, which we determined at that time to be the most difficult to treat selenium waste. This untreated waste contained up to 700 ppm total selenium and 3.74 mg/L selenium in the TCLP leachate. The resulting post-treatment levels of selenium in the TCLP leachate were between 0.154 mg/L and 1.80, which led to our establishment of a national treatment standard of 5.7 mg/L for D010 selenium non-wastewaters. This D010 mineral processing waste also contained toxic metals (*i.e.*, arsenic, cadmium, and lead) above characteristic levels. The treatment technology used to establish the selenium levels also resulted in meeting the LDR treatment standards for these non-selenium metals. The reagent to waste ratios varied from 1.3 to 2.7 (62 FR 26041, May 12, 1997).

In the Phase IV final rule, the Agency determined that a treatment standard of 5.7 mg/L, as measured by the TCLP, continued to be appropriate for D010 non-wastewaters (63 FR 28556, May 26, 1998). The Agency also changed the universal treatment standard (UTS) for selenium nonwastewaters from 0.16 mg/L to 5.7 mg/L.

C. Previously Approved Variances for Selenium Waste

When EPA established the treatment standards for metal wastes and mineral processing wastes (63 FR 28555, May 26, 1998), we noted that we received comments from one company, Chemical Waste Management Inc. (CWM), indicating that it was attempting to stabilize selenium-bearing wastes with concentrations much higher than those EPA had examined when it established the national treatment standard for wastes exhibiting the toxicity characteristic for selenium. In response, we indicated that for two high-level selenium waste streams, we would propose two site-specific treatment variances, which we granted on May 26, 1999 (63 FR 56886). EPA granted this variance for three years, and required CWM to conduct studies on approaches to further reduce the leachability of such treated wastes. EPA also required CWM to investigate alternative treatment technologies that might provide more effective treatment and remove the need for a treatment variance. EPA required CWM to report annually on these investigations and to provide any analytical data from the treatment studies.[1] The annual reports include stabilization recipes being utilized to meet the alternative treatment standards, the selenium concentrations in the untreated wastes and the analytical results from leach testing of the treated wastes. On May 28, 2002 (67 FR 36849), EPA renewed this variance for another three year term, and continued to require CWM to report on its treatability studies and to investigate whether more effective treatment is available.

D. Reasons for Lack of U.S. Secondary Selenium Recovery Capacity

Primary selenium[2] is a co-product in the mining of copper ores. The principal markets for selenium are in electronics (30%), glass manufacturing (20%), pigments (19%), metallurgical additives (14%) and agricultural/biological applications (6%).[3] In glass manufacturing, selenium is used to color container glass and other soda-lime silica glasses and to reduce solar heat transmission in architectural plate and automotive glass.

Because selenium is a non-renewable resource, and because the wastes in question contain high selenium concentrations, EPA's preference would be to recover the selenium in an environmentally sound manner over stabilization and land disposal. However, there was no recorded domestic production of secondary selenium in 2002.[4] All potential selenium recovery technologies being considered have remained pilot projects and none of them have been shown to be economically viable. These factors suggest that development of an environmentally protective secondary selenium recovery system in the U.S. is not reasonably expected in the near future. That leaves stabilization as the best available treatment technology.

II. Basis for Heritage Variance Petition

Under 40 CFR 268.44(h), facilities can apply for a site-specific variance in cases where a waste that is generated under conditions specific to only one site cannot be treated to the specified levels. In such cases, the generator or treatment facility may apply to the Administrator, or to EPA's delegated

[1] All four of CWM's annual reports are in the docket supporting today's rulemaking.

[2] "Selenium is found in 75 different mineral species; however, pure selenium does not exist as an ore. For this reason, primary selenium is recovered from anode slimes generated in the electrolytic refining of copper." U.S. EPA (F–96–PH4A–S0001): Identification and Description of Mineral Processing Sectors and Waste Streams.

[3] "Canadian Mineral Yearbook" 1995.

[4] "Selenium" U.S. Geological Survey—Minerals Yearbook—2003.

representative, for a site-specific variance from a treatment standard. The applicant for a site-specific variance must demonstrate that, because the physical or chemical properties of the waste differ significantly from the waste analyzed in developing the treatment standard, the waste cannot be treated to the specified levels or by the specified methods. There are other grounds for obtaining treatment variances, but this is the only provision relevant to this action.

On May 14, 2003, Heritage Environmental Services submitted their petition for a treatment variance to EPA. All information and data used in the development of this treatment variance can be found in the RCRA docket (RCRA–2003–0025) for this rulemaking.

A. Waste Characteristics

Guardian Industries Corp., in Jefferson Hills, Pennsylvania, is a specialty glass manufacturing facility. Emissions from its glass furnace are first subject to lime injection, and subsequently captured in an electrostatic precipitator. Lime is added to remove sulphur compounds and selenium from the glass furnace gases. Heritage stabilizes the selenium-bearing waste from Guardian at their RCRA permitted facility in Indianapolis, Indiana.

The Guardian waste is a dry powder with a bulk density of about 0.4 g/cm^3, and contains no free liquids or organic constituents. The calcium content is high, approximately 30%, since the waste contains lime injected to the furnace exhaust. Concentrations of total selenium in the untreated waste vary between 10,000 ppm and 70,000 ppm (1%–7%). The dust is a D010 characteristic waste because the selenium concentration exceeds 1.0 mg/L, as measured by the TCLP. The rate of variation in the amount of waste is related to the demand, and ranges from 20–50 tons/month.

The land disposal restrictions found in 40 CFR 268.40(e) require characteristic wastes to meet the universal treatment standards (UTS) in 40 CFR 286.48 for all underlying hazardous constituents (UHCs) before the waste can be land disposed. Analytical data on the raw Guardian waste indicate that the only underlying hazardous constituent present is chromium; occasionally the dust is a D007 waste because the chromium exceeds the hazardous waste characteristic level of 5 mg/L, as measured by the TCLP. The universal treatment standard for chromium is 0.6 mg/L, as measured by the TCLP. As an underlying hazardous constituent, chromium must be treated to below the 0.6 mg/L universal treatment standard for the waste to be properly land disposed (45 FR 74889; November 12, 1980 and 52 FR 25942; July 9, 1987).

B. Chemical Properties and Treatability Information on Heritage's Selenium Wastes

Selenium emissions from the Guardian glass furnace are captured by a lime scrubber. Lime treatment is used to remove sulphur compounds and selenium from the glass furnace gases. An approach to immobilize the selenium in the Guardian waste and to reduce its exposure to leaching agents is to stabilize it with cement. With this technology option, the waste is solidified into a solid of high compressive strength, thereby incorporating the hazardous components of the electrostatic precipitator dust into a solid matrix. The solid matrix substantially lowers the surface area potentially exposed to leaching from that of untreated dust. As a result, the solidified waste should have a lower leaching potential after the waste is disposed in a hazardous waste landfill.

As mentioned earlier, analytical data on the raw Guardian waste indicate that the only underlying hazardous constituent present is chromium. Heritage conducted treatability studies demonstrating that the addition of Portland cement alone is not sufficient to reduce the chromium levels to below the 0.6 mg/L treatment standard. To further treat the chromium in the waste, the hexavalent chromium ion must be reduced to the trivalent state so that precipitation can occur. Heritage used ferric sulfate for this purpose.

Heritage conducted approximately 200 preliminary rounds of testing using different stabilization recipes. Heritage then conducted additional tests using the stabilization recipes used by Chemical Waste Management (see Section III). Collectively, the TCLP tests on treated Guardian waste samples indicate a significant reduction in leachability. This reduction, however, is not enough to meet the LDR treatment standard of 5.7 mg/L, as measured by the TCLP.

EPA has determined, in analyzing the data from the preliminary tests, that the most effective stabilization recipe for this waste consists of 0.35 parts ferrous sulfate combined with 1.0 part cement and 1.0 part cement kiln dust, resulting in a reagent to waste ratio of 2.35 to 1. Water is also added to make a thick paste, that upon curing, solidifies the treated waste into a hard cementitious material.

Table I shows the results of leaching, as measured by the TCLP, of Guardian's waste treated using the optimized stabilization recipe. Heritage stabilized the samples with reagent to waste ratios of 2.35 to 1. Reagents included cement, cement kiln dust, and iron sulfate. Treated selenium TCLP concentrations for the five samples ranged from 28.4 mg/L to 35.6 mg/L.

TABLE I.—SUMMARY OF GUARDIAN SELENIUM WASTE

Guardian sample No.	Total selenium content estimate (%)	Untreated Se waste TCLP (mg/L)	Treated Se waste TCLP (mg/L)
1183982	6.7% (67,000 ppm)	70	30.4
1183983	5.8% (58,000 ppm)	72	35.6
1184103	6.0% (60,000 ppm)	66	25.6
1184104	7.2% (72,000 ppm)	120	26.7
1184340	6.3% (63,000 ppm)	68	28.4

C. Alternative Treatment Standard for Heritage To Treat the Guardian Selenium Waste

The glass manufacturing waste from Guardian is significantly different in chemical composition from the waste used in establishing the original selenium treatment standard. Data from Heritage demonstrate that wastes containing high concentrations of selenium are not easily treated using the BDAT technology of stabilization. As previously acknowledged and discussed by the Agency in a past rulemaking (*see* 62 FR 26041), it can be technically challenging to treat wastes containing selenium and other metals, *e.g.*, cadmium, lead or chromium, because of their different chemical properties and solubility curves.

In the Phase IV rule, the Agency did not generally use stabilization data with reagent to waste ratios greater than 1.[5] However, in the case for selenium, the existing treatment standard, as discussed earlier, was calculated from data with reagent to waste ratios ranging from 1.8 to 2.7.

Using the BDAT methodology[6], the Agency has calculated an alternative treatment standard of 39.4 mg/L, as measured by the TCLP, based on five data points (25.6, 26.7, 28.4, 30.4, and 35.6 from table I) that were the result of stabilization treatment using a reagent to waste ratio of 2.35 for the waste generated by Guardian Industries Corp. The treatment recipe is consistent with the reagent to waste ratios used to establish the existing treatment standard of 5.7 mg/L, as measured by the TCLP, and the treatment data from CWM's annual selenium reports (the CWM variance treatment standards are discussed in Section III of this notice).

D. What Is the Basis for EPA's Approval of Heritage's Request for an Alternative D010 Treatment Standard?

After careful review of the data and petition submitted by Heritage, we conclude that Heritage has adequately demonstrated that the wastes satisfy the requirements for a treatment variance under 40 CFR 268.44(h)(1). Heritage has demonstrated that Guardian's glass manufacturing waste differs significantly in chemical composition from the waste used to establish the original selenium treatment standard. Selenium TCLP concentrations in the untreated waste are one to two orders of magnitude higher than TCLP concentrations in the waste used to develop the treatment standard for D010 hazardous wastes. Furthermore, Heritage is using stabilization as the treatment technology, which is consistent with EPA's determination that stabilization is the best available treatment technology for this waste, and the process is well-designed and operated.

An added benefit of stabilizing the Guardian waste with cement is that the hazardous components of the electrostatic precipitator dust are put into a solid matrix. The solid matrix substantially lowers the surface area potentially exposed to leaching from that of very fine untreated dust. The TCLP results show that, even when the solid is ground to less 9.5 mm, the solidified waste should reduce leaching potential after the waste is disposed in a hazardous waste landfill.

Before determining that stabilization was the best treatment technology option for the Guardian waste, Heritage explored the feasibility of selenium recovery technologies. Heritage established a pilot project to evaluate the extraction of selenium from raw waste at one of their facilities using hydrometallurgical recovery methods. Results from the pilot tests are not yet complete, but preliminary indications are that the amounts of by-product wastes generated during the recovery process exceed the amount of raw waste processed. In addition, the reactions are difficult to control, chemical consumption is very high, and a product of reasonable quality has not yet been achieved. Therefore, the technology does not appear to be economically viable.

Heritage has also looked into techniques for modifying Guardian's production processes to change the chemical composition of this selenium-bearing hazardous waste as it is generated. If workable, the selenium content of the waste would remain high, but the selenium would be in a different chemical form that might simplify its recovery or reuse. One of the concerns is that full-scale modifications in its production processes could cause greater selenium and SO_2 air emissions.

Finally, EPA has reviewed CWM's selenium variance annual reports on the stabilization recipes being utilized to meet the alternative treatment standards and has determined that stabilization of selenium with cement and cement kiln dust, in addition to adding ferrous sulfate as a reagent for chromium, is the best demonstrated available technology for the Guardian waste.

Therefore, EPA is today granting a site-specific treatment variance from the D010 treatment standards for the Guardian waste stream in question. Today's alternative treatment standard will provide sufficient latitude for Heritage to treat the other metal present in the waste to LDR treatment standards and, by raising the selenium treatment standard, will avoid the difficulty posed by the different metal solubility curves. EPA is amending 40 CFR 268.44 to note that Heritage Environmental Services, LLC would be subject to a selenium treatment standard of 39.4 mg/L, as measured by the TCLP.

E. What Are the Terms and Conditions of the Variance?

Since this rule approves a variance from a numerical treatment standard, Heritage may vary the reagent recipe it uses to best meet the alternative numerical standard. The Agency notes that, to avoid questions of impermissible dilution, Heritage will need to keep the reagent to waste ratios within acceptable bounds. No specific ratios are being established in today's rule because the Agency does not desire to prevent further optimization of the treatment process. However, the Agency recommends that Heritage use a reagent to waste ratio of 2.35 to 1 as an upper limit. This is the ratio used by the Agency in establishing today's alternative treatment standard.

The treated waste, provided it meets the applicable LDR treatment standard for the other hazardous constituent in the waste,[7] will be disposed in a RCRA Subtitle C landfill.

III. Basis for Permanently Establishing Chemical Waste Management's Selenium Variances

Also in today's notice, EPA is establishing two permanent site-specific treatment variances from the LDR treatment standards for two selenium-bearing hazardous wastes treated by Chemical Waste Management (CWM). The Agency previously granted treatment variances to CWM for these wastes on a temporary basis. These variances apply to two waste streams: Electrostatic precipitator dust generated during glass manufacturing operations at Owens Brockway Glass Container Company, and dry scrubber solid from glass manufacturing wastes at St.

[5] "Final Draft Site Visit Report for the August 20–21 Site Visit to Rollins Environmental's Highway 36 Commercial Waste Treatment Facility Located in Deer Trail, Colorado," November 21, 1996, and the economic analysis supporting the Phase IV final rule.

[6] BDAT Background Document for Quality Assurance/Quality Control Procedures and Methodology, October 23, 1991.

[7] Note that disposal in a Subtitle C landfill is required because the treated waste is still characteristic for selenium (*i.e.*, the waste has TCLP values above the toxicity characteristic level for selenium of 1.0 mg/L).

Gobain (formerly Ball-Foster Glass Container Corporation).

Specifically, on October 23, 1998, EPA proposed to grant site-specific treatment variances for two high-level selenium waste streams to be stabilized by CWM at their Kettleman City, California facility (63 FR 56886). The temporary variances were granted to CWM on May 26, 1999 (64 FR 28387) for a three year period and required CWM to conduct studies on approaches to reduce the leachability of the treated wastes. EPA also required CWM to report on alternative treatment technologies being investigated and provide any analytical data from these studies. On May 28, 2002 (67 FR 36849), EPA renewed these variances for a consecutive three year term with the same conditions to investigate treatment technologies and to report on the effectiveness of their ongoing treatment. These variances expire on May 28, 2005.

A. History of CWM Variances

CWM has applied to the Agency for treatment variances for two companies. In these petitions and in subsequently reported data, CWM has shown that selenium TCLP concentrations in the untreated wastes are one to three orders of magnitude higher than the untreated mineral processing wastes that EPA used to develop the current D010 selenium treatment standard [8]. The data also show that neither treated waste stream could reliably meet the numerical treatment standard of 5.7 mg/L, as measured by the TCLP, even though CWM had shown that it is using the BDAT treatment technology (properly designed and operated) on which EPA based the selenium treatment standard.

CWM submitted stabilization data from each facility using combinations of the following stabilization reagents: Ferrous sulfate, calcium polysulfide, ferric chloride, sodium bisulfate, Portland cement, and cement kiln dust. For more detailed information about these petitions, see the proposed rule (63 FR 56886, October 23, 1998), the docket supporting the proposed rule (docket number F–98–CWMP–FFFFF), and this direct final rule (docket number RCRA–2003–0025).

As part of CWM's current site-specific treatment variances, EPA required CWM to report on alternative treatment technologies being investigated and provide any analytical data from these studies [9]. These annual reports include stabilization recipes being used to meet the alternative treatment standards, the selenium concentrations in untreated wastes, and the analytical results from these wastes. EPA has reviewed the stabilization recipes being utilized to meet the alternative treatment standards and has determined that stabilization of selenium with cement and cement kiln dust, in addition to adding ferrous sulfate as a reagent for the other toxic metals, is the best demonstrated available technology for these selenium-bearing hazardous wastes.

B. What Is the Basis for Establishing Permanently CWM's Alternative D010 Treatment Standards?

After careful review of the data in CWM's selenium variance annual reports, we conclude that CWM has continued to adequately demonstrate that the wastes satisfy the requirements for a treatment variance under 40 CFR 268.44(h)(1). CWM has demonstrated that the two glass manufacturing waste streams differ significantly in chemical composition from the waste used to establish the original treatment standard. Selenium TCLP concentrations in the untreated wastes are one to three orders of magnitude higher than those in the waste used to develop the treatment standard for D010 hazardous wastes. Furthermore, CWM is using stabilization as the treatment technology, which is consistent with EPA's determination of BDAT, and the process is well-designed and operated.

Treatment of these two wastes is especially difficult because of the presence of other metals (*i.e.*, arsenic, cadmium, chromium, and lead) above their respective characteristic levels. It is difficult to optimize treatment for selenium when other metals are being treated because the selenium solubility curve differs from that of most other metals.

In light of the information presented by CWM to the Agency, and EPA's inability to find selenium recovery capability in the US, EPA is changing the status of CWM's treatment variances from temporary to permanent. In addition, consistent with the Heritage treatment variance discussed in Section II of today's notice, EPA is not requiring annual reporting on selenium recovery and treatment technologies.

Therefore, EPA is today permanently establishing two site-specific treatment variances from the D010 treatment standards for the two waste streams in question. We are making this change to the CWM selenium treatment variances in this direct final rule without prior proposal. We view this action as noncontroversial since we did not receive any significant adverse comments when we renewed these variances in 2002.

C. What Are the Terms and Conditions of the Variances?

Upon promulgation of this final rule, CWM will continue to treat these two specific wastes to alternate treatment standards of 51 mg/L, as measured by the TCLP, for the Owens-Brockway waste and 25 mg/L, as measured by the TCLP, for the St. Gobian (formerly Ball-Foster) waste. CWM will continue to dispose of the treated wastes in a RCRA Subtitle C landfill provided they meet the applicable LDR treatment standards for the other hazardous constituents in the wastes. Finally, CWM will no longer be required to submit annual reports on selenium treatment and recovery technologies.

IV. Technical Correction to the Table in Paragraph (O) in 268.44

The table in paragraph (o) under 40 CFR 268.44 (July 1, 2003 version) with the title: Wastes Excluded From the Treatment Standards Under § 268.40, includes a list of facilities that are excluded from the treatment standards under § 268.40 and are subject to treatment variances for specific hazardous constituents. The table includes the following footnote: (5)—Alternative D010 selenium standard only applies to dry scrubber solid from glass manufacturing wastes.

The Agency is revising footnote 6 as follows: "(6)—Alternative D010 selenium standard only applies to electrostatic precipitator dust generated during glass manufacturing operations." This footnote was inadvertently changed when EPA extended the site-specific variance for CWM in May, 2002 (67 FR 36849). This technical correction restores the original text that identifies the source of the selenium-bearing hazardous waste. The selenium-bearing hazardous waste at each facility is generated by emissions from their glass furnaces that are captured in electrostatic precipitators. We are revising the table in paragraph (o) to reflect this change.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is "significant" and therefore

[8] Selenium concentrations in the untreated Owens Brockway wastes were between 465 and 1024 mg/L, as measured by TCLP, while the selenium concentration in the untreated Ball Foster waste was 59.8 mg/L, as measured by the TCLP.

[9] All four of CWM's annual reports are in the docket supporting today's rulemaking.

subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Because this rule does not create any new regulatory requirements, it is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This rule contains no new information collection requirements. The variance only changes the treatment standard applicable to a D010 waste stream at the Heritage Environmental Services, LLC facility in Indianapolis, Indiana, and establishes permanently the treatment standards set for two D10 wastes at the Chemical Waste Management Inc. facility in Kettleman City, California. These actions do not change in any way the paperwork requirements already applicable to these wastes. Therefore, this rule is not subject to the Paperwork Reduction Act.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996) whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities.

This treatment variance does not create any new regulatory requirements. Rather, they establish alternative treatment standards for three specific wastes, and it applies to two facilities; Heritage Environmental Services, LLC facility in Indianapolis, Indiana and Chemical Waste Management Inc. facility in Kettleman City, California. Therefore, I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities. This rule, therefore, does not require a regulatory flexibility analysis.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, and it does not impose any Federal mandate on State, local, or tribal governments or the private sector within the meaning of the Unfunded Mandates Reform Act of 1995. This rule also does not create new regulatory requirements; rather, it merely establishes alternative treatment standards for specific wastes that replace standards already in effect. EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA. For the same reasons, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications."

• Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government."

This rule does not have federalism implications. It 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. The rule will not impose substantial costs on states and localities. The rule does not impose any enforceable duties on these entities, therefore, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13175, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13175 requires EPA to provide to the Office of

Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13175 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rule does not significantly or uniquely affect these communities of Indian tribal governments. The rule does not impose any mandate on tribal governments or impose any duties on these entities. This rule issues a variance from the LDR treatment standards for specific characteristic selenium wastes. Accordingly, the requirements of section 3(b) of Executive Order 13175 do not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, entitled "Protection of Children From Environmental Health and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that EPA determines is (1) "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. EPA interprets the Executive Order 13045 as encompassing only those regulatory actions that are risk based or health based, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it does not involve decisions regarding environmental health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Pub. L. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards based on new methodologies. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA is committed to addressing environmental justice concerns and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income bears disproportionately high and adverse human health and environmental impacts as a result of EPA's policies, programs, and activities, and that all people live in clean and sustainable communities. In response to Executive Order 12898 and to concerns voiced by many groups outside the Agency, EPA's Office of Solid Waste and Emergency Response formed an Environmental Justice Task Force to analyze the array of environmental justice issues specific to waste programs and to develop an overall strategy to identify and address these issues (OSWER Directive No. 9200.3–17). Today's variance applies to a D010 waste stream at the Heritage Environmental Services, LLC facility in Indianapolis, Indiana and two D10 wastes at the Chemical Waste Management Inc. facility in Kettleman City, California. These selenium wastes will be disposed of in RCRA Subtitle C landfills, ensuring protection to human health and the environment. Therefore, the Agency does not believe that today's rule will result in any disproportionately negative impacts on minority or low-income communities relative to affluent or non-minority communities.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability, applying only to a specific waste type at two facilities under particular circumstances.

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). This rule will be effective March 29, 2004.

List of Subjects in 40 CFR Part 268

Environmental Protection, Hazardous waste, Variance.

Dated: February 4, 2004.

Marianne Lamont Horinko,

Assistant Administrator, Office of Solid Waste and Emergency Response.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 268—LAND DISPOSAL RESTRICTIONS

■ 1. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 2. Section 268.44, the table in paragraph (o) is amended by:

■ a. Adding in alphabetical order the entry for "Guardian Industries Corp., Jefferson Hills, PA"

■ b. Adding footnote number 11.

■ c. Revising footnotes 6 and 7.

■ d. Revising the entry for Owens Brockway Glass Container Company, Vernon, CA.

■ e. Revising the entry for St. Gobian Containers, El Monte, CA.

The revisions and additions read as follows:

§ 268.44 Variance from a treatment standard.

(o) * * *

* * * * *

TABLE-WASTES EXCLUDED FROM THE TREATMENT STANDARDS UNDER § 268.40

Facility name [1] and address	Waste code	See also	Regulated hazardous constituent	Wastewaters		Nonwastewaters	
				Concentration (mg/L)	Notes	Concentration (mg/L)	Notes
*	*	*	*	*		*	*
Guardian Industries Corp., Jefferson Hills, PA [6 11].	D010	Standards under § 268.40.	Selenium	NA	NA	39.4 mg/L TCLP	NA.
Owens Brockway Glass Container Company, Vernon CA [6 7].	D010	Standards under § 268.40.	Selenium	NA	NA	51 mg/L TCLP	NA.
St. Gobain Containers, El Monte, CA [5 7].	D010	Standards under § 268.40.	Selenium	NA	NA	25 mg/L TCLP	NA.
*	*	*	*	*		*	*

Note: NA means Not Applicable.

[1] A facility may certify compliance with these treatment standards according to provisions in 40 CFR 268.7.

* * * * * * * *

[5] Alternative DO10 selenium standard only applies to dry scrubber solid from glass manufacturing wastes.

[6] Alternative D010 selenium standard only applies to electrostatic precipitator dust generated during glass manufacturing operations.

[7] D010 wastes generated by these two facilities must be treated by Chemical Waste Management, Inc. at their Kettleman Hills facility in Kettleman City, California.

* * * * * * * *

[11] D010 wastes generated by this facility must be treated by Heritage Environmental Services, LLC. at their treatment facility in Indianapolis, Indiana.

[FR Doc. 04–2821 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–U

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 12

[USCG–2003–14500]

RIN 1625–AA81

Validation of Merchant Mariners' Vital Information and Issuance of Coast Guard Merchant Mariner's Document (MMDs); Correction

AGENCY: Coast Guard, DHS.

ACTION: Interim rule; correction.

SUMMARY: On January 6, 2004, the Coast Guard published an interim rule in the **Federal Register** implementing regulations for the validation of Merchant Mariner's vital information and issuance of Coast Guard Merchant Mariner's Documents (MMDs). This notice contains a correction to that rule.

DATE: Effective on February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Commander Dave Dolloff, Project Manager, National Maritime Center (NMC), Coast Guard, telephone 202–493–1021.

SUPPLEMENTARY INFORMATION: The Coast Guard published an interim rule in the **Federal Register** of January 6, 2004, (69 FR 526) concerning Merchant Mariners Documents. An essential paragraph was inadvertently omitted from the "Background and Purpose" section. The omitted paragraph is needed to further clarify the Coast Guard's intentions governing the validation of merchant mariners' vital information and issuance of Merchant Mariner's Documents. This correction adds that paragraph.

In interim rule FR Doc. 03–32318, published January 6, 2004, (69 FR 526) make the following correction. On page 528, in the first column, following the paragraph ending in the word "appeal," add the following paragraph:

The Department of Homeland Security (DHS), under the authority of the Aviation and Transportation Security Act and the Maritime Transportation Security Act of 2002, is developing a program that can be used to control access to secure areas in vessels, facilities, and ports. This program includes a system-wide transportation worker identification card which is currently under development. DHS is developing this program through the Transportation Security Administration (TSA), the Coast Guard, and other Federal agencies, including others within DHS.

The Coast Guard will work with TSA to ensure that the regulations for obtaining Merchant Mariner Documents are consistent with this initiative to minimize future impacts on mariners.

Dated: January 30, 2004.

T.H. Gilmour,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. 04–2992 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 16

[USCG–2003–16414]

RIN 1625–AA80

Chemical Testing

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising its chemical drug testing regulations to conform with the Department of Transportation's (DOT) final rule concerning Drug and Alcohol Management Information System Reporting published in the **Federal Register** on July 25, 2003. The DOT rule consolidated the 21 different Management Information System (MIS) forms into one single-page form for use by all DOT agencies and the Coast Guard. This conforming amendment

will change the Coast Guard regulations to conform to DOT's final rule.

DATES: This final rule is effective March 12, 2004.

ADDRESSES: Documents mentioned in this rule are available to the public and are part of dockets USCG–2003–16414 and OST–2002–13435. Both are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 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 document on the Internet at *http://dms.dot.gov.* The MIS form in Appendix H of 49 CFR part 40 may be downloaded from the U.S. Coast Guard Marine Safety, Security, and Environmental Protection Web site at *http://www.uscg.mil/hq/g-m/moa/dapip.htm.* This form will also be available from any Marine Safety Office.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Robert C. Schoening, Coast Guard, at 202–267–1430, by fax at 202–267–1416, or by e-mail at *Rschoening@comdt.uscg.mil.* If you have questions on the DOT final rule published on July 25, 2003, contact Mr. Jim Swart, Drug and Alcohol Policy Advisor (S–1), Office of Drug and Alcohol Policy and Compliance, at 202–366–3784, by fax at 202–366–3897 or by e-mail at *Jim.Swart@ost.dot.gov.* If you have questions on viewing material in the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone (202) 366–0271.

SUPPLEMENTARY INFORMATION:

Viewing Comments and Documents

To view comments as well as documents mentioned in this rule as available in the docket, go to *http://dms.dot.gov* at anytime and conduct a simple search using the docket number. You may also visit the Docket Management Facility in Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Background

On July 25, 2003, the Department of Transportation (DOT) published a final rule entitled "Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Drug and Alcohol Management Information System Reporting" in the **Federal Register** (68 FR 43946). This rule changed the annual Management Information System (MIS) submission format for employee drug and alcohol testing data for all DOT agencies and the Coast Guard through the use of a common (MIS) data collection form. The Coast Guard must conform to the DOT final rule and use the new DOT form to avoid duplication, conflict, or confusion with the DOT regulatory requirements. Therefore, the Coast Guard is amending its drug testing regulations in 46 CFR part 16 to conform to 49 CFR part 40.

The DOT rule reduced the number of data elements on the MIS reporting form to be submitted annually by individual marine employers. Employers will no longer have to submit:

1. The number of persons denied a position for a positive drug test;
2. The number of employees returned to duty following a drug violation;
3. Employee drug and alcohol training data;
4. Supervisor drug and alcohol training data;
5. Post-accident alcohol testing data; and
6. Reasonable cause alcohol testing data.

The DOT has stated that its agencies and the Coast Guard could continue to provide direction to their respective regulated employers regarding how, when, and where to report MIS data. This conforming rule is designed to correspond to the DOT MIS reporting regulations now contained in 49 CFR part 40. It requires the use of the new DOT MIS form for annual reporting. It also revises and clarifies the definition for "positive rate" in 46 CFR 16.105 to eliminate any confusion that reporting employers had regarding the types of tests to include in this calculation.

Discussion of Changes

The Coast Guard is amending its chemical drug testing regulations in 46 CFR part 16 to conform to the DOT's final rule revising 49 CFR part 40 drug testing reporting procedures.

Management Information System Requirements

In § 16.500(b), we are changing form number CG–5573 to OMB form 2105–0529 issued October 28, 2003, and providing information on obtaining the new form.

The provisions of 49 CFR part 40 regarding alcohol testing and reporting of alcohol tests do not apply to the Coast Guard or to marine employers. Only the drug testing provisions of 49 CFR part 40 apply to the Coast Guard and marine employers. Therefore, alcohol testing information is not required or permitted to be submitted on the new form. Marine employers are required to submit alcohol testing information in accordance with 46 CFR part 4.

We are removing §§ 16.500 (a)(1) through (a)(10) because the drug testing information to be submitted is now specified in Appendix H to 49 CFR part 40.

Submission of Electronic Information

Employers desiring to report MIS data electronically on the Internet can do so at *http://www.uscg.mil/hq/g-m/moa/dapip.htm.* Submitters must obtain a password from Mr. Robert C. Schoening, listed under **FOR FURTHER INFORMATION CONTACT,** for electronic submission.

The MIS form in Appendix H of 49 CFR part 40 may be downloaded from the U.S. Coast Guard Marine Safety, Security, and Environmental Protection Web site at *http://www.uscg.mil/hq/g-m/moa/dapip.htm.* The form will also be available from any Marine Safety Office.

Regulatory Evaluation

This conforming amendment is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). We expect the economic impact of this conforming amendment to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. The basis for the DOT rule was to "streamline" the (MIS) reporting requirements for all five agencies and the Coast Guard through the use of one reporting form, thereby eliminating the need for each agency to publish a separate NPRM.

The DOT issued a notice of proposed rulemaking (NPRM) in the **Federal Register** on September 30, 2002 (67 FR 61306), proposing the use of a new MIS form as well as a simplified explanation for form submission and completion.

The majority of public comments and suggestions were in favor of the new rule. The final DOT rule mandating the use of the new MIS form was published in the **Federal Register** on July 25, 2003 (68 FR 43946).

Assistance for Small Entities

Under section 213(a) of the Small Business Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this conforming amendment so that they can better evaluate its effects on them. If the amendment would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, contact Mr. Robert Schoening, Coast Guard, telephone (202) 267–1430.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

The DOT's final rule contained information collection requirements that were submitted, as required by the Paperwork Reduction Act of 1995, (the PRA, 44 U.S.C. 3507(d)), to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) for review. Therefore, the DOT agencies and the Coast Guard will remove PRA requirements for the MIS form from their next PRA submission packages. In addition, the DOT will place its entire PRA package for the MIS form on the Internet when that submission is approved by OMB.

As stated in the DOT's final MIS rule, according to OMB's regulations implementing the PRA (5 CFR 1320.8(b)(2)(vi)), an agency may not conduct or sponsor, and a person need not respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for the DOT MIS form is 2105–0529, dated October 28, 2003.

Federalism

A rule has implications under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this conforming amendment under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

We have analyzed this conforming amendment under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This amendment is not economically significant and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

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

Energy Effects

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. This rule changes the reporting requirements for submission of employee drug and alcohol testing. It is procedural in nature and therefore is categorically excluded, under figure 2–1, paragraph (34)(a), of the Instruction from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket where indicated under **ADDRESSES.**

List of Subjects in 46 CFR Part 16

Drug testing, Marine safety, Penalties, Reporting and recordkeeping requirements, Safety, Transportation.

■ For the reasons discussed in the preamble, the Coast Guard amends 46 CFR part 16 as follows:

PART 16—CHEMICAL TESTING

■ 1. Revise the authority citation for part 16 to read as follows:

Authority: 46 U.S.C. 2103, 3306, 7101, 7301, and 7701; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 16.105, remove the definition for "positive rate" and add, in alphabetical order, the new definition for "positive rate for random drug testing" to read as follows:

§ 16.105 Definitions of terms used in this part.

* * * * *

Positive rate for random drug testing means the number of verified positive results for random drug tests conducted under this part plus the number of refusals of random drug tests required by this part, divided by the total number of random drug test results (*i.e.*,

positives, negatives, and refusals) under this part.

* * * * *

■ 3. In § 16.500, revise paragraphs (a), (b)(1), and (b)(2); and remove paragraph (d) to read as follows:

§ 16.500 Management Information System requirements.

(a) *Data collection.* (1) All marine employers must submit drug testing program data required by 49 CFR 40.26 and Appendix H to 49 CFR part 40.

(2) The provisions in 49 CFR part 40 for alcohol testing do not apply to the Coast Guard or to marine employers, and alcohol testing data is not required or permitted to be submitted by this section.

(b) * * *

(1) By March 15 of the year following the collection of the data in paragraph (a) of this section, marine employers must submit the data on the form titled U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form (OMB Number: 2105–0529) by mail to Commandant (G–MOA), 2100 Second Street, SW, Washington, DC 20593–0001 or by Internet at *http://www.uscg.mil/hq/g-m/moa/dapip.htm.*

(2) The DOT Drug and Alcohol Testing MIS form can be downloaded and printed from *http://www.uscg.mil/hq/g-m/moa/dapip.htm* or may be obtained from any Marine Safety Office.

* * * * *

Appendix B [Removed]

■ 4. Remove Appendix B.

Dated: January 29, 2004.

Joseph J. Angelo,

Acting Assistant Commandant for Marine, Safety, Security and Environmental Protection.

[FR Doc. 04–2993 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 20 and 25

[CC Docket No. 94–102, IB Docket No. 99–67; FCC 03–290]

Scope of Enhanced 911 Requirements

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission revises the scope of its enhanced 911 rules to clarify which technologies and services will be required to be capable of transmitting enhanced 911 information to public safety answering points (PSAP). As many citizens, elected representatives, and public safety personnel recognize, 911 service is critical to our Nation's ability to respond to a host of crises and this document enhances the Nation's ability to do so.

DATES: Effective April 12, 2004, with the exception of new rule § 25.284 which will become effective February 11, 2005.

FOR FURTHER INFORMATION CONTACT: Greg Guice, Policy Division, Wireless Telecommunications Bureau, at (202) 418–0095, or David Siehl, Policy Division, Wireless Telecommunications Bureau, at (202) 418–1310, or Arthur Lechtman, Satellite Division, International Bureau, at (202) 418–1465, or Marcy Greene, Competition Policy Division, Wireline Competition Bureau, at (202) 418–2410.

SUPPLEMENTARY INFORMATION: This is a summary of the *Report and Order* adopted on November 13, 2003, and released on December 1, 2003. The full text of the *Report and Order* 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. This document 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.*

I. Overview

1. In the Report and Order, the Commission addresses the obligation of mobile satellite services, telematics services, multi-line telephone systems, resold and pre-paid service, and disposable phones to provide enhanced 911 (E911) capabilities. Its analysis includes a discussion of the four criteria set out in the E911 Scope Further Notice of Proposed Rulemaking, 68 FR 3214 (January 23, 2003), released on December 20, 2002, and its understanding of whether the particular service meets those criteria as informed by the substantial record developed in the course of the proceeding. In addition, the Commission bases its determination on other criteria that may mitigate its need to impose a requirement on a particular service.

2. Mobile satellite service (MSS) carriers that provide interconnected two-way voice service must establish call centers for the purpose of answering 911 emergency calls and forwarding these calls to an appropriate PSAP. In addition, the Commission directs the rechartered Network Reliability and Interoperability Council to study a number of issues pertaining to MSS enhanced 911 deployment.

3. Telematics providers that offer a commercial wireless service may have E911 obligations and need to work with the underlying licensees to ensure that E911 requirements are met. Those providers that do not offer such services, while they do not have an obligation, should continue their efforts with industry and public safety stakeholders to implement advanced telematics safety capabilities.

4. Although the Commission will not adopt federal rules at this time requiring multi-line telephone systems (MLTS) operators to implement E911, it expects that states will act expeditiously on this topic. The Order also references the Model Legislation filed in the record by public safety organizations as a valuable guide. The Commission also issues a *Second Further Notice of Proposed Rulemaking* to continue its consideration of this issue, and to ensure that it is in a position to take appropriate action should states fail to do so or should it otherwise be warranted. Additionally, the Commission will issue a public notice in a year to examine states' progress on implementing E911 in this area.

5. Resold and pre-paid mobile wireless service providers have an independent obligation to comply with our 911 rules to the extent that the underlying licensee has deployed the technology necessary to deliver enhanced 911 service.

6. The Commission finds it is unnecessary to place a separate obligation on manufacturers of disposable phones or personal data assistants that contain a voice service component because the obligation for ensuring access to enhanced 911 service is with the wireless service provider, and they are responsible for ensuring that the devices used with their service satisfy their 911 obligations.

7. Automated maritime telecommunications systems (AMTS) are not required to comply with the Commission's rules because their service fails to meet the four criteria.

8. The Commission believes that these decisions represent a balanced approach, which takes into consideration the expectations of consumers, the need to strengthen Americans' ability to access public safety in times of crisis, and the needs of entities offering these services to be able to compete in a competitive marketplace.

II. Final Regulatory Flexibility Analysis

9. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Revision of the Commission's rules to Ensure Compatibility With Enhanced 911 Emergency Calling Systems Further Notice of Proposed Rulemaking, 66 FR 31878 (June 13, 2001). The Commission sought written public comment on the proposal in the Further Notice of Proposed Rulemaking, including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

A. Need for, and Objectives of, Adopted Rules

10. In the *Report and Order*, the Commission modifies existing rules to broaden the scope of those rules to include new services that were either not in existence or were just beginning to emerge at the time of the rules' adoption. Specifically, the Commission, through the *Report and Order*, modifies its 911 rules to include within the scope of those rules certain mobile satellite service providers and resellers, including pre-paid calling card providers. The Commission takes this action in recognition of Congress' directive to "facilitate the prompt deployment throughout the United States of a seamless, ubiquitous, and reliable end-to-end infrastructure for communications, including wireless communications, to meet the Nation's public safety and other communications needs." In addition, the Commission takes these actions to ensure consumers' expectations regarding access to enhanced 911 service are met, and to strengthen Americans' ability to access public safety. It has balanced those goals against the needs of entities offering these services to be able to compete in a competitive marketplace.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

11. We received no comments directly in response to the IRFA in this proceeding. The Commission, however, considered the potential impact of its rules on smaller wireless service providers and in response to concerns expressed by some commenters, we adopted phase-in periods and decided in the case of certain small wireless handset manufacturers, such as disposable phone manufacturers, and smaller wireless service providers, such as automated maritime telecommunications service providers, not to impose an obligation at this time. The Commission believes that such actions should ensure that smaller entities operating in these areas are able to do so with minimal regulatory interference.

C. Description and Estimate of the Number of Small Entities To Which the Adopted Rules Will Apply

12. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the adopted rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act. Under the Small Business Act, a "small business concern" is one that: (i) Is independently owned and operated; (ii) is not dominant in its field of operation; and (iii) satisfies any additional criteria established by the Small Business Administration (SBA). A small organization is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."

13. We have included small incumbent local exchange carriers in this present RFS analysis. As noted above, a "small business" under the RFA is one that, *inter alia*, meets the pertinent small business size standard (*e.g.*, a telephone communications business, having 1,500 or fewer employees), and "is not dominant in its field of operation." The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not "national" in scope.

14. Incumbent Local Exchange Carriers. Neither the Commission nor the SBA has developed a specific small business size standard for providers of incumbent local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 1,337 incumbent local exchange carriers reported that they were engaged in the provision of local exchange services. Of these 1,337 carriers, an estimated 1,032 have 1,500 or fewer employees and 305 have more than 1,500 employees. Consequently, we estimate that the majority of providers of local exchange service are small entities that may be affected by the rules and policies adopted herein.

15. Competitive Local Exchange Carriers. Neither the Commission nor the SBA has developed a specific small business size standard for providers of competitive local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 609 companies reported that they were engaged in the provision of either competitive access provider services or competitive local exchange carrier services. Of these 609 companies, an estimated 458 have 1,500 or fewer employees and 151 have more than 1,500 employees. Consequently, the Commission estimates that the majority of providers of competitive local exchange service are small entities that may be affected by the rules.

16. Competitive Access Providers. Neither the Commission nor the SBA has developed a specific size standard for competitive access providers (CAPS). The closest applicable standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 609 CAPs or competitive local exchange carriers and 35 other local exchange carriers reported that they were engaged in the provision of either competitive access provider services or competitive local exchange carrier services. Of these 609 competitive access providers and competitive local exchange carriers, an estimated 458 have 1,500 or fewer employees and 151 have more than 1,500 employees. Of the 35 other local exchange carriers, an estimated 34 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that the majority of small entity CAPS and the majority of other local exchange carriers may be affected by the rules.

17. Local Resellers. The SBA has developed a specific size standard for small businesses within the category of Telecommunications Resellers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 133 companies reported that they were engaged in the provision of local resale services. Of these 133 companies, an estimated 127 have 1,500 or fewer employees and 6 have more than 1,500 employees. Consequently, the Commission

estimates that the majority of local resellers may be affected by the rules.

18. Toll Resellers. The SBA has developed a specific size standard for small businesses within the category of Telecommunications Resellers. Under that SBA definition, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 625 companies reported that they were engaged in the provision of toll resale services. Of these 625 companies, an estimated 590 have 1,500 or fewer employees and 35 have more than 1,500 employees. Consequently, the Commission estimates that a majority of toll resellers may be affected by the rules.

19. Interexchange Carriers. Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to providers of interexchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 261 carriers reported that their primary telecommunications service activity was the provision of interexchange services. Of these 261 carriers, an estimated 223 have 1,500 or fewer employees and 38 have more than 1,500 employees. Consequently, we estimate that a majority of interexchange carriers may be affected by the rules.

20. Operator Service Providers. Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to operator service providers. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 23 companies reported that they were engaged in the provision of operator services. Of these 23 companies, an estimated 22 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that a majority of local resellers may be affected by the rules.

21. Prepaid Calling Card Providers. The SBA has developed a size standard for small businesses within the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 37 companies reported that they were engaged in the provision of prepaid calling cards. Of these 37 companies, an estimated 36 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that a majority of prepaid calling providers may be affected by the rules.

22. Mobile Satellite Service Carriers. Neither the Commission nor the U.S. Small Business Administration has developed a small business size standard specifically for mobile satellite service licensees. The appropriate size standard is therefore the SBA standard for Satellite Telecommunications, which provides that such entities are small if they have $12.5 million or less in annual revenues. Currently, nearly a dozen entities are authorized to provide voice MSS in the United States. We have ascertained from published data that four of those companies are not small entities according to the SBA's definition, but we do not have sufficient information to determine which, if any, of the others are small entities. We anticipate issuing several licenses for 2 GHz mobile earth stations that would be subject to the requirements we are adopting here. We do not know how many of those licenses will be held by small entities, however, as we do not yet know exactly how many 2 GHz mobile-earth-station licenses will be issued or who will receive them. The Commission notes that small businesses are not likely to have the financial ability to become MSS system operators because of high implementation costs, including construction of satellite space stations and rocket launch, associated with satellite systems and services. Still, we request comment on the number and identity of small entities that would be significantly impacted by the proposed rule changes.

23. Other Toll Carriers. Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to "Other Toll Carriers." This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 92 carriers reported that they were engaged in the provision of "Other Toll Services." Of these 92 carriers, an estimated 82 have 1,500 or fewer employees and ten have more than 1,500 employees. Consequently, the Commission estimates that a majority of "Other Toll Carriers" may be affected by the rules.

24. Wireless Service Providers. The SBA has developed a size standard for small businesses within the two separate categories of Cellular and Other Wireless Telecommunications and Paging. Under these standards, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 1,387 companies reported that they were engaged in the provision of wireless service. Of these 1,387 companies, an estimated 945 have 1,500 or fewer employees and 442 have more than 1,500 employees. Consequently, we estimate that a majority of wireless service providers may be affected by the rules.

D. Description of Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

25. The reporting, recordkeeping, or other compliance requirements adopted require that any and all of the affected entities to which the Commission's adopted rules apply must comply with the Commission's rules adopted in the Report and Order.

26. In paragraph 31 of the *Report and Order* that addresses mobile satellite systems (MSS), the Commission requires that MSS providers provide Emergency Call Center service to the extent that they offer real-time, two way switched voice service that is interconnected to the public switched network and utilize an in-network switching facility which enables the provider to reuse frequencies and/or accomplish seamless hand-offs of subscriber calls. The Commission declines to mandate specific procedural requirements for this call center service, and instead, is requiring that the Emergency Call Centers be capable of determining the emergency caller's phone number and location. These Call Centers are then required to transfer or redirect the emergency call to an appropriate public safety answering point. At paragraph 37, the Commission determines that although it intends to eventually apply enhanced 911 requirements to MSS providers subject to the foregoing call center requirements, there is not a sufficient basis in the record to require immediate E911 compliance.

27. In the telematics section of the Report and Order at paragraphs 64–90, the Commission declines to require that providers of standard telematics services, *i.e.*, those that do not offer a commercial wireless voice service (CMRS) that connects the telematics user to end users other than the

telematics call center, comply with the Commission's E911 requirements. For those telematics providers that do offer CMRS, however, the Commission determines that they may have E911 obligations and will need to work with the underlying wireless carriers, so that regardless of the legal relationship between the carrier and the telematics provider the Commission's E911 requirements can be met.

28. For resellers and pre-paid calling providers, at paragraphs 91–100 of the Report and Order, the Commission decides that they have an independent obligation to comply with the Commission's 911 rules to the extent that the underlying licensee deploys the technology for E911 service. In paragraphs 101–104, the Commission finds that it is unnecessary to impose E911 obligations on manufacturers of disposable phone and personal digital assistants that contain a voice component.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

29. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its adopted approach, which may include the following four alternatives (among others): (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (ii) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (iii) the use of performance, rather than design, standards; and (iv) an exemption from coverage of the rule, or any part thereof, for small entities.

30. In the Report and Order, the Commission adopted a phase-in period for resellers of wireless service to comply with its rules. This phase-in period was set to allow time for the wholesale price of wireless handsets capable of transmitting the required callback and location information to decline based on economies of scale; and to allow resellers sufficient time to make any necessary changes to their wireless handsets. This alternative will assist all affected licensees, and may be especially helpful to small entities that require more time to comply with the new rules. Additionally, instead of imposing a E911 Phase II requirement on resellers that considered its embedded base of handsets, as it did to licensees, the Commission only places a forward-looking requirement on resellers.

31. By tailoring its rules in this manner, the Commission seeks to fulfill its obligation of ensuring "a seamless, ubiquitous, and reliable end-to-end infrastructure for communications, including wireless communications, to meet the Nation's public safety and other communications needs."

F. Report to Congress

32. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Order, including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

III. Ordering Clauses

33. Pursuant to sections 1, 4(i), 7, 10, 201, 202, 208, 214, 222(d)(4)(A)–(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)–(5), 251(e)(3), 301, 303, 308, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 208, 214, 222(d)(4)(A)–(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)–(5), 251(e)(3), 301, 303, 308, 310, this Report and Order is hereby adopted.

34. The rule changes set forth will become effective April 12, 2004, with the exception of new rule § 25.284 which will become effective February 11, 2005.

35. The Commission's Office of Consumer and Government Affairs, Reference Information Center, shall send a copy of the *Report and Order*, including the Final Regulatory Flexibility Analysis and the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects 47 CFR Parts 20 and 25

Communications common carriers, satellite communications.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Final Rules

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 20 and 25 as follows:

PART 20—COMMERCIAL MOBILE RADIO SERVICES

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

Authority: 47 U.S.C. 154, 160, 251–254, 303 and 332 unless otherwise noted.

■ 2. Section 20.18 is amended by revising paragraphs (a), (b) and (c), by adding paragraphs (g)(1)(vi) and (m) to read as follows:

§ 20.18 911 Service.

(a) *Scope of section.* The following requirements are only applicable to Broadband Personal Communications Services (part 24, subpart E of this chapter), Cellular Radio Telephone Service (part 22, subpart H of this chapter), and Geographic Area Specialized Mobile Radio Services and Incumbent Wide Area SMR Licensees in the 800 MHz and 900 MHz bands (included in part 90, subpart S of this chapter) and those entities that offer voice service to consumers by purchasing airtime or capacity at wholesale rates from these licensees, collectively CMRS providers. In addition, service providers in these enumerated services are subject to the following requirements solely to the extent that they offer real-time, two way switched voice service that is interconnected with the public switched network and utilize an in-network switching facility which enables the provider to reuse frequencies and accomplish seamless hand-offs of subscriber calls.

(b) *Basic 911 Service.* CMRS providers subject to this section must transmit all wireless 911 calls without respect to their call validation process to a Public Safety Answering Point, or, where no Public Safety Answering Point has been designated, to a designated statewide default answering point or appropriate local emergency authority pursuant to § 64.3001 of this chapter, provided that "all wireless 911 calls" is defined as "any call initiated by a wireless user dialing 911 on a phone using a compliant radio frequency protocol of the serving carrier."

(c) *TTY Access to 911 Services.* CMRS providers subject to this section must be capable of transmitting 911 calls from individuals with speech or hearing disabilities through means other than mobile radio handsets, *e.g.*, through the use of Text Telephone Devices (TTY).

* * * * *

(g) * * *

(1) * * *

(vi) Licensees that meet the enhanced 911 compliance obligations through GPS-enabled handsets and have commercial agreements with resellers will not be required to include the resellers' handset counts in their compliance percentages.

* * * * *

(m) *Reseller obligation.* (1) Beginning December 31, 2006, resellers have an

obligation, independent of the underlying licensee, to provide access to basic and enhanced 911 service to the extent that the underlying licensee of the facilities the reseller uses to provide access to the public switched network complies with sections 20.18(d)–(g).

(2) Resellers have an independent obligation to ensure that all handsets or other devices offered to their customers for voice communications and sold after December 31, 2006 are capable of transmitting enhanced 911 information to the appropriate PSAP, in accordance with the accuracy requirements of section 20.18(i).

* * * * *

PART 25—SATELLITE COMMUNICATIONS

■ 3. The authority citation for part 25 continues to read as follows:

Authority: 47 U.S.C. 701–744. Interprets or applies Sections 4, 301, 302, 303, 307, 309 and 332 of the Communications Act, as amended, 47 U.S.C. Sections 154, 301, 302, 303, 307, 309 and 332, unless otherwise noted.

■ 4. Section 25.103 is amended by adding paragraph (g) to read as follows:

§ 25.103 Definitions.

* * * * *

(g) *Emergency call center (ECC).* A facility that subscribers of satellite commercial mobile radio services call when in need of emergency assistance by dialing "911" on their mobile satellite earth terminal.

■ 5. Section 25.284 is added to read as follows:

§ 25.284 Emergency Call Center Service.

Providers of mobile satellite service to end-user customers (part 25, subparts A–D) must provide Emergency Call Center service to the extent that they offer real-time, two way switched voice service that is interconnected with the public switched network and utilize an in-network switching facility which enables the provider to reuse frequencies and/or accomplish seamless hand-offs of subscriber calls. Emergency Call Center personnel must determine the emergency caller's phone number and location and then transfer or otherwise redirect the call to an appropriate public safety answering point. Providers of mobile satellite services that utilize earth terminals that are not capable of use while in motion are exempt from providing Emergency Call Center service for such terminals.

[FR Doc. 04–2124 Filed 2–10–04; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[FCC 03–327; MM Docket No. 01–131, RM–10148, MM Docket No. 01–133, 10143, RM–10150]

Radio Broadcasting Services; Benjamin and Mason, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule; denial of application for review.

SUMMARY: This document denies an Application for Review filed by Charles Crawford directed to both the *Memorandum Opinion and Order* in MM Docket No. 01–131 and MM Docket No. 01–133 concerning his respective proposals for a Channel 257C2 allotment at Benjamin, Texas, and a Channel 249C3 allotment at Mason, Texas. *See* 68 FR 5854, February 5, 2003. With this action, the proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau (202) 418–2177.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 01–131, and MM Docket No. 01–133 adopted December 18, 2003, and released January 8, 2004. The full text of this decision is available for inspection and copying during normal business hours in the FCC Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy 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 *qualixint@aol.com*.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–2896 Filed 2–10–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[FCC 04–1; MM Docket No. 98–112, RM–9027, RM–9268, RM–9384]

Radio Broadcasting Services; Anniston and Asland, AL, and College Park, Covington, Milledgeville, and Social Circle, GA

AGENCY: Federal Communications Commission.

ACTION: Final rule; denial of petition for reconsideration.

SUMMARY: This document denies a Petition for Reconsideration and Motion to Reopen the Record filed by Preston Small directed to the *Memorandum Opinion and Order* in this proceeding which denied an earlier Petition for Reconsideration and Request for Protection filed by Preston Small. *See* 66 FR 14862, March 4, 2001. With this action, the proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau (202) 418–2177.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order* in MM Docket No. 98–112, adopted January 8, 2004, and released January 22, 2004. The full text of this decision is available for inspection and copying during normal business hours in the FCC Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy 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 *qualixint@aol.com*.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–2895 Filed 2–10–04; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–03–17032]

Federal Motor Vehicle Safety Standards; Fuel System Integrity

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule, correcting amendment.

SUMMARY: This document contains a correction to the final rule published on December 1, 2003 (68 FR 67068), that amended the rear and side impact test procedures for the fuel system integrity.

DATES: The effective date of this final rule is April 12, 2004. Petitions for reconsideration must be submitted so they are received by the agency March 29, 2004.

ADDRESSES: Petitions for reconsideration must be identified by the Docket Number in the title to this document and submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For technical and other non-legal issues, you may call Dr. William J.J. Liu, Office of Crashworthiness Standards (Telephone: 202–366–2264) (Fax: 202–366–4329).

For legal issues, you may call Mr. Chris Calamita, Office of Chief Counsel (Telephone: 202–366–2992) (Fax: 202–366–3820).

You may send mail to both of these officials at the National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background

The standard and regulation that are subject to this correction are Federal Motor Vehicle Safety Standard (FMVSS) No. 301, *Fuel system integrity*, and 49 CFR part 586, *Fuel System Integrity Upgrade Phase-In*. In December 2003, we published a final rule upgrading the rear impact test in FMVSS No. 301. To increase the stringency of the standard in order to save more lives and prevent more injuries, the final rule replaces the current full rear impact test procedure performed at 48 km/h (30 mph) with an offset rear impact test procedure specifying that only a portion of the width of the rear of the test vehicle be impacted at 80 km/h (50 mph). Under the new rear impact procedure, a lighter, deformable barrier is used. The final rule also replaces the standard's lateral (side) impact test procedure with the procedure specified in the agency's side impact protection standard at an impact speed range of 53 ± 1 km/h.

The rear impact test requirements of the final rule are being phased-in over a period of three years beginning September 1, 2006. During the phase-in, increasing percentages of motor vehicles will be required to meet the upgraded rear impact test.

Finally, the final rule revises part 586 to establish Fuel System Integrity Upgrade Phase-In Reporting Requirements.

Need for Correction

As published, the December 2003 final rule contained an error that needs correction. The final rule requires manufacturers of vehicles produced by more than one manufacturer to report to the agency the name of the manufacturer to which a vehicle will be attributed for purposes of the phase-in reporting. However, FMVSS No. 301, as amended by the final rule, references 49 CFR part 590 [Reserved], instead of part 586.

This correction amends S8.3.2 of FMVSS No. 301 to reference part 586.

Correction of Publication

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, NHTSA is amending 49 CFR part 571 as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

■ 2. In Section 571.301, paragraph S8.3.2 is revised to read as follows:

§ 571.301 Standard No. 301; Fuel system integrity.

* * * * *

S8.3.2 A vehicle produced by more than one manufacturer must be attributed to any one of the vehicle's manufacturers specified by an express written contract, reported to the National Highway Traffic Safety Administration under 49 CFR part 586, between the manufacturer so specified and the manufacturer to which the vehicle would otherwise be attributed under S8.3.1.

* * * * *

Issued on: February 5, 2004.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 04–2995 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 950605147–5209–0; I.D. 052395C]

RIN 0648–AH33

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Authorization for Commercial Fisheries; Correction

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

ACTION: Final rule, correcting amendment.

SUMMARY: NMFS issued a final rule to implement a new management regime for the unintentional taking of marine mammals incidental to commercial fishing operations, which was published in the **Federal Register** on August 30, 1995. The purpose of this document is to correct an unintended error in the definition of "negligible impact," which provides a reference to a section number of the regulations that has been changed.

DATES: Effective February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Patricia Lawson, NMFS, Office of Protected Resources, (301) 713–2322.

SUPPLEMENTARY INFORMATION:

Background

The regulations that are the subject of this correction pertain to section 118 of the Marine Mammal Protection Act of 1972, as amended, which provides for exceptions for the taking of marine mammals incidental to certain commercial fishing operations from the Act's general moratorium on the taking of marine mammals.

Correction

This document corrects an unintended error. The definition of "negligible impact" in 50 CFR 229.2 simply refers to the definition of the same term in 50 CFR 228.3. The

definition in 50 CFR 228.3 has been moved to 50 CFR 216.103. However, the definition in 50 CFR 229.2 still refers to 50 CFR 228.3. Therefore, in 50 CFR 229.2, the definition for "negligible impact" refers to § 228.3; the correct reference is § 216.103.

Classification

The Assistant Administrator finds that good cause exists to waive the requirement to provide prior notice and the opportunity for comment, pursuant to authority set forth at 5 U.S.C. 553(b)(B), as such procedures would be unnecessary. Prior notice and opportunity for comment are unnecessary because this amendment corrects an error in a reference to a section number in the regulations and will have a de minimus effect, if any, on the regulated community. This correction does not increase the scope of the regulated community. This correction does not increase the scope of the regulated community nor add new requirements. In addition, because this rule corrects a provision and makes non-substantive or de minimus changes to the regulations, the Assistant Administrator finds good cause under 5 U.S.C. 553(d) not to delay the effective date of this final rule for 30 days.

Because a general notice of proposed rulemaking is not required under 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Dated: February 4, 2003.

William T. Hogarth,

Assistant Administrator, National Marine Fisheries Service.

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble, 50 CFR part 229 is amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

■ 1. The authority citation for part 229 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. In § 229.2, the definition of "Negligible impact" is revised to read as follows:

§ 229.2 Definitions.

* * * * *

Negligible impact has the same meaning as in § 216.103 of this chapter.

* * * * *

[FR Doc. 04–2981 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 69, No. 28
Wednesday, February 11, 2004

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–CE–64–AD]

RIN 2120–AA64

Airworthiness Directives; Alexander Schleicher GmbH & Co. Segelflugzeugbau Model ASH 25M Sailplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Alexander Schleicher GmbH & Co. Segelflugzeugbau (Alexander Schleicher) Model ASH 25M sailplanes equipped with fuel injected engine IAE50R–AA. This proposed AD would require you to inspect the fuel line for correct fittings, and, if any incorrect fitting is found, replace the fuel line. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. We are issuing this proposed AD to detect and correct any fuel lines with improper fittings, which could result in fuel leakage and a possible fire hazard.

DATES: We must receive any comments on this proposed AD by March 22, 2004.

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

- *By mail:* FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–64–AD, 901 Locust, Room 506, Kansas City, Missouri 64106.
- *By fax:* (816) 329–3771.
- *By e-mail: 9-ACE-7-Docket@faa.gov.* Comments sent electronically must contain "Docket No. 2003–CE–64–AD" in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII.

You may get the service information identified in this proposed AD from Alexander Schleicher GmbH & Co. Segelflugzeugbau, D–36163 Poppenhausen, Federal Republic of Germany; telephone: (011–49) 6658 89–0; facsimile: (011–49) 6658 89–40.

You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–64–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include "AD Docket No. 2003–CE–64–AD" in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it. We will date-stamp your postcard and mail it back to you.

Are there any specific portions of this proposed AD I should pay attention to? We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend this proposed AD in light of those comments and contacts.

Discussion

What events have caused this proposed AD? The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified FAA that an unsafe condition may exist on Alexander Schleicher sailplanes. The LBA reports that an incorrect fitting at one end of a fuel line was installed during production of the Model ASH 25M sailplane equipped with fuel injected engine IAE50R–AA. The incorrect fitting includes a combination of sealing cones. After maintenance, the incorrect combination of sealing cones inside the fittings might cause a fuel leak.

What are the consequences if the condition is not corrected? Any fuel line with improper fittings could result in fuel leakage and a possible fire hazard.

Is there service information that applies to this subject? Alexander Schleicher has issued ASH 25 Mi Technical Note No. 22, dated February 21, 2003.

What are the provisions of this service information? The service bulletin includes procedures for:

—Inspecting the fuel line for correct fittings; and

—If any incorrect fitting is found, replacing the fuel line.

What action did the LBA take? The LBA classified this service bulletin as mandatory and issued German AD Number 2003–129, dated March 21, 2003, to ensure the continued airworthiness of these sailplanes in Germany.

Did the LBA inform the United States under the bilateral airworthiness agreement? These Alexander Schleicher Model ASH 25M sailplanes are manufactured in Germany and are type-certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Under this bilateral airworthiness agreement, the LBA has kept us informed of the situation described above.

FAA's Determination and Requirements of This Proposed AD

What has FAA decided? We have examined the LBA's findings, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since the unsafe condition described previously is likely to exist or develop on other Alexander Schleicher Model ASH 25M sailplanes of the same type design that are registered in the United States, we are proposing AD action to detect and correct any fuel lines with

improper fittings, which could result in fuel leakage and a possible fire hazard.

What would this proposed AD require? This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

How does the revision to 14 CFR part 39 affect this proposed AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

How many sailplanes would this proposed AD impact? We estimate that this proposed AD affects 2 sailplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected sailplanes? We estimate the following costs to accomplish this proposed inspection:

Labor cost	Parts cost	Total cost per sailplane	Total cost on U.S. operators
1 workhour at $65 per hour = $65	Not Applicable.	$65	$130

We estimate the following costs to accomplish any necessary replacement that would be required based on the results of this proposed inspection. We have no way of determining the number of sailplanes that may need this replacement:

Labor cost	Parts cost	Total cost per sailplane
1 workhour at $65 per hour = $65	$160	$65 + $160 = $225

Regulatory Findings

Would this proposed AD impact various entities? We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed AD:

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

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

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

We prepared a summary of the costs to comply with this proposed AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2003–CE–64–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Alexander Schleicher GMBH & Co. Segelflugzeugbau: Docket No. 2003–CE–64–AD.

When Is the Last Date I Can Submit Comments on This Proposed AD?

(a) We must receive comments on this proposed airworthiness directive (AD) by March 22, 2004.

What Other ADs Are Affected by This Action?

(b) None.

What Sailplanes Are Affected by This AD?

(c) This AD affects all Model ASH 25M sailplanes, all serial numbers, that are:

(1) Certificated in any category; and

(2) Equipped with fuel injected engine IAE50R–AA.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified in this AD are intended to detect and correct fuel lines with improper fittings, which could result in fuel leakage and a possible fire hazard.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) Inspect the fuel line between the injection valve and pressure regulator for the correct color of connecting fittings (The connecting fitting at the injection valve must be blue and the connecting fitting at the pressure regulator must be black.).	Within the next 50 hours time-in-service (TIS) after the effective date of this AD, unless already done.	Follow Alexander Schleicher GmbH & Co. Segelflugzeugbau ASH 25 Mi Technical Note No. 22, dated February 21, 2003.

Actions	Compliance	Procedures
(2) If you find any fuel line with blue connecting fittings at both ends, then replace the fuel line with a fuel line with a blue connecting fitting at the injection valve and a black connecting fitting at the pressure regulator.	Before further flight after the inspection required by paragraph (e)(1) of this AD.	Follow Alexander Schleicher GmbH & Co. Segelflugzeugbau ASH 25 Mi Technical Note No. 22, dated February 21, 2003.
(3) Do not install any fuel line that uses blue connecting fittings at both ends.	As of the effective date of this AD	Not Applicable.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, FAA. For information on any already approved alternative methods of compliance, contact Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; facsimile: (816) 329–4090.

May I Get Copies of the Documents Referenced in This AD?

(g) You may get copies of the documents referenced in this AD from Alexander Schleicher GmbH & Co. Segelflugzeugbau, D–36163 Poppenhausen, Federal Republic of Germany; telephone: (011–49) 6658 89–0; facsimile: (011–49) 6658 89–40. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Is There Other Information That Relates to This Subject?

(h) German AD Number 2003–129, dated March 21, 2003, also addresses the subject of this AD.

Issued in Kansas City, Missouri, on February 4, 2004.

Dorenda D. Baker,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2954 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–186–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of three existing airworthiness directives (AD), applicable to certain Boeing Model 767–200, –300, and –300F series airplanes. One AD currently requires modification of the nacelle strut and wing structure for certain Boeing Model 767–200, –300, and –300F series airplanes powered by Pratt & Whitney engines. The second AD currently requires a similar modification for certain Boeing Model 767–200, –300, and –300F series airplanes powered by General Electric engines. The third AD currently requires repetitive inspections for cracking of the outboard pitch load fittings of the wing front spar, and corrective action if necessary, for certain Boeing Model 767–200 series airplanes. The third AD also provides a terminating action for the repetitive inspections, which is optional for uncracked pitch load fittings. This proposed AD would require, for airplanes subject to the first and second existing ADs on which certain modifications have been accomplished previously, reworking the aft pitch load fitting, and installing a new diagonal brace fuse pin. This proposed AD also would require, for airplanes subject to the third existing AD, replacing the outboard pitch load fitting of the wing front spar with a new, improved fitting, which would terminate certain currently required repetitive inspections. The actions specified by the proposed AD are intended to prevent fatigue cracking in primary strut structure, which could result in separation of the strut and engine from the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by March 29, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–186–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2002–NM–186–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Suzanne Masterson, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6441; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2002–NM–186–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–186–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On January 17, 2001, the FAA issued AD 2001–02–07, amendment 39–12091 (66 FR 8085, January 29, 2001), applicable to certain Boeing Model 767–200, –300, and –300F series airplanes powered by Pratt & Whitney engines. On March 22, 2001, we issued AD 2001–06–12, amendment 39–12159 (66 FR 17492, April 2, 2001), applicable to certain Boeing Model 767–200, –300, and –300F series airplanes powered by General Electric engines. Those ADs require modification of the nacelle strut and wing structure. Those actions were prompted by the airplane manufacturer's structural reassessment of the damage tolerance capabilities of Boeing Model 767 series airplanes, which indicated that the actual operational loads on the nacelle strut and wing structure are higher than the analytical loads used during the initial design. Service history and analysis subsequent to this reassessment revealed numerous reports of fatigue cracking of the primary structure that occurred prior to the airplane's reaching its design service objective of 20 years or 50,000 total flight cycles. The requirements of those ADs are intended to prevent fatigue cracking in primary strut structure and consequent reduced structural integrity of the strut.

Later, on April 18, 2001, we issued AD 2001–08–23, amendment 39–12200 (66 FR 21069, April 27, 2001), applicable to certain Boeing Model 767–200 series airplanes. That AD requires repetitive inspections for cracking of the outboard pitch load fittings of the wing front spar, and corrective action if necessary. That AD also provides a terminating action for the repetitive inspections, which is optional for uncracked pitch load fittings. That action was prompted by reports that fatigue cracking of the outboard pitch load fittings on the wing front spar had been found on certain Boeing Model 767–200 series airplanes. The requirements of that AD are intended to find and fix cracking of the outboard pitch load fittings of the wing front spar, which could lead to loss of the upper link load path and result in separation of the strut and engine from the airplane.

Actions Since Issuance of Previous Rules

AD 2001–02–07 cites Boeing Service Bulletin 767–54–0080, dated October 7, 1999; and AD 2001–06–12 cites Boeing Service Bulletin 767–54–0081, dated July 29, 1999; as the appropriate sources of service information for the primary actions required by those ADs. Since the issuance of those ADs, we have received reports that certain parts kits supplied by the airplane manufacturer for the modifications specified in those service bulletins contained bushings for the aft pitch load fitting that were too large in the inner diameter. This discrepancy could cause an excessive gap between the diagonal brace fuse pin and the aft pitch load fitting, which could reduce the life of the fuse pin. Failure of the fuse pin, if not corrected, would result in increased loads in the other wing-to-strut joints, which could result in separation of the strut and engine from the airplane.

With regard to AD 2001–08–23, the preamble to that AD explains that we consider the requirements in that AD "interim action" and that we're considering further rulemaking to require replacing the outboard pitch load fitting of the wing front spar with a new, improved fitting. (AD 2001–08–23 provides for that replacement as an optional terminating action for uncracked pitch load fittings, or as a required terminating action for cracked pitch load fittings.) We now have determined that further rulemaking is indeed necessary, and this proposed AD follows from that determination.

Explanation of Relevant Service Information

We have reviewed and approved Boeing Service Bulletin 767–54–0080, Revision 1, dated May 9, 2002; and 767–54–0081, Revision 1, dated February 7, 2002. Those service bulletins describe procedures similar to those in the original issue of the service bulletins, which are referenced in ADs 2001–02–07 and 2001–06–12. However, for both service bulletins, Revision 1 describes additional work that is necessary for airplanes in certain groups. For airplanes in Groups 4 through 10 in Boeing Service Bulletin 767–54–0080, Revision 1; and in Groups 3 through 12 in Boeing Service Bulletin 767–54–0081, Revision 1; on which the actions in the original issue of the service bulletin were accomplished; the additional work includes installing new markers on the diagonal brace of the left-hand and right-hand struts, reworking the aft load pitch fitting, and installing a new diagonal brace fuse pin. For airplanes in Group 1 of those service bulletins, the additional work includes replacing the outboard pitch load fitting of the wing front spar in accordance with Boeing Service Bulletin 767–57A0070 (described below).

We have reviewed and approved Boeing Service Bulletin 767–57A0070, Revision 3, dated November 8, 2001, which is effective for certain Model 767–200 series airplanes. (AD 2001–08–23 refers to Revision 1 of that service bulletin, dated November 16, 2000, as the appropriate source of service information for the actions required by that AD.) Among other actions, Revision 3 of the service bulletin describes procedures for replacing the outboard pitch load fitting of the wing front spar, on the left- and right-hand sides of the airplane, with a new, improved fitting. Procedures for this replacement include doing a high frequency eddy current (HFEC) inspection for damaged fastener holes, oversizing the fastener holes and repeating the HFEC inspections if necessary, installing an improved outboard pitch load fitting, and machining the outboard pitch load fitting. Boeing Service Bulletin 767–57A0070, Revision 3, refers to Boeing Service Bulletin 767–57–0053 as an appropriate source of service information for additional necessary actions. (Paragraph (b) of AD 2001–02–07 requires, among other actions, accomplishment of the actions specified in Boeing Service Bulletin 767–57–0053, Revision 2, dated September 23, 1999.)

We have also reviewed and approved Boeing Service Bulletin 767–29–0057, Revision 1, dated August 14, 2003. (Paragraph (b) of AD 2001–02–07 and paragraph (b) of AD 2001–06–12 refer to the original issue of that service bulletin, dated December 16, 1993; as an acceptable source of service information for certain actions required to be accomplished prior to or concurrently

with the modification of the nacelle strut and wing structure required by paragraph (a) of those ADs.) Revision 1 of the service bulletin describes procedures for changing wire bundle routing and improving wire bundle support to ensure that there is sufficient separation between wire bundles and hydraulic tubes in the aft fairing area of the strut. These procedures are essentially the same as those described in the original issue of the service bulletin. Thus, we have revised paragraph (b) (under the heading "Requirements of AD 2001–02–07") and paragraph (e) (under the heading "Requirements of AD 2001–06–12") in this proposed AD to refer to Boeing Service Bulletin 767–29–0057, Revision 1, as an acceptable source of service information for the applicable actions required by those paragraphs.

We have also reviewed and approved Boeing Service Bulletin 767–54A0094, Revision 2, dated February 7, 2002. (Paragraph (b) of AD 2001–02–07 and paragraph (b) of AD 2001–06–12 refer to Revision 1 of that service bulletin, dated September 16, 1999; as an acceptable source of service information for certain actions required to be accomplished prior to or concurrently with the modification of the nacelle strut and wing structure required by paragraph (a) of those ADs.) Revision 2 of the service bulletin describes procedures for a detailed visual inspection for cracking of the forward and aft lugs of the diagonal brace, and follow-on actions. There are no substantial differences between the procedures in Revisions 1 and 2 of the service bulletin. Thus, we have revised paragraph (b) (under the heading "Requirements of AD 2001–02–07") and paragraph (e) (under the heading "Requirements of AD 2001–06–12") in this proposed AD to refer to Boeing Service Bulletin 767–54A0094, Revision 2, as an acceptable source of service information for the applicable actions required by that paragraph.

Accomplishment of the actions specified in Boeing Service Bulletins 767–54–0080, Revision 1, and 767–57A0070, Revision 3, along with the other service bulletins specified in AD 2001–02–07, is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede ADs 2001–02–07 and 2001–06–12 to continue to require modification of the nacelle strut and wing structure. For certain airplanes on which certain modifications have been accomplished previously, the proposed AD would require reworking the aft load pitch fitting, and installing a new diagonal brace fuse pin. The proposed AD also would supersede AD 2001–08–23 to continue to require repetitive inspections for cracking of the outboard pitch load fittings of the wing front spar, and corrective action if necessary. For certain airplanes, the proposed AD would require replacing the outboard pitch load fitting of the wing front spar with a new, improved fitting on the left- and right-hand sides of the airplane, which would terminate the repetitive inspections required by AD 2001–08–23. Except as discussed below under the heading "Differences Between Proposed AD and Service Bulletins," the actions would be required to be accomplished in accordance with the service bulletins described previously in this proposed AD, as well as other service bulletins that were referenced in ADs 2001–02–07 and 2001–06–12.

Differences Between Proposed AD and Service Bulletins

Although the Accomplishment Instructions of Revision 1 of Boeing Service Bulletins 767–54–0080 and 767–54–0081 specify installing new markers on the diagonal brace of the left-hand and right-hand struts, the proposed AD would not require such installation. We find that not installing such markers will not affect safety of flight for the affected airplane fleet.

Paragraphs (k) and (l) of this proposed AD specify an inspection to determine the part number of the aft pitch load fitting. While Revision 1 of Boeing Service Bulletins 767–54–0080 and 767–54–0081 state that rework of the aft pitch load fitting is not necessary if an aft pitch load fitting was reworked previously, those service bulletins do not provide for determining the part number of the aft pitch load fitting. We find that an inspection is the best method for operators to use to determine the part number of the aft load pitch fitting.

Explanation of Changes to Existing Requirements

For clarification, we have revised all references to "Boeing Model 767 series airplanes" from ADs 2001–02–07 and 2001–06–12 to refer more specifically to Boeing Model 767–200, –300, and –300F series airplanes. Boeing Model 767–400ER series airplanes are not subject to these ADs.

For clarity, we have revised paragraph (b) of this proposed AD, under the heading "Requirements of AD 2001–02–07," to remove a reference to page 8 of Boeing Service Bulletin 767–54–0080. Similarly, we have revised paragraphs (d)(1) and (e) of this proposed AD, under the heading "Requirements of AD 2001–06–12," to remove references to pages 8 and 54 of Boeing Service Bulletin 767–54–0081.

Paragraph (b) of AD 2001–02–07 states that accomplishment of that paragraph constitutes terminating action for AD 99–07–06, amendment 39–11091 (64 FR 14578, March 26, 1999). AD 99–07–06 has been superseded by AD 2000–07–05, amendment 39–11659 (65 FR 18883, April 10, 2000). Therefore, we have revised paragraph (b) of this proposed AD to refer to AD 2000–07–05 instead of AD 99–07–06.

Similarly, we have revised paragraph (b) of this proposed AD to note that accomplishment of that paragraph constitutes terminating action for AD 2000–12–17, amendment 39–11795 (65 FR 37843, June 19, 2000). AD 2000–12–17 requires accomplishment of the actions specified in Boeing Service Bulletin 767–57–0053, Revision 2, and paragraph (g) of that AD states that modification of the nacelle strut and wing structure in accordance with Boeing Service Bulletin 767–54–0080 constitutes terminating action for the actions required by AD 2000–12–17. A reference to AD 2000–12–17 would have been appropriate in AD 2001–02–07 but was inadvertently omitted.

Also, we have revised the cost impact estimate in this proposed AD for the actions specified in Boeing Service Bulletin 767–54–0080 and 767–54–0081. These changes are due in part to increases in the work hour estimates in that service bulletin. For the actions in Boeing Service Bulletin 767–54–0080, the revision of the cost impact estimate is due to our determination that, in this case, it is appropriate to include time for gaining access and closing up in the cost impact estimate. While cost impact figures in AD actions typically do not include incidental costs such as the time required to gain access and close up, we find that certain actions associated with gaining access to perform the actions that would be required by this proposed AD (*e.g.*, removing engines, draining fuel) would not ordinarily be accomplished if this proposed AD were not adopted. (AD 2001–06–12 already includes time for gaining access and closing up in the cost impact estimate for the actions associated with Boeing Service Bulletin 767–54–0081.)

Cost Impact

There are approximately 619 airplanes of the affected design in the worldwide fleet. The FAA estimates that

255 airplanes of U.S. registry would be affected by this proposed AD.

The following table shows the estimated costs associated with the actions currently required by ADs 2001–02–07, 2001–06–12, and 2001–08–23, at an average labor rate of $65 per work hour:

ESTIMATED COST IMPACT—ACTIONS CURRENTLY REQUIRED

Actions in Boeing Service Bulletin—	Number of affected U.S.–registered airplanes	Work hours	Parts cost	Cost per airplane	Fleet cost
767–54–0080	86	[1] 1,423–1,519	Free	$92,495–98,735	$7,954,570–8,491,210
767–54–0081	169	[1] 1,474	Free	95,810	16,191,890
767–54–0069	249	106	Free	6,890	1,715,610
767–54–0083	228	1	Free	65	14,820
767–54–0088	255	2	Free	130	33,150
767–54A0094	117	20	Free	1,300	152,100
767–57–0053	255	5	None	325	82,875
767–29–0057	200	16	Free	1,040	208,000
767–57A0070	67	4	None	[2] 260	[2] 17,420

[1] Including time for gaining access and closing up.
[2] Per inspection cycle.

For affected airplanes, the new inspection to determine the part number of the aft load pitch fittings that is proposed in this AD action would take approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of this proposed requirement is estimated to be $65 per airplane.

For affected airplanes, the new replacement of the outboard pitch load fittings that is proposed in this AD action would take approximately 14 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Required parts would cost approximately $14,438 per airplane. Based on these figures, the cost impact of this proposed requirement is estimated to be $15,348 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions; however, as explained previously, time to gain access and close up has been included for certain actions in this proposed AD.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendments 39–12091 (66 FR 8085, January 29, 2001), 39–12159 (66 FR 17492, April 2, 2001), and 39–12200 (66 FR 21069, April 27, 2001); and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 2002–NM–186–AD. Supersedes AD 2001–02–07, amendment 39–12091; AD 2001–06–12, amendment 39–12159; and AD 2001–08–23, amendment 39–12200.

Applicability: Model 767–200, –300, and –300F series airplanes; certificated in any category; line numbers (L/Ns) 1 through 663 inclusive; powered by Pratt & Whitney or General Electric engines.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking in primary strut structure, which could result in separation of the strut and engine from the airplane, accomplish the following:

Requirements of AD 2001–02–07

Modifications

(a) For Model 767–200, –300, and –300F series airplanes powered by Pratt & Whitney engines, L/Ns 1 through 663 inclusive: When the airplane has reached the flight cycle threshold as defined by the flight cycle threshold formula described in Figure 1 of Boeing Service Bulletin 767–54–0080, dated October 7, 1999, or Revision 1, dated May 9, 2002; or within 20 years since the date of manufacture; whichever occurs first; modify the nacelle strut and wing structure on both the left-hand and right-hand sides of the airplane, in accordance with the service bulletin. Use of the flight cycle threshold formula described in Figure 1 of the service bulletin is an acceptable alternative to the 20-year threshold, provided the corrosion prevention and control program inspections, as described in paragraphs 1 and 2 of Figure 1, have been met. As of the effective date of this AD, only Revision 1 of the service bulletin may be used.

(b) For Model 767–200, –300, and –300F series airplanes powered by Pratt & Whitney engines, L/Ns 1 through 663 inclusive: Prior to or concurrently with the accomplishment

of the modification of the nacelle strut and wing structure required by paragraph (a) of this AD; as specified in paragraph 1.D., Table 2, of Boeing Service Bulletin 767–54–0080, dated October 7, 1999, or Revision 1, dated May 9, 2002; accomplish the actions specified in Boeing Service Bulletins 767–54–0069, Revision 1, dated January 29, 1998, or Revision 2, dated August 31, 2000; 767–54–0083, dated September 17, 1998; 767–54–0088, Revision 1, dated July 29, 1999; 767–54A0094, Revision 1, dated September 16, 1999, or Revision 2, dated February 7, 2002; 767–57–0053, Revision 2, dated September 23, 1999; and 767–29–0057, dated December 16, 1993, including Notice of Status Change NSC 1, dated November 23, 1994, or Revision 1, dated August 14, 2003; as applicable; in accordance with those service bulletins. Accomplishment of this paragraph constitutes terminating action for the repetitive inspections required by AD 94–11–02, amendment 39–8918; AD 2000–07–05, amendment 39–11659; and AD 2000–12–17, amendment 39–11795.

Note 1: Paragraph (b) of this AD specifies prior or concurrent accomplishment of Boeing Service Bulletin 767–57–0053, Revision 2, dated September 23, 1999; however, Table 2 of Boeing Service Bulletin 767–54–0080, dated October 7, 1999, specifies prior or concurrent accomplishment of the original issue of the service bulletin. Therefore, accomplishment of the applicable actions specified in Boeing Service Bulletin 767–57–0053, dated June 27, 1996, or Revision 1, dated October 31, 1996, prior to the effective date of this AD, is considered acceptable for compliance with the actions in Boeing Service Bulletin 767–57–0053 required by paragraph (b) of this AD.

Repair

(c) For Model 767–200, –300, and –300F series airplanes powered by Pratt & Whitney engines, L/Ns 1 through 663 inclusive: If any damage (corrosion or cracking) to the airplane structure is found during the accomplishment of the modification required by paragraph (a) of this AD; and the service bulletin specifies to contact Boeing for appropriate action: Prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the FAA to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

Requirements of AD 2001–06–12

Modification

(d) For Model 767–200, –300, and –300F series airplanes powered by General Electric engines, L/Ns 1 through 663 inclusive: Modify the nacelle strut and wing structure on both the left-hand and right-hand sides of the airplane, in accordance with Boeing Service Bulletin 767–54–0081, dated July 29, 1999; or Revision 1, dated February 7, 2002; at the later of the times specified in paragraphs (d)(1) and (d)(2) of this AD. After the effective date of this AD, only Revision 1 may be used.

(1) Prior to the accumulation of 37,500 total flight cycles, or within 20 years since date of manufacture, whichever occurs first. Use of the optional threshold formula described in Figure 1 of the service bulletin is an acceptable alternative to the 20-year threshold provided that the conditions specified in Figure 1 of the service bulletin are met. For the optional threshold formula in Figure 1 to be used, actions in the service bulletins listed in Item 2 of Figure 1 must be accomplished no later than 20 years since the airplane's date of manufacture.

(2) Within 3,000 flight cycles after May 7, 2001 (the effective date of AD 2001–06–12).

(e) For Model 767–200, –300, and –300F series airplanes powered by General Electric engines, L/Ns 1 through 663 inclusive: Prior to or concurrently with the accomplishment of the modification of the nacelle strut and wing structure required by paragraph (d) of this AD; as specified in paragraph 1.D., Table 2, "Prior or Concurrent Service Bulletins," of Boeing Service Bulletin 767–54–0081, dated July 29, 1999; or Revision 1, dated February 7, 2002; accomplish the actions specified in Boeing Service Bulletin 767–29–0057, dated December 16, 1993, or Revision 1, dated August 14, 2003; Boeing Service Bulletin 767–54–0069, Revision 1, dated January 29, 1998, or Revision 2, dated August 31, 2000; Boeing Service Bulletin 767–54–0083, dated September 17, 1998; Boeing Service Bulletin 767–54–0088, Revision 1, dated July 29, 1999; Boeing Service Bulletin 767–54A0094, Revision 1, dated September 16, 1999, or Revision 2, dated February 7, 2002; and Boeing Service Bulletin 767–57–0053, Revision 2, dated September 23, 1999; as applicable, in accordance with those service bulletins.

Note 2: AD 2000–12–17, amendment 39–11795, requires accomplishment of Boeing Service Bulletin 767–57–0053, Revision 2, dated September 23, 1999. However, inspections and rework accomplished in accordance with Boeing Service Bulletin 767–57–0053, Revision 1, dated October 31, 1996, are acceptable for compliance with the applicable actions required by paragraph (e) of this AD.

Note 3: AD 2000–07–05, amendment 39–11659, requires accomplishment of Boeing Service Bulletin 767–54A0094, dated May 22, 1998. Inspections and rework accomplished in accordance with Boeing Service Bulletin 767–54A0094, dated May 22, 1998, are acceptable for compliance with the applicable actions required by paragraph (e) of this AD.

Note 4: AD 2001–02–07, amendment 39–12091, requires accomplishment of Boeing Service Bulletin 767–54–0069, Revision 1, dated January 29, 1998, or Revision 2, dated August 31, 2000. Inspections and rework accomplished in accordance with those service bulletins are acceptable for compliance with the applicable actions required by paragraph (e) of this AD.

Repairs

(f) For Model 767–200, –300, and –300F series airplanes powered by General Electric engines, L/Ns 1 through 663 inclusive: If any damage to the airplane structure is found during the accomplishment of the modification required by paragraph (d) of this AD, and the service bulletin specifies to contact Boeing for appropriate action, prior to further flight, repair in accordance with a method approved by the Manager, Seattle ACO, or a Boeing Company DER who has been authorized by the FAA to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

Requirements OF AD 2001–08–23

Initial and Repetitive Inspections

(g) For Model 767–200 series airplanes, as listed in Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000: Within 30 days after May 14, 2001 (the effective date of AD 2001–08–23, amendment 39–12200), perform a high frequency eddy current (HFEC) inspection for cracking of the outboard pitch load fitting of the wing front spar, on the left-hand and right-hand sides of the airplane, according to Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000; Revision 2, dated August 2, 2001; or Revision 3, dated November 8, 2001. If no cracking is found, repeat the inspection at intervals not to exceed 3,000 flight cycles or 18 months, whichever occurs first, until paragraph (i) or (m) of this AD is done.

Note 5: Inspections done prior to the effective date of this AD, in accordance with Boeing Service Bulletin 767–57A0070, dated March 2, 2000, as revised by Information Notice 767–57A0070 IN 01, dated March 23, 2000, are considered acceptable for compliance with paragraph (g) of this AD.

Corrective Action

(h) For Model 767–200 series airplanes, as listed in Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000: If any cracking is found during any inspection per paragraph (g) of this AD, prior to further flight, do paragraph (h)(1) or (h)(2) of this AD.

(1) Rework the cracked outboard pitch load fitting according to a method approved by the Manager, Seattle ACO, or according to data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a rework method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

(2) Replace the cracked outboard pitch load fitting with a new, improved fitting (including removing the existing fittings, performing an HFEC inspection for damage of fastener holes, repairing damaged fastener holes—if necessary, and installing new fittings of improved design), according to Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000; Revision 2, dated August 2, 2001; or Revision

3, dated November 8, 2001. Such replacement terminates the repetitive inspections required by paragraph (g) of this AD for the replaced fitting.

Note 6: Boeing Service Bulletin 767–57A0070, Revision 1, refers to Boeing Service Bulletin 767–57–0053 as an additional source of service information for accomplishment of the replacement of the outboard pitch load fitting on Model 767–200 series airplanes.

Optional Terminating Action

(i) For Model 767–200 series airplanes, as listed in Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000: Replacement of the outboard pitch load fitting of the wing front spar with a new, improved fitting, according to Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000; Revision 2, dated August 2, 2001; or Revision 3, dated November 8, 2001; terminates the repetitive inspections required by paragraph (g) of this AD for the replaced fitting.

Spares

(j) For Model 767–200 series airplanes, as listed in Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000: As of May 14, 2001, no one may install on any airplane an outboard pitch load fitting that has a part number listed in the "Existing Part Number" column of Paragraph 2.E. of Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000.

New Requirements of This AD

Boeing Service Bulletin 767–54–0080, Revision 1, Groups 4 through 10: Inspection and Additional Work, if Necessary

(k) For airplanes listed in Groups 4 through 10 of Boeing Service Bulletin 767–54–0080, Revision 1, dated May 9, 2002, on which the modification required by paragraph (a) of this AD has been accomplished prior to the effective date of this AD: Within 18 months after the effective date of this AD, perform an inspection of the aft pitch load fitting of the wing front spar to determine the part number (P/N) of the fitting.

(1) If the aft pitch load fitting on the left-hand side of the airplane has P/N 112T7005–57 and the aft pitch load fitting on the right-hand side of the airplane has P/N 112T7005–58: No further action is required by this paragraph.

(2) If the aft pitch load fitting on the left-hand side of the airplane has P/N 112T7005–53 or the aft pitch load fitting on the right-hand side of the airplane has P/N 112T7005–54: Within 18 months after the effective date of this AD, rework the affected aft pitch load fitting and install the diagonal brace with a new fuse pin, in accordance with Steps E. and F. under the heading "Additional Work Required—Group 4 through 10 Airplanes" in the Accomplishment Instructions of the service bulletin.

Note 7: This AD does not require the installation of new markers that is specified under the heading "Additional Work Required—Group 4 through 10 Airplanes" in the Accomplishment Instructions of Boeing Service Bulletin 767–54–0080, Revision 1, dated May 9, 2002.

Boeing Service Bulletin 767–54–0081, Revision 1, Groups 3 Through 12: Inspection and Additional Work, if Necessary

(l) For airplanes listed in Groups 3 through 12 of Boeing Service Bulletin 767–54–0081, Revision 1, dated February 7, 2002, on which the modification required by paragraph (d) of this AD has been accomplished prior to the effective date of this AD: Within 18 months after the effective date of this AD, perform an inspection of the aft pitch load fitting of the wing front spar to determine the P/N of the fitting.

(1) If the aft pitch load fitting on the left-hand side of the airplane has P/N 112T7005–57 and the aft pitch load fitting on the right-hand side of the airplane has P/N 112T7005–58: No further action is required by this paragraph.

(2) If the aft pitch load fitting on the left-hand side of the airplane has P/N 112T7005–53 or the aft pitch load fitting on the right-hand side of the airplane has P/N 112T7005–54: Within 18 months after the effective date of this AD, rework the affected aft pitch load fitting and install the diagonal brace with a new fuse pin, in accordance with Steps CB. and CC. under the heading "Additional Work Required—Group 3 through 12 Airplanes" in the Accomplishment Instructions of the service bulletin.

Note 8: This AD does not require the installation of new markers that is specified under the heading "Additional Work Required—Group 3 through 12 Airplanes" in the Accomplishment Instructions of Boeing Service Bulletin 767–54–0081, Revision 1, dated February 7, 2002.

L/Ns 1—101 Inclusive: Replacement of Outboard Pitch Load Fitting

(m) For Model 767–200 series airplanes having L/Ns 1 through 101 inclusive: At the applicable time specified in paragraph (m)(1) or (m)(2) of this AD, replace the outboard pitch load fitting of the wing front spar, on the left- and right-hand sides of the airplane, with a new, improved fitting, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–57A0070, Revision 1, dated November 16, 2000; Revision 2, dated August 2, 2001; or Revision 3, dated November 8, 2001. Accomplishment of this replacement constitutes terminating action for the repetitive inspections required by paragraph (g) of this AD.

(1) For airplanes on which the modification required by paragraph (a) or (d) of this AD, as applicable, has not been accomplished before the effective date of this AD: Do the replacement prior to or concurrently with the accomplishment of the modification of the nacelle strut and wing structure required by paragraph (a) of this AD, as specified in paragraph 1.D., Table 2, of Boeing Service Bulletin 767–54–0080, Revision 1, dated May 9, 2002.

(2) For airplanes on which the modification required by paragraph (a) or (d) of this AD, as applicable, has been accomplished before the effective date of this AD: Do the replacement within 48 months after the effective date of this AD.

Alternative Methods of Compliance

(n)(1) In accordance with 14 CFR 39.19, the Manager, Seattle ACO, is authorized to approve alternative methods of compliance (AMOCs) for this AD.

(2) An AMOC that provides an acceptable level of safety may be used for a repair required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings.

(3) AMOCs approved previously per AD 2001–02–07, amendment 39–12091, are approved as alternative methods of compliance with the applicable actions in paragraphs (a), (b), and (c) of this AD.

(4) AMOCs approved previously per AD 2001–06–12, amendment 39–12159, are approved as alternative methods of compliance with the applicable actions in paragraphs (d), (e), and (f) of this AD.

(5) AMOCs approved previously in accordance with AD 2000–12–17, amendment 39–11795; AD 2000–07–05, amendment 39–11659; AD 2001–02–07, amendment 39–12091; and AD 94–11–02, amendment 39–8918; are approved as alternative methods of compliance with the applicable actions in paragraph (e) of this AD.

(6) AMOCs approved previously per AD 2001–08–23, amendment 39–12200, are approved as alternative methods of compliance with the applicable actions in paragraphs (g), (h), and (i) of this AD.

Issued in Renton, Washington, on February 2, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2959 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 30, 31, 33, 35 and 40

[Docket ID No. OA–2002–0001; FRL–7620–7]

RIN 2020–AA39

Public Hearings on Participation by Disadvantaged Business Enterprises in Procurement Under Environmental Protection Agency (EPA) Financial Assistance Agreements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; comment period reopening; public hearing.

SUMMARY: EPA published its proposed rule for Participation by Disadvantaged Business Enterprises in Procurement under Environmental Protection Agency (EPA) Financial Assistance Agreements on July 24, 2003 at 68 FR 43824. In response to requests to increase the

proposed rule comment period, EPA finds it appropriate to extend the comment period an additional 45 days beyond the January 20, 2004 date previously in effect. All interested parties are notified that the comment period of this public notice is hereby reopened until March 4, 2004.

This document also announces the date and location of a Tribal hearing wherein EPA will take comments on its proposed rule for "Participation by Disadvantaged Business Enterprises in Procurement under Environmental Protection Agency (EPA) Financial Assistance Agreements."

DATES: Comments are reopened until March 4, 2004. The Tribal hearing will be held on February 10, 2004, 3:30 pm to 4:45 pm.

ADDRESSES: Comments must be submitted to:

1. *Electronically*—EPA Dockets at *http://www.epa.gov/edoctket*. Please follow online instructions for submitting comments and reference Docket ID No. OA–2002–0001;
2. *By Mail*—Office of Environmental Information Docket, Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OA–2002–0001; or
3. *By Hand Delivery or Courier*—EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OA–2002–0001.

The Tribal hearing will be held at: Anchorage Egan Convention Center, 555 West Fifth Avenue, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Kimberly Patrick, Attorney Advisor, at (202) 564–5386, or David Sutton, Deputy Director at (202) 564–4444, Office of Small and Disadvantaged Business Utilization, U.S. Environmental Protection Agency, Mail Code 1230A, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: EPA published its proposed rule for Participation by Disadvantaged Business Enterprises in Procurement under Environmental Protection Agency (EPA) Financial Assistance Agreements on July 24, 2003 at 68 FR 43824. EPA has established an official public docket for this action under Docket ID No. OA–2002–0001. The proposed rule and supporting materials are available for public viewing at the Office of Environmental Information 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 Office of Environmental Information is (202) 566–1752. An electronic version of public docket is available through EPA's electronic public docket and comment systems, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," and then key in docket identification number OA–2002–0001. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr.*

Dated: February 5, 2004.

Thomas J. Gibson,

Chief of Staff.

[FR Doc. 04–2957 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 268

[RCRA–2003–0025; FRL–7620–3]

Land Disposal Restrictions: Site-Specific Treatment Variances for Heritage Environmental Services LLC and Chemical Waste Management Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is today proposing to grant three site-specific treatment variances from the Land Disposal Restrictions (LDR) treatment standards for selenium-bearing hazardous wastes from the glass manufacturing industry. EPA is proposing to grant these variances because the chemical properties of the wastes differ significantly from those of the waste used to establish the current LDR standard for selenium (5.7 mg/L, as measured by the Toxicity Characteristic Leaching Procedure (TCLP)), and the petitions have adequately demonstrated that the wastes cannot be treated to meet this treatment standard.

In the "Rules and Regulations" section of the **Federal Register**, we are publishing a direct final rule that would grant these site-specific treatment variances without prior proposal because we view these actions as noncontroversial and we anticipate no significant adverse comment. We have explained our reasons for this approach in the preamble to the direct final rule. If we receive significant adverse comment on a distinct amendment, however, we will withdraw the direct final action for that amendment and the amendment will not take effect. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting on these proposed variances must do so at this time.

DATES: Written comments must be received by March 12, 2004.

ADDRESSES: Comments may be submitted by mail to: OSWER Docket, Environmental Protection Agency, Mailcode: 5305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. RCRA–2003–0025. Comments may also be submitted electronically, or through hand delivery/courier. Follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703 412–9810 or TDD 703 412–3323. For more detailed information on specific aspects of this rulemaking, contact Juan Parra at (703) 308–0478 , send your e-mail to *parra.juan@epa.gov*, or mail your inquiry to Office of Solid Waste (MC 5302 W), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. General Information

This document is proposing to grant three site-specific treatment variances from the Land Disposal Restrictions (LDR) treatment standards for selenium-bearing hazardous wastes from the glass manufacturing industry. These selenium wastes will be treated by Heritage Environmental Services LLC and Chemical Waste Management Inc. We have explained our reasons for these actions in the preamble to the direct final rule, and do not believe it necessary to repeat those discussions here. For further information, please see the direct final action that is located in the "Rules and Regulations" section of this **Federal Register** publication.

A. How Can I Get Copies of This Variance Proposal?

1. Docket. EPA has established an official public docket for this action under Docket ID No. RCRA–2003–0025. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the OSWER 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 Public Reading Room is (202) 566–1744, and the telephone number for the OSWER Docket is (202) 566–0272. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/* and you can make comments on this proposed rule at the Federal e-rulemaking portal, *http://www.regulations.gov.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Section I.A.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.C. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. Once in the system, select "search," and then key in Docket ID No. RCRA–2003–0025. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to *rcra-docket@epa.gov,* Attention Docket ID No. RCRA–2003–0025. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.A.1. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: OSWER Docket, Environmental Protection Agency, Mailcode: 5305T, 1200 Pennsylvania Ave., NW.,

Washington, DC, 20460, Attention Docket ID No. RCRA–2003–0025.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center Reading Room, EPA West, Room B102, 1301 Constitution Ave NW., Washington, DC., Attention Docket ID No. RCRA–2003–0025. Such deliveries are only accepted during the Docket's normal hours of operation as identified in Section I.A.1.

C. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

II. Description of Proposed Amendments

The United States Environmental Protection Agency (EPA or Agency) is today proposing to grant three site-specific treatment variances from the Land Disposal Restrictions (LDR) treatment standards for selenium-bearing hazardous wastes from the glass manufacturing industry.

In its first action, EPA is proposing to grant a variance to Heritage Environmental Services LLC (Heritage) to stabilize a selenium-bearing waste generated by Guardian Industries Corp. (Guardian) at their RCRA permitted facility in Indianapolis, Indiana. If this proposal is finalized, Heritage may treat the specific waste to an alternate selenium treatment standard of 39.4 mg/L, as measured by the TCLP, for the Guardian waste. Heritage may dispose of the treated wastes in a RCRA Subtitle C landfill, provided they meet the applicable LDR treatment standards for the other hazardous constituents in the waste.

In its second and third actions, EPA is proposing to permanently establish two site-specific variances from Land Disposal Restrictions treatment standards for Chemical Waste Management Inc. (CWM), at their Kettleman Hills facility in Kettleman City, California, for two selenium bearing hazardous wastes. EPA previously granted variances to these wastes on a temporary basis on May 26, 1999 (64 FR 28387). On May 28, 2002 (67 FR 36849), EPA renewed these variances for a consecutive three year term with the same condition to investigate treatment technologies and to report effectiveness of their ongoing treatment. These variances expire on May 28, 2005. In light of the information presented by CWM to the Agency and EPA's inability to find selenium recovery capability in the US, EPA is proposing to change the status of CWM variances from temporary to permanent. If this proposal is finalized, CWM will continue to be required to treat these two specific wastes to alternative selenium treatment standards of 51 mg/L, as measured by the TCLP, for the Owens-Brockway waste, and 25 mg/L, as measured by the TCLP, for the St. Gobain (formally Ball Foster) waste. CWM will continue to dispose of the treated wastes in a RCRA Subtitle C landfill provided they meet the applicable LDR treatment standards for the other hazardous constituents in the wastes.

List of Subjects in 40 CFR Part 268

Environmental Protection, Hazardous waste, Variance.

Dated: February 4, 2004.

Marianne Lamont Horinko,

Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 04–2820 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 20, 25, 64 and 68

[CC Docket No. 94–102, IB Docket No. 99–67; FCC 03–290]

Scope of Enhanced 911 Requirements

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Commission seeks comment on issues pertaining to expanding the scope of its enhanced 911 (E911) rules to cover mobile satellite service providers that have an ancillary terrestrial component. The Commission also seeks comment on recordkeeping and reporting proposals in connection with mobile satellite service providers' implementation of 911 emergency call centers. Further, the Commission considers whether multi-line telephone systems (MLTS) should be required to provide access to enhanced 911 service and questions whether the Commission should adopt revisions to its rules. As many citizens, elected representatives, and public safety personnel recognize, 911 service is critical to our Nation's ability to respond to a host of crises and this document enhances the Nation's ability to do so.

DATES: Comments must be filed on or before March 29, 2004. Reply comments are due April 26, 2004. To file formally in this proceeding, interested parties must file an original plus six copies of all comments, reply comments, and supporting comments. If parties filing comments want each Commissioner to receive a personal copy of the comments, the parties must file an original plus eleven copies. Written comments on the proposed information collection(s) must be submitted by the public, Office of Management and Budget (OMB), and other interested parties on or before April 12, 2004.

ADDRESSES: All comments should be addressed to the Office of the Secretary, Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any Paperwork Reduction Act (PRA) comments on the information collection(s) contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov*, and to Kristy L. LaLonde, OMB Desk Officer, Room 10234 NEOB, 725 17th Street, NW., Washington, DC 20503 via the Internet to *Kristy_L._LaLonde@omb.eop.gov* or by fax to 202–395–5167.

FOR FURTHER INFORMATION CONTACT: Arthur Lechtman, Satellite Division, International Bureau, at (202) 418–1465, or Marcy Greene, Competition Policy Division, Wireline Competition Bureau, at (202) 418–2410. For additional information concerning the information collection(s) contained in this document, contact Judith B. Herman at

202–418–0214, or via the Internet at Judith-B.Herman@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the *Second Further Notice of Proposed Rulemaking*, adopted on November 13, 2003, and released on December 1, 2003 in connection with the *Report and Order* adopted in the same proceeding (and published separately in the **Federal Register**). The full text of the *Second Further Notice of Proposed Rulemaking* 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. This document 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*. This NPRM contains proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public and other Federal agencies are invited to comment on the proposed information collections contained in this proceeding.

Paperwork Reduction Act of 1995 Analysis

Initial Paperwork Reduction Act of 1995 Analysis

This NPRM contained proposed new information collection(s). The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection(s) contained in this NPRM, as required by the Paperwork Reduction Act (PRA) of 1995, Public Law No. 104–13. Public and agency comments are due April 12, 2004. PRA comments should address: (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 estimates; (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.

OMB Control Number: 3060–XXXX.

Title: Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems; Amendment of parts 2 and 25 to Implement the Global Mobile Personal Communications by Satellite (GMPCS), Memorandum of Understanding.

Form No.: N/A.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents: 25 respondents; 75 responses.

Estimated Time Per Response: 1–2 hours.

Frequency of Response: On occasion, annual and other reporting requirements, recordkeeping requirement, and third party disclosure requirement.

Total Annual Burden: 75 hours.

Total Annual Costs: $8,000.

Needs and Uses: The Commission proposes that Mobile Satellite Service (MSS) carriers subject to the call center requirement should prepare and submit a report on their plans for implementing call centers no later than three months prior to the call center's effective date (*i.e.*, 12 months after **Federal Register** publication of the E911 Scope proceeding.) These advance reports would assist FCC efforts to monitor call center development and provide the public with valuable information about MSS emergency services.

I. Overview

1. In this Second Further Notice of Proposed Rulemaking, the Commission addresses the obligation of mobile satellite services (MSS) and multi-line telephone systems (MLTS) to provide enhanced 911 capabilities. Its analysis includes a discussion of (a) 911 obligations for MSS providers that have an ancillary terrestrial component to their service and (b) recordkeeping and reporting proposals in connection with implementation of MSS emergency call centers (*see Report and Order*, FCC 03–290, rel. December 1, 2003). It also seeks comment on the Commission's role in requiring multi-line telephone systems to deliver call-back and location information, and seeks comment on the value of a national approach where states have failed to act.

A. Integration of Ancillary Terrestrial Component

2. *Discussion.* The Commission believes for those calls that utilize only the ancillary terrestrial component (ATC) of an MSS system, the carrier should provide access to the same 911 services as terrestrial CMRS providers. Including 911 features in the design stage of ATC systems will prevent potentially costly and complicated retrofitting at a later date. The Commission seeks additional comment, however, concerning whether transition periods for compliance are warranted, and if so what an appropriate schedule would be. The Commission also seeks comment whether MSS carriers with integrated ATC will be able to comply with the location accuracy standards (for both network-based and handset-based solutions) of § 20.18, and if they cannot, why. The Commission directs the rechartered Network Reliability and Interoperability Council (NRIC) to study whether hand-off of calls between terrestrial and satellite network components will be a factor and if so what the impact will be on 911 service.

B. MSS Carriers' Reporting and Recordkeeping Requirements

3. *Background and Discussion.* The call center rule requires MSS carriers to deploy call centers 12 months after publication of the *Report and Order* (FCC 03–290, released December 1, 2003). The Commission seeks comment whether MSS carriers subject to the call center requirement should prepare and submit a report on their plans for implementing call centers no later than three (3) months prior to the call center rule's effective date. The report would have to include basic information concerning the carrier's call center plans, including staffing and site considerations and the public safety answering point (PSAP) database to be used. The Commission expects that the reports would assist its efforts to monitor call center development and then take any necessary actions to ensure that the implementation deadline is met. The reports would also provide the public with valuable information about MSS emergency services.

4. The Commission also seeks comment on recordkeeping and reporting requirements post-call center deployment. The Commission is interested in collecting data on MSS call center use, including the volume of calls that the call centers receive. The Commission would find other call data useful as well, such as the number of calls that required forwarding to a local PSAP and the success rate in handing off calls to the proper PSAP. The Commission seeks comment on whether MSS carriers should record and store this information themselves, subject to inspection by the Commission at any time, or whether MSS carriers should file the information in the form of a report once a year with the Commission or another entity. Collection of call data would allow the Commission to monitor compliance with the call center

requirement and track usage trends. The Commission also seeks comment on sunset provisions for any recordkeeping or reporting requirements, and requests information about appropriate sunset timeframes.

C. Multi-Line Telephone Systems

5. Through this Notice, the Commission seeks further comment on its role in requiring multi-line systems to deliver call-back and location information, and specifically seeks comment on the value of a national approach where states have failed to act. While the Commission continues to study the need for federal action, it expects states to work quickly to adopt legislation to reduce any gaps in this area. The Commission notes that if state action proves uniformly effective, further action by the Commission may not be necessary.

6. As an initial matter, the Commission seeks to refresh the record on the prevalence of MLTS and on the status of E911 implementation for those systems. The Commission seeks comment on the number of lines that are served by multi-line systems, and the full range of operators who manage them. The Commission encourages commenters to provide as comprehensive a picture as possible of the status of MLTS deployment, but to also note particular variations by location or type of user. The Commission seeks comment on how the growth of Internet-protocol telephony will affect the manufacture and deployment of new MLTS equipment and its use for 911/E911 calls. Does this development affect the policy question of whether MLTS E911 standards should be uniform nationally, or instead can be set on state by state basis? With regard to MLTS manufacturers, the Commission seeks comment as to whether E911 features represent an opportunity for manufacturers to improve the value of their equipment. If so, is the value added by these improvements worth the increased costs to their customers? If the status of MLTS E911 implementation has changed over time, the Commission seeks comment on the application of the four criteria discussed in the *Report and Order*.

7. The Commission also seeks updated comment on its authority to require compliance with E911 rules it may adopt, on all of the affected parties: carriers, manufacturers, PSAPs, and MLTS operators. In particular, the Commission asks commenters to focus on the nature of the Commission's jurisdiction over MLTS operators, in light of the Commission's earlier interpretations of section 4(i) authority and its prior statement that "the reliability of 911 service is integrally related to our responsibilities under section 1 of the Act, which include 'promoting safety of life and property through the use of wire and radio communication.'" To the extent that parties ask the Commission to adopt rules in this area, the Commission also seeks comment on whether any such rules would have a disproportionate impact on small entities. The Commission also seeks comment generally on steps that it can take to ensure that small entities are not disproportionately impacted, if any such steps are necessary.

8. Finally, the Commission seeks comment on NENA's proposed new section to our part 64 rules requiring that LEC central offices be provisioned to permit connection of MLTS equipment for E911 purposes "in any accepted industry standard format, as defined by the FCC, requested by the MLTS operator." In connection with this recommendation, the Commission seeks comment on NEC's recommendation that the Commission adopt the ANSI T1.628–2000 ISDN network interface standard as an "accepted industry standard," thereby requiring LECs to enable MLTS operators to use a more efficient means of interfacing with the network than is currently available in most instances.

II. Initial Regulatory Flexibility Analysis

9. As required by the Regulatory Flexibility Act, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *Second Further Notice* of Proposed Rulemaking (*Second Further Notice*), IB Docket No. 99–67 and CC Docket No. 94–102. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the *Second Further Notice*. The Commission will send a copy of the *Second Further Notice*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. *See* 5 U.S.C. 603(a). In addition, the *Second Further Notice* and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

10. The *Second Further Notice* continues a reevaluation of the scope of communications services that should provide access to emergency services that was initiated with the *Further Notice of Proposed Rulemaking*, CC Docket No. 94–102 and IB Docket No. 99–67. The *Second Further Notice* examines and seeks comment on the need to require compliance with the Commission's basic and enhanced 911 (E911) rules, or similar requirements, by mobile satellite service (MSS) providers, including MSS providers having an ancillary terrestrial component (ATC). The *Second Further Notice* also seeks comment on a proposal to require mobile satellite service (MSS) providers to comply with reporting and recordkeeping requirements in connection with emergency call center implementation. Further, the *Second Further Notice* considers whether multi-line telephone systems (MLTS) should be required to provide access to enhanced 911 (E911) service and questions whether the Commission should adopt revisions to its part 64 rules.

B. Legal Basis for Proposed Rules

11. The proposed action is authorized under Sections 1, 4(i), 7, 10, 201, 202, 208, 214, 222(d)(4)(A)–(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)–(5), 251(e)(3), 301, 303, 308, 309(j), and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 208, 214, 222(d)(4)(A)–(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)-(5), 251(e)(3), 301, 303, 308, 309(j), 310.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

12. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the adopted rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act. Under the Small Business Act, a "small business concern" is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). A small organization is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."

13. We have included small incumbent local exchange carriers in

this present RFA analysis. As noted above, a "small business" under the RFA is one that, *inter alia*, meets the pertinent small business size standard (*e.g.*, a telephone communications business, having 1,500 or fewer employees), and "is not dominant in its field of operation." The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not "national" in scope.

14. *Incumbent Local Exchange Carriers.* Neither the Commission nor the SBA has developed a specific small business size standard for providers of incumbent local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 1,337 incumbent local exchange carriers reported that they were engaged in the provision of local exchange services. Of these 1,337 carriers, an estimated 1,032 have 1,500 or fewer employees and 305 have more than 1,500 employees. Consequently, we estimate that the majority of providers of local exchange service are small entities that may be affected by the rules and policies adopted herein.

15. *Competitive Local Exchange Carriers.* Neither the Commission nor the SBA has developed a specific small business size standard for providers of competitive local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 609 companies reported that they were engaged in the provision of either competitive access provider services or competitive local exchange carrier services. Of these 609 companies, an estimated 458 have 1,500 or fewer employees and 151 have more than 1,500 employees. Consequently, the Commission estimates that the majority of providers of competitive local exchange service are small entities that may be affected by the rules.

16. *Competitive Access Providers.* Neither the Commission nor the SBA has developed a specific size standard for competitive access providers (CAPS). The closest applicable standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 609 CAPs or competitive local exchange carriers and 35 other local exchange carriers reported that they were engaged in the provision of either competitive access provider services or competitive local exchange carrier services. Of these 609 competitive access providers and competitive local exchange carriers, an estimated 458 have 1,500 or fewer employees and 151 have more than 1,500 employees. Of the 35 other local exchange carriers, an estimated 34 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that the majority of small entity CAPS and the majority of other local exchange carriers may be affected by the rules.

17. *Local Resellers.* The SBA has developed a specific size standard for small businesses within the category of Telecommunications Resellers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 133 companies reported that they were engaged in the provision of local resale services. Of these 133 companies, an estimated 127 have 1,500 or fewer employees and 6 have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers may be affected by the rules.

18. *Toll Resellers.* The SBA has developed a specific size standard for small businesses within the category of Telecommunications Resellers. Under that SBA definition, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 625 companies reported that they were engaged in the provision of toll resale services. Of these 625 companies, an estimated 590 have 1,500 or fewer employees and 35 have more than 1,500 employees. Consequently, the Commission estimates that a majority of toll resellers may be affected by the rules.

19. *Interexchange Carriers.* Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to providers of interexchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 261 carriers reported that their primary telecommunications service activity was the provision of interexchange services. Of these 261 carriers, an estimated 223 have 1,500 or fewer employees and 38 have more than 1,500 employees. Consequently, we estimate that a majority of interexchange carriers may be affected by the rules.

20. *Operator Service Providers.* Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to operator service providers. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 23 companies reported that they were engaged in the provision of operator services. Of these 23 companies, an estimated 22 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that a majority of local resellers may be affected by the rules.

21. *Prepaid Calling Card Providers.* The SBA has developed a size standard for small businesses within the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 37 companies reported that they were engaged in the provision of prepaid calling cards. Of these 37 companies, an estimated 36 have 1,500 or fewer employees and one has more than 1,500 employees. Consequently, the Commission estimates that a majority of prepaid calling providers may be affected by the rules.

22. *Mobile Satellite Service Carriers.* Neither the Commission nor the U.S. Small Business Administration has developed a small business size standard specifically for mobile satellite service licensees. The appropriate size standard is therefore the SBA standard for Satellite Telecommunications, which provides that such entities are small if they have $12.5 million or less in annual revenues. Currently, nearly a dozen entities are authorized to provide voice MSS in the United States. We have ascertained from published data that four of those companies are not small entities according to the SBA's definition, but we do not have sufficient information to determine which, if any, of the others are small entities. We anticipate issuing several licenses for 2 GHz mobile earth stations that would be subject to the requirements we are adopting here. We do not know how many of those licenses will be held by small entities, however, as we do not yet know exactly how many 2 GHz mobile-earth-station licenses will be issued or who will receive them. The Commission notes that small businesses are not

likely to have the financial ability to become MSS system operators because of high implementation costs, including construction of satellite space stations and rocket launch, associated with satellite systems and services. Still, we request comment on the number and identity of small entities that would be significantly impacted by the proposed rule changes.

23. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a specific size standard for small entities specifically applicable to "Other Toll Carriers." This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under that standard, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 92 carriers reported that they were engaged in the provision of "Other Toll Services." Of these 92 carriers, an estimated 82 have 1,500 or fewer employees and ten have more than 1,500 employees. Consequently, the Commission estimates that a majority of "Other Toll Carriers" may be affected by the rules.

24. *Wireless Service Providers.* The SBA has developed a size standard for small businesses within the two separate categories of Cellular and Other Wireless Telecommunications and Paging. Under these standards, such a business is small if it has 1,500 or fewer employees. According to the FCC's *Telephone Trends Report* data, 1,387 companies reported that they were engaged in the provision of wireless service. Of these 1,387 companies, an estimated 945 have 1,500 or fewer employees and 442 have more than 1,500 employees. Consequently, we estimate that a majority of wireless service providers may be affected by the rules.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

25. The reporting, recordkeeping, or other compliance requirements ultimately adopted will depend on the rules adopted and the services subject to those rules. First, any and all of the affected entities who the Commission finds appropriate to provide 911 and E911 services (*See* Legal Authority, for example, in paragraphs 12–17 of the *Report and Order*) would need to comply with the Commission's basic or enhanced 911 rules. This would involve a schedule for implementing 911 and E911 service, and possibly regulations mandating the provision of automatic number identification (ANI), possible software modification to assist in recognition of single or multiple emergency numbers, and provision of automatic location information (ALI) and interference precautions, as well as regulations, specific to individual services. Additionally, paragraphs 111–112 of the *Second Further Notice* seek comment on proposals that all Mobile Satellite Service (MSS) licensees subject to the emergency call center requirement both (a) submit implementation progress reports prior to the effective date of the call center requirement and (b) record data on call center operations for possible reporting purposes.

26. The *Second Further Notice*, in paragraphs 113–117, examines whether to require multi-line telephone systems, including wireline, wireless, and Internet protocol-based systems, to deliver call-back and location information. Possible requirements that the *Second Further Notice* suggests if the Commission decides that multi-line telephone systems should provide these services include technical standards as discussed in paragraph 117. Paragraphs 114–116 seek comment on the scope of deployment of MLTS and on the Commission's jurisdiction over all parties involved in the provision of E911 over MLTS, including carriers, MLTS manufacturers, PSAPs, and MLTS operators.

27. Other regulations and requirements are possible for those services discussed in the *Second Further Notice* found suitable for 911 and E911 service. Such rules and requirements could be found appropriate, based on comment filed in response to the *Second Further Notice* and would be designed to meet the consumer needs and licensee situations in each service and service area.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

28. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

29. The critical nature of the 911 and E911 proceedings limit the Commission's ability to provide small carriers with a less burdensome set of E911 regulations than that placed on large entities. A delayed or less than adequate response to an E911 call can be disastrous regardless of whether a small carrier or a large carrier is involved. MSS providers have been exempt to date from the Commission's 911 and E911 regulations as the Commission sought information from which to judge the appropriateness of requiring that these services provide 911 and E911 service. The *Second Further Notice* continues this examination and reflects the Commission's concern that only those entities that can reasonably be expected to provide emergency services, financially and otherwise, be asked to provide this service. The *Second Further Notice* affords small entities another opportunity to comment on the appropriateness of the affected services providing emergency services and on what the Commission can do to minimize the regulatory burden on those entities who meet the Commission's criteria for providing such service.

30. Throughout the *Second Further Notice*, the Commission tailors its request for comment to devise a prospective regulatory plan for the affected entities, emphasizing the individual needs of the service providers, manufacturers, and operators as well as the critical public safety needs at the core of this proceeding. The Commission will consider all of the alternatives contained not only in the *Second Further Notice*, but also in the resultant comments, particularly those relating to minimizing the effect on small businesses.

31. The most obvious alternatives raised in the *Second Further Notice* are whether the services under discussion should be required to comply with the Commission's basic and enhanced 911 rules or whether the Commission should continue to exempt these entities from providing this service.

32. Along these lines, discussion of criteria and alternatives could focus on implementation schedules. In discussing the prospective entities and soliciting further information, throughout the *Second Further Notice* the Commission invites comment on the schedule for implementing 911 and E911 services which best meets the abilities, technically and financially, of the individual entities. In the past, the Commission has best been able to offer

affected small and rural entities some relief from E911 by providing small entities with longer implementation periods than larger, more financially flexible entities that are better able to buy the equipment necessary to successful 911 and E911 implementation and to first attract the attention of equipment manufacturers. We again seek comment on such possible alternatives.

33. In its discussion of MSS, the *Second Further Notice* recognizes that although satellite carriers face unique technical difficulties in implementing both basic and enhanced 911 features, these difficulties are avoided to a larger extent when the carrier has an ancillary terrestrial component (ATC) to its service. Thus, in paragraphs 107–110, the *Second Further Notice* examines the impact of ATC on MSS providers' ability to offer the same enhanced 911 service that terrestrial wireless carriers provide. Paragraph 108 of the *Second Further Notice* notes that several commenters, thus far, have indicated that MSS basic and enhanced 911 service can be improved with ATC. The *Second Further Notice* suggests alternative solutions to this problem, asking whether MSS providers with ATC should be allowed additional time (or transition periods) in order to come into compliance with terrestrial E911 rules, and whether they can meet the location identification standards of § 20.18 (47 CFR 20.18). The *Second Further Notice* also directs the Network Reliability and Interoperability Council to study issues associated with hand-off of calls between satellite and terrestrial components.

34. As mentioned, the *Second Further Notice* seeks comment on reporting and recordkeeping proposals in connection with implementation of the MSS emergency call center requirement. Call center 911 service is a new form of 911 service, and the *Second Further Notice* seeks comment on the collection of call center data, including total volume of calls received during a given period, the number of calls requiring forwarding to a PSAP, and the success rate in handing off the call to an appropriate PSAP. The *Second Further Notice* suggests alternatives for this data collection, seeking comment on whether the information should simply be retained by service providers and available upon Commission request, whether the information should be submitted to the Commission on a regular basis, or whether the information should be submitted to a third party for review. In addition, the *Second Further Notice* seeks comment on whether the proposed data collection/recordkeeping requirement should be subject to sunset provisions.

35. The *Second Further Notice*, in paragraphs 113–117, examines potential 911 and E911 requirements for multi-line telephone systems. In that regard, the Commission considers whether to impose such regulations on a national basis or whether it is sufficient to rely on actions by state and local authorities to ensure reliable coverage. NENA and APCO, for example, have proposed Model Legislation that would allow states, through legislation, to adopt many of the standards and protocol association with delivering E911 services through multi-line systems. Paragraph 117 considers adopting NENA's proposed new section to our part 64 rules requiring that LEC central offices be provisioned to permit connection of MLTS equipment for E911 purposes in any accepted industry standard format, as defined by the Commission, requested by the MLTS operator. In connection with this recommendation, the *Second Further Notice* seeks comment on NEC's recommendation that the Commission adopt the ANSI T1.628–2000 ISDN network interface standard as an "accepted industry standard," thereby requiring LECs to enable MLTS operators to use a more efficient means of interfacing with the network than is currently available in most instances. Additionally, the *Second Further Notice* asked parties to comment on whether any rules that the Commission adopts may have a disproportionate impact on small entities and requested comment how it might ameliorate any such impacts.

F. Federal Rules That Overlap, Duplicate, or Conflict With the Proposed Rules

36. None.

III. Ordering Clauses

37. Pursuant to sections 1, 4(i), 7, 10, 201, 202, 208, 214, 222(d)(4)(A)-(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)-(5), 251(e)(3), 301, 303, 308, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 208, 214, 222(d)(4)(A)–(C), 222(f), 222(g), 222(h)(1)(A), 222(h)(4)–(5), 251(e)(3), 301, 303, 308, 310, this *Report and Order* is hereby *adopted*.

38. The Commission's Office of Consumer and Government Affairs, Reference Information Center, *shall send* a copy of this *Report and Order and Second Further Notice of Proposed Rulemaking*, including the Final Regulatory Flexibility Analysis and the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Parts 20, 25, 64, and 68

Communications common carriers, satellite communications.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–2125 Filed 2–10–04; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI44

Endangered and Threatened Wildlife and Plants; Listing the Southwest Alaska Distinct Population Segment of the Northern Sea Otter (*Enhydra lutris kenyoni*) as Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the Fish and Wildlife Service (Service), propose to list the southwest Alaska distinct population segment of the northern sea otter (*Enhydra lutris kenyoni*) as threatened under the authority of the Endangered Species Act of 1973, as amended (Act). Once containing more than half of the world's sea otters, this population segment has undergone a precipitous population decline of at least 56–68 percent since the mid-1980s.

DATES: We will consider comments on this proposed rule received until the close of business on June 10, 2004. Requests for public hearings must be received by us on or before April 12, 2004.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments to the Supervisor, U.S. Fish and Wildlife Service, Marine Mammals Management Office, 1011 East Tudor Road, Anchorage, Alaska 99503.

2. You may hand deliver written comments to our office at the address given above.

3. You may send comments by electronic mail (e-mail) to: *fw7_swakseaotter@fws.gov. See* the Public Comments Solicited section below for file format and other information about electronic filing.

FOR FURTHER INFORMATION CONTACT: Douglas Burn, (*see* **ADDRESSES**) (telephone 907/786–3800; facsimile 907/786–3816).

SUPPLEMENTARY INFORMATION:

Background

The sea otter (*Enhydra lutris*) is a mammal in the family Mustelidae and it is the only species in the genus *Enhydra*. There are three recognized subspecies (Wilson *et al.* 1991): *E. l. lutris,* known as the northern sea otter, occurs in the Kuril Islands, Kamchatka Peninsula, and Commander Islands in Russia; *E. l. kenyoni,* also known as the northern sea otter, has a range that extends from the Aleutian Islands in southwestern Alaska to the coast of the State of Washington; and *E. l. nereis,* known as the southern sea otter, occurs in coastal southern California and is known as the southern sea otter. Figure 1 illustrates the approximate ranges of the three subspecies.

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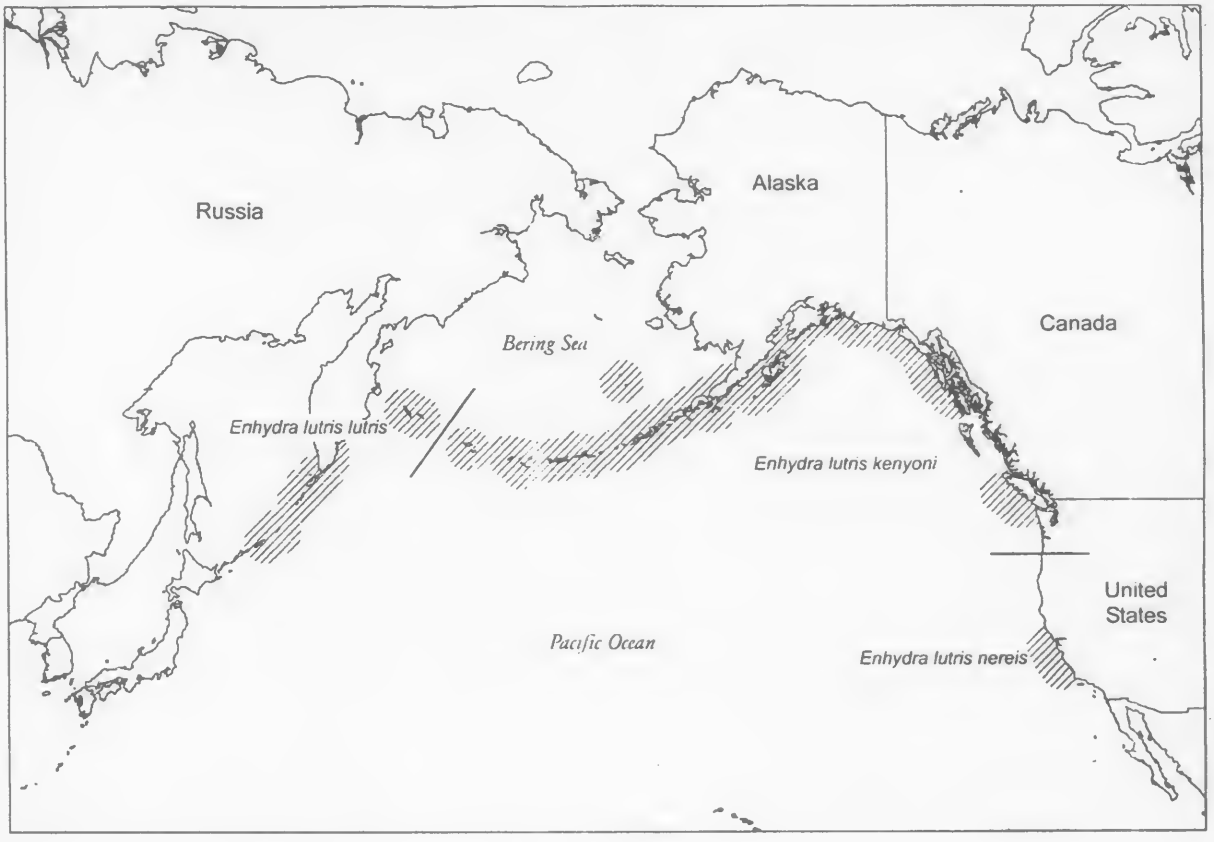

Figure 1. Present distribution of three supspecies of sea otters (hatched areas).

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The two subspecies of northern sea otter are separated by an expanse of open water that measures approximately 320 kilometers (km) (200 miles (mi)) between the Commander Islands in Russia, at the northeastern edge of the range of *E. l. lutris*, and the Near Islands of the United States, which are the northwestern edge of the range of *E. l. kenyoni*. Wide, deep-water passes are an effective barrier to sea otter movements (Kenyon 1969) and thus interaction between these two subspecies is considered very unlikely. (*See* later sections on food habits and animal movements.)

The southernmost extent of the range of *E. l. kenyoni* is in Washington state and British Columbia, and is the result of translocations of sea otters from Alaska between 1969 and 1972 (Jameson *et al.* 1982). The Washington and British Columbia population is separated from the nearest sea otters in Alaska by a distance roughly of 483 km (300 mi) to the north, and is separated from the southern sea otter (*E. l. nereis*) by a distance of more than 965 km (600 mi) to the south.

The sea otter is the smallest species of marine mammal in the world. Adult males average 130 centimeters (cm) (4.3 feet (ft)) in length and 30 kilograms (kg) (66 pounds (lbs)) in weight; adult females average 120 cm (3.9 ft) in length and 20 kg (44 lbs) in weight (Kenyon 1969). The northern sea otter in Russian waters (*E. l. lutris*) is the largest of the three subspecies, characterized as having a wide skull with short nasal bones (Wilson *et al.* 1991). The southern sea otter (*E. l. nereis*) is smaller and has a narrower skull with a long rostrum and small teeth. The northern sea otter in Alaska (*E. l. kenyoni*) is intermediate in size and has a longer mandible than either of the other two subspecies.

Sea otters lack the blubber layer found in most marine mammals and depend entirely upon their fur for insulation (Riedman and Estes 1990). Their pelage consists of a sparse outer layer of guard hairs and an underfur that is the densest mammalian fur in the world, averaging more than 100,000 hairs per square centimeter (645,000 hairs per square inch) (Kenyon 1969). As compared to pinnipeds (seals and sea lions) that have a distinct molting season, sea otters molt gradually throughout the year (Kenyon 1969).

Sea otters have a much higher rate of metabolism than land mammals of similar size (Costa 1978; Costa and Kooyman 1982, 1984). To maintain the level of heat production required to sustain them, sea otters eat large amounts of food, estimated at 23–33 percent of their body weight per day (Riedman and Estes 1990). Sea otters are carnivores that primarily eat a wide variety of benthic (living in or on the sea floor) invertebrates, including sea urchins, clams, mussels, crabs, and octopus. In some parts of Alaska, sea otters also eat epibenthic (living upon the sea floor) fishes (Estes *et al.* 1982; Estes 1990).

Much of the marine habitat of the sea otter in southwest Alaska is characterized by a rocky substrate. In these areas, sea otters typically are concentrated between the shoreline and the outer limit of the kelp canopy (Riedman and Estes 1990). Sea otters also inhabit marine environments that have soft sediment substrates, such as Bristol Bay and the Kodiak archipelago. As communities of benthic invertebrates differ between rocky and soft sediment substrate areas, so do sea otter diets. In general, prey species in rocky substrate habitats include sea urchins, octopus, and mussels, while in soft substrates, clams dominate the diet.

Sea otters are considered a keystone species, strongly influencing the composition and diversity of the nearshore marine environment they inhabit (Estes *et al.* 1978). For example, studies of subtidal communities in Alaska have demonstrated that, when sea otters are abundant, epibenthic herbivores such as sea urchins will be present at low densities whereas kelp, which are consumed by sea urchins, will flourish. Conversely, when sea otters are absent, abundant sea urchin populations create areas of low kelp abundance, known as urchin barrens (Estes and Harrold 1988).

Sea otters generally occur in shallow water areas that are near the shoreline. They primarily forage in shallow water areas less than 100 meters (m) (328 feet (ft)) in depth, and the majority of all foraging dives take place in waters less than 40 m (131 ft) in depth. As water depth is generally correlated with distance to shore, sea otters typically inhabit waters within 1–2 km (0.62–1.24 mi) of shore (Riedman and Estes 1990). One notable exception occurs along the coast of Bristol Bay, along the north side of the Alaska Peninsula, where a broad shelf of shallow water extends several miles from shore. Prior to the onset of the sea otter population decline (described below), large rafts of sea otters were commonly observed above this shelf of shallow water at distances as far as 40 km (25 mi) from shore (Schneider 1976).

Since the end of the commercial fur harvests, movement patterns of sea otters have been influenced by the processes of natural population recolonization and the translocation of sea otters into former habitat. While sea otters have been known to make long distance movements up to 350 km (217 mi) over a relatively short period of time when translocated to new or vacant habitat (Ralls *et al.* 1992), the home ranges of sea otters in established populations are relatively small. Once a population has become established and has reached a relatively steady state within the habitat, movement of individual sea otters appears to be largely dictated by social behaviors and by factors in the local environment, including gender, breeding status, age, climatic variables (*e.g.* weather, tidal state, season), and human disturbance, as described below.

Home range and movement patterns of sea otters vary depending on the gender and breeding status of the otter. In the Aleutian Islands, breeding males remain for all or part of the year within the bounds of their breeding territory, which constitutes a length of coastline anywhere from 100 m (328 ft) to approximately 1 km (0.62 mi). Sexually mature females have home ranges of approximately 8–16 km (5–10 mi), which may include one or more male territories. Male sea otters that are not part of the breeding population do not hold territories and may move greater distances between resting and foraging areas than breeding males (Lensink 1962, Kenyon 1969, Riedman and Estes 1990, Estes and Tinker 1996).

Studies of movement patterns of juvenile sea otters found that juvenile males (1–2 years of age) were found to disperse later and for greater distances, up to 120 km (75 mi), from their natal (birth) area than 1-year-old females, for which the greatest distance traveled was 38 km (23.6 mi) (Garshelis and Garshelis 1984, Monnett and Rotterman 1988, Riedman and Estes 1990). Intraspecific aggression between breeding males and juvenile sea otters may cause juvenile otters to move from their natal areas to lower quality habitat (Ralls *et al.* 1996), and survival of juvenile sea otters, though highly variable, is influenced by intraspecific aggression and dispersal (Ballachey *et al.* in litt.).

Sea otter movements are also influenced by local climatic conditions such as storm events, prevailing winds, and in some areas, tidal state. Sea otters tend to move to protected or sheltered waters (bays, inlets, or lees) during storm events or high winds. In calm weather conditions, sea otters may be encountered further from shore (Lensink 1962, Kenyon 1969). In the Commander Islands, Russia , weather, season, time of day, and human disturbance have been cited as factors that induce sea

otter movement (Barabash-Nikiforov 1947, Barabash-Nikiforov *et al.* 1968).

Due to their dependence on shallow water feeding areas, most sea otters in Alaska occur within 1–2 km (0.62–1.24 mi) from shore. Thus, most sea otters are within State-owned waters, which include the area from mean high tide to 4.8 km (3 miles) offshore, and any that go further offshore are within the U.S. Exclusive Economic Zone, which extends 370.4 km (200 nautical miles) seaward from the coast of the United States.

While sea otters typically sleep in the water, they also haul out and sleep on shore (Kenyon 1969). Female sea otters have also been observed to give birth while on shore (Barabash-Nikiforov *et al.* 1968, Jameson 1983). Although they typically haul out and remain close to the water's edge, sea otters have been observed on land at distances up to several hundred meters from the water (Riedman and Estes 1990). The majority of coastal lands within the range of the southwest Alaska population of the northern sea otter are part of our National Wildlife Refuge (NWR) system, including Alaska Maritime NWR, Izembek NWR, Alaska Peninsula/Becharof NWR, and Kodiak NWR. The National Park Service also has large parcels of coastal lands in southwest Alaska, including Katmai National Park and Aniakchak National Monument and Preserve. The vast majority of remaining coastal lands in southwest Alaska are owned by the State of Alaska and Alaska Native Corporations. Privately owned lands constitute a very minor proportion of coastal lands in southwest Alaska.

Female sea otters in Alaska live an estimated 15–20 years, while male lifespan appears to be about 10–15 years (Calkins and Schneider 1985). First-year survival of sea otter pups is generally substantially lower than that for prime age (2–10 years old) animals (Monson and DeGange 1995, Monson *et al.* 2000). Male sea otters appear to reach sexual maturity at 5–6 years of age (Schneider 1978, Garshelis 1983). The average age of sexual maturity for female sea otters is 3–4 years, but some appear to reach sexual maturity as early as 2 years of age. The presence of pups and fetuses at different stages of development throughout the year suggests that reproduction occurs at all times of the year. Some areas show evidence of one or more seasonal peaks in pupping (Rotterman and Simon-Jackson 1988).

Similar to other mustelids, sea otters can have delayed implantation of the blastocyst (developing embryo) (Sinha *et al.* 1966). As a result, pregnancy can have two phases: from fertilization to implantation, and from implantation to birth (Rotterman and Simon-Jackson 1988). The average time between copulation and birth is around 6–7 months. Female sea otters typically will not mate while accompanied by a pup (Lensink 1962; Kenyon 1969; Schneider 1978; Garshelis *et al.* 1984). Although females are physically capable of producing pups annually, the length of pup dependency may be the primary factor determining pupping interval.

Maximum productivity rates have not been measured through much of the sea otter's range in Alaska. Estes (1990) estimated a population growth rate of 17–20 percent per year for four northern sea otter populations expanding into unoccupied habitat. In areas where resources are limiting or where populations are approaching equilibrium density, slower rates of growth are expected. Equilibrium density is defined as the average density, relatively stable over time, that can be supported by the habitat (Estes 1990).

Distribution and Status

Historically, sea otters occurred throughout the coastal waters of the north Pacific Ocean, from the northern Japanese archipelago around the north Pacific rim to central Baja California, Mexico. The historic distribution of sea otters is depicted in Figure 2.

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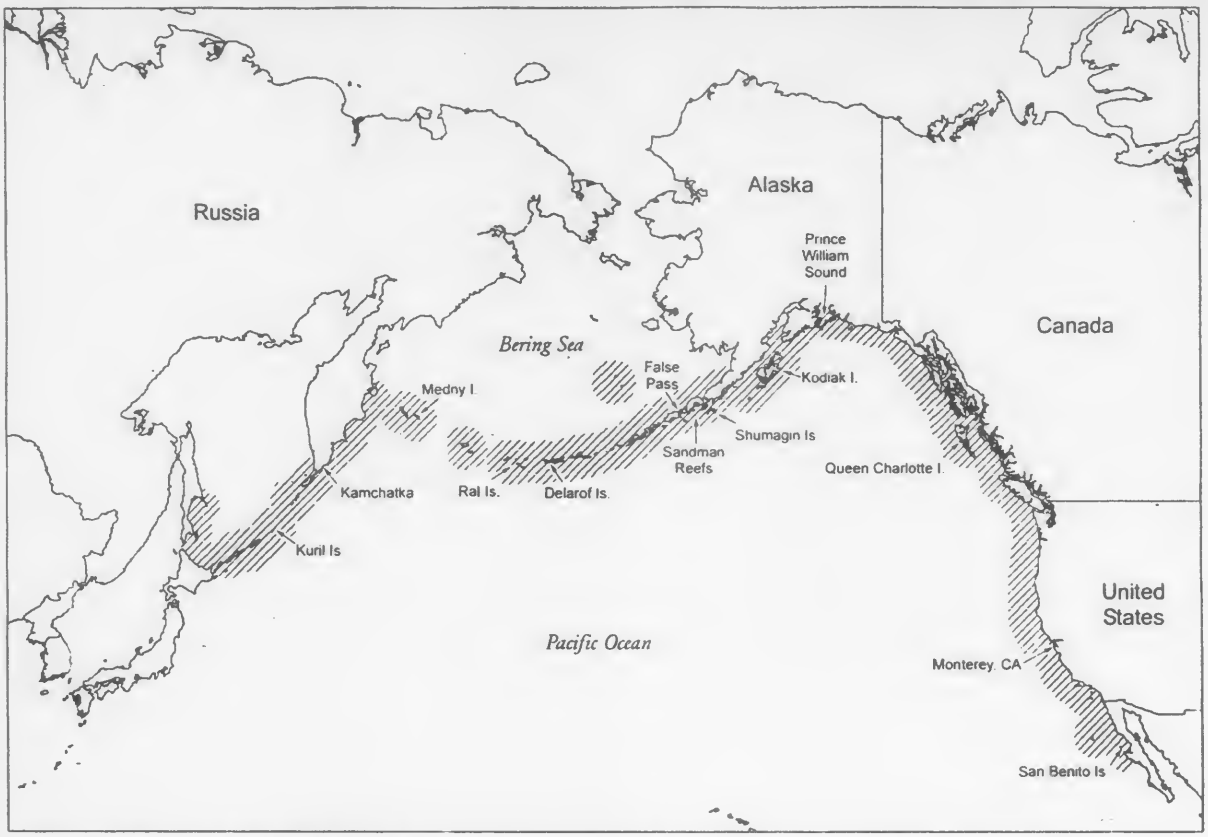

Figure 2. Worldwide distribution of sea otters prior to commercial exploitation (hatched areas) and location of remnant colonies in 1911 (arrows).

Prior to commercial exploitation, the range-wide estimate for the species was 150,000–300,000 individuals (Kenyon 1969, Johnson 1982). Commercial hunting of sea otters began shortly after the Bering/Chirikof expedition to Alaska in 1741. Over the next 170 years, sea otters were hunted to the brink of extinction first by Russian, and later by American fur hunters.

Sea otters became protected from commercial harvests under the International Fur Seal Treaty of 1911, when only 13 small remnant populations were known to still exist (Figure 2). The entire species at that time may have been reduced to only 1,000–2,000 animals. Two of the 13 remnant populations (Queen Charlotte Island and San Benito Islands) subsequently became extinct (Kenyon 1969, Estes 1980). The remaining 11 populations began to grow in number, and expanded to recolonize much of the former range. Six of the remnant populations (Rat Islands, Delarof Islands, False Pass, Sandman Reefs, Shumagin Islands, and Kodiak Island) were located within the bounds of what we now recognize as the southwest Alaska population of the northern sea otter (*see* Distinct Vertebrate Population Segment, below). These remnant populations grew rapidly during the first 50 years following protection from further commercial hunting. At several locations in the Aleutian Islands, the rapid growth of sea otter populations appears to have initially exceeded the carrying capacity of the local environment, as sea otter abundance at these islands then declined, either by starvation or emigration, eventually reaching what has been described as "relative equilibrium" (Kenyon 1969).

Population Trends of Sea Otters in Southwest Alaska

The following discussion of population trends is related to the southwest Alaska distinct population segment of sea otters addressed in this proposed rule. The southwest Alaska population ranges from Attu Island at the western end of Near Islands in the Aleutians, east to Kamishak Bay on the western side of lower Cook Inlet, and includes waters adjacent to the Aleutian Islands, the Alaska Peninsula, the Kodiak archipelago, and the Barren Islands (Figure 3).

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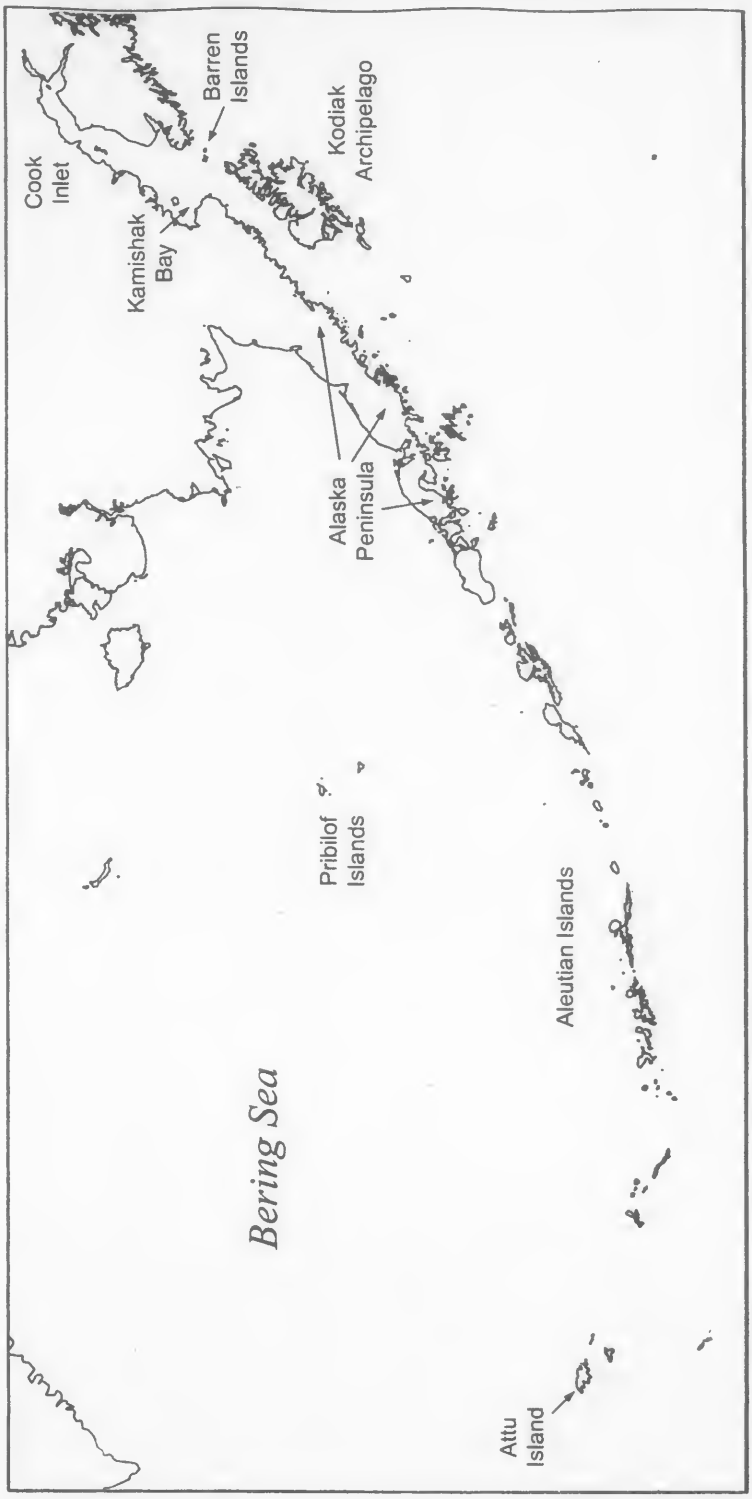

Figure 3. Range of the southwest Alaska DPS of the northern sea otter.

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Survey procedures vary in different locations. In some parts of southwest Alaska, sea otters have been counted in a narrow band of water adjacent to the shoreline; in others, transects by boat or plane have been used to sample an area, and the resulting sea otter density is extrapolated to generate a population estimate for the entire study area. Like survey efforts of most species, detection of all the individuals present is not always possible. Sea otters spend considerable time under water, and it is not possible to detect individuals that are below the surface at the time a survey is conducted. Also, observers do not always detect every individual present on the surface. Only a few surveys have been conducted using methods that allow for calculation of a correction factor to adjust for the estimated proportion of otters not detected by observers. Making such an adjustment entails having an independent estimate of the number of otters present in an area, also known as "ground-truth," and combining it with the regular survey data in order to calculate a correction factor to adjust for sea otters not detected during the survey. Thus, survey results can be of several types: They can be direct counts or estimates, and in either case they may be adjusted or unadjusted for sea otters not detected by observers.

In the following discussion of population trends, results are presented separately for surveys conducted in the Aleutian Islands, the Alaska Peninsula, the Kodiak Archipelago, and Kamishak Bay. For the Alaska Peninsula, results are presented for the separate surveys that have been conducted for north Peninsula offshore areas, south Peninsula offshore areas, south Alaska Peninsula Islands, and the South Alaska Peninsula shoreline. The general locations of the survey areas are depicted in Figure 4 A–D.

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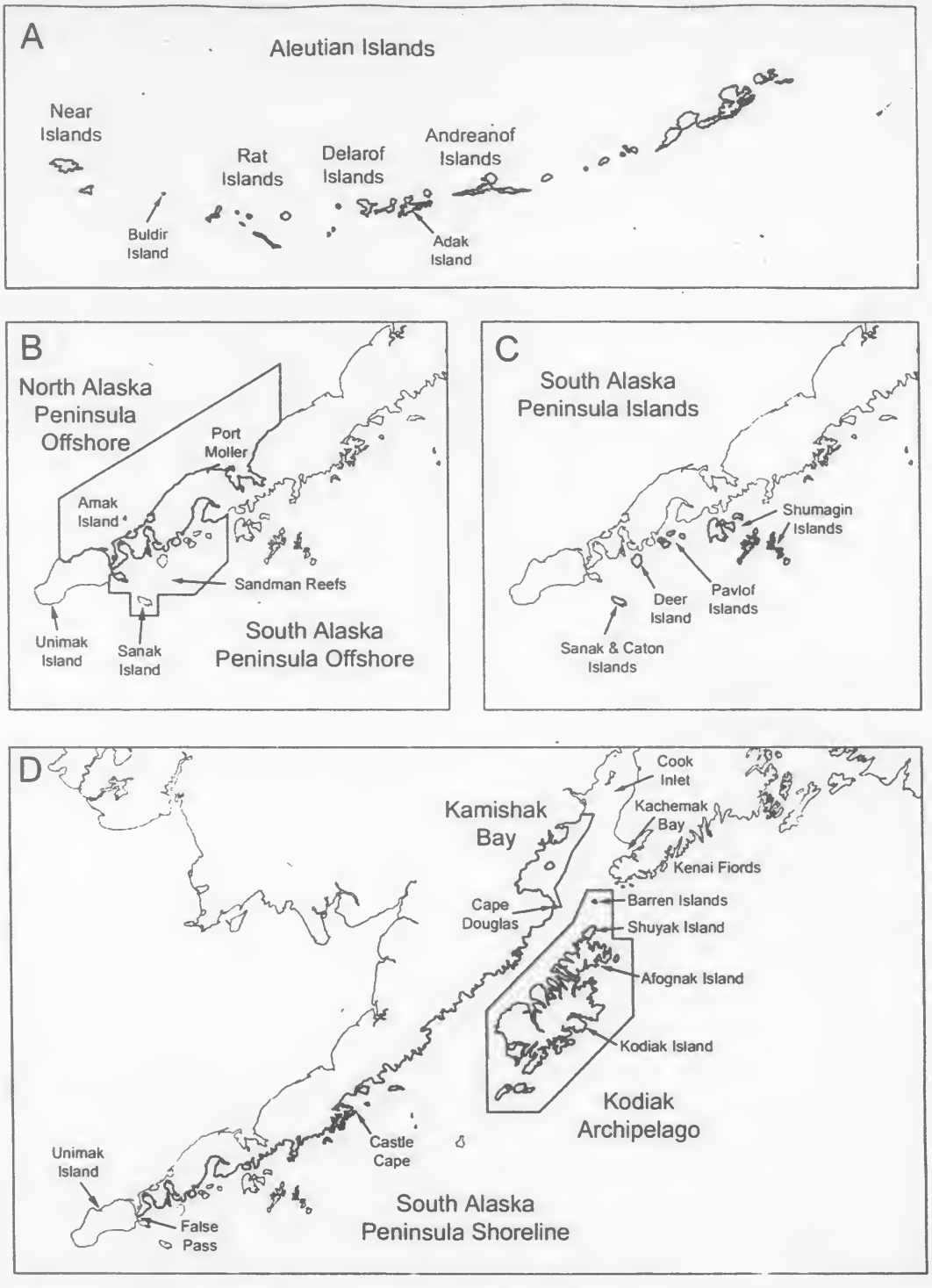

Figure 4 A-D. Sea otter survey areas in southwest Alaska.

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Unless otherwise specified, the survey results are unadjusted for otters not detected by observers. Within each study area, recent surveys were conducted using methods similar to those used in the past, so that counts or estimates would be as comparable as possible with baseline information for that area. Although there may be slight differences in the time of year that surveys were conducted, we do not believe these timing differences hinder comparisons of survey results because otters are likely to remain in the same general area, as they are not migratory. A summary of sea otter survey data from each survey area within the southwest Alaska population is presented in Table 1, followed by a narrative description of the results for each area.

TABLE 1.—SUMMARY OF SEA OTTER POPULATION SURVEYS IN SOUTHWEST ALASKA

[Estimates include 95% confidence intervals where available. Estimates for the Kodiak archipelago and Kamishak Bay are the only values adjusted for sea otters not detected.]

Survey Area	Year	Count or estimate	Source
Aleutian Islands	1965	9,700	Kenyon (1969).
	1992	8,048	Evans *et al.* (1997).
	2000	2,442	Doroff *et al.* (2003).
North Alaska Peninsula Offshore Areas	1976	11,681	Schneider (1976).
	*1986	6,474 ± 2,003 (JUN) 9,215 ± 3,709 (AUG) 7,539 ± 2,103 (OCT)	Brueggerman *et al.* (1988), Burn and Doroff in prep.
South Alaska Peninsula Offshore Areas	*1986	13,900 ± 6,456 (MAR) 14,042 ± 5,178 (JUN) 17,500 ± 5,768 (OCT)	Brueggerman *et al.* (1988). Burn and Doroff in prep.
	2001	1,005 ± 1,597 (APR)	Burn and Doroff in prep.
South Alaska Peninsula Islands	1962	2,195	Kenyon (1969).
	1986	2,122	Brueggeman *et al.* (1988).
	1989	1,589	DeGange *et al.* (1995).
	2001	405	Burn and Doroff in prep.
South Alaska Peninsula Shoreline	1989	2,632	DeGange *et al.* (1995).
	2001	2,651	Burn and Doroff in prep.
Kodiak Archipelago	1989	13,526 ± 2,350	DeGange *et al.* (1995).
	1994	9,817 ± 5,169	Doroff *et al.* (in prep.).
	2001	5,893 ± 2,630	Doroff *et al.* (in prep.).
Kamishak Bay	2002	6,918 ± 4,271	USGS in litt. (2002).

* Estimates recalculated by the Service (Burn and Doroff in prep.) from original data of Brueggeman *et al* (1988).

Aleutian Islands

The first systematic, large-scale population surveys of sea otters in the Aleutian Islands (Figure 4A) were conducted from 1957 to 1965 by Kenyon (1969). The descendants of two remnant colonies had expanded throughout the Rat, Delarof, and western Andreanof Island groups. The total unadjusted count for the entire Aleutian archipelago during the 1965 survey was 9,700 sea otters. In 1965, sea otters were believed to have reached equilibrium densities at roughly one-third of the Aleutian archipelago, ranging from Adak Island in the east to Buldir Island in the west (Estes 1990). Islands in the other two-thirds of the archipelago had few sea otters, and researchers expected additional population growth in the Aleutian to occur through range expansion.

From the mid-1960's to the mid-1980's, otters expanded their range, and presumably their numbers as well, until they had recolonized all the major island groups in the Aleutian. Although the exact size of the sea otter population at the onset of the decline is unknown, a habitat-based computer model estimates the pre-decline population in the late-1980s may have numbered approximately 74,000 individuals (Burn *et al.* 2003).

In a 1992 aerial survey of the entire Aleutian archipelago we counted a total of 8,048 otters (Evans *et al.* 1997), approximately 1,650 (19 percent) fewer than the total reported for the 1965 survey. Although sea otters had recolonized all major island groups, they had unexpectedly declined in number by roughly 50 percent in portions of the western and central Aleutian since 1965, based on a comparison of the 1965 and 1992 survey results. Sea otter surveys conducted from skiffs during the mid-1990s at several islands also indicated substantial declines in the western and central Aleutians (Estes et *al.* 1998). It was not known at the time if these observed declines were due to an actual reduction in numbers of sea otters or a redistribution of otters between Aleutian Islands.

In April 2000, we conducted another complete aerial survey of the Aleutian archipelago. We counted 2,442 sea otters, which is a 70-percent decline from the count eight years previously (Doroff *et al.* 2003). Along the more than 5,000 km (3,107 miles) of shoreline surveyed, sea otter density was at a uniformly low level. this result showed clearly that a decline in abundance of sea otters in the archipelago had occurred, as opposed to redistribution among islands.

The aerial and skiff survey data both indicate that the onset of the decline began in the latter half of the 1980s or early 1990s. Doroff *et al.* (2003) have calculated that the decline proceeded at an average rate of −17.5 percent per year in the Aleutians. Although otters had declined in all island groups within the archipelago, the greatest declines were observed in the Rat, Delarof, and Andreanof Island groups. this result was unexpected, as the remnant colonies in these island groups were the first to recover from the effects of commercial harvests, and sea otters were believed to have been at equilibrium density at most of these islands in the mid-1960s.

The current estimate of the population in the Aleutian Islands is 8,742 sea otters. This estimate is based on results of the survey conducted in April of 2000, adjusted for otters not detected.

Alaska Peninsula

Three remnant colonies (at False Pass, Sandman Reefs, and Shumagin Islands) were believed to have existed near the western end of the Alaska Peninsula

after commercial fur harvests ended in 1911 (Kenyon 1969). During surveys in the late 1950s and early 1960s, substantial numbers of sea otters were observed between Unimak Island and Amak Island (2,892 in 1965) on the north side of the Peninsula, and around Sanak Island and the Sandman reefs (1,186 in 1962), and the Shumagin Islands on the south side (1,352 in 1962) (Kenyon 1969).

As summarized in Table 1 and described below, surveys of sea otters along the Alaska Peninsula have covered four areas, with the same method being used in a given area. For the north Alaska Peninsula offshore area (Figure 4B), shoreline counts are not an appropriate survey method due to the broad, shallow shelf in Bristol Bay, a condition under which sea otters occur further from the shore than elsewhere. Consequently, the north Alaska Peninsula offshore area has been surveyed from aircraft using north-south transects extending from the shoreline out over the shelf. Using this method, Schneider (1976) calculated an unadjusted population estimate of 11,681 sea otters on the north side of the Alaska Peninsula in 1976, which he believed to have been within the carrying capacity for that area. Brueggeman *et al.* (1988) conducted replicate surveys of the same area during three time periods in 1986. We re-analyzed the original 1986 survey data to address computational errors in the survey report; our re-calculated estimates range from 6,474–9,215 sea otters for this area for the three surveys in 1986 (Burn and Doroff in prep.). In May 2000, we replicated the survey design of Brueggeman *et al.* (1988) using identical survey methods. The 2000 survey estimate of 4,728 sea otters indicates abundance on the north side of the Alaska Peninsula had fallen by 27–49 percent in comparison with the minimum and maximum point estimates of the 1986 survey (Burn and Doroff in prep.).

We believe the decline in this particular area may have been even greater than these results indicate, as the severity of sea ice in Bristol Bay makes the North Alaska Peninsula the only area where seasonal differences in the distribution of otters are likely to occur. Substantially more otters were counted in transects of the Port Moller area in the May 2000 survey than in the 1986 surveys, which occurred later in the year. Large aggregations of sea otters in Port Moller may be a seasonal phenomenon related to sea ice; overflights in July and August, when the sea ice has left, have not recorded large numbers of sea otters in this area (B. Murphy, Alaska Department of Fish and Game, in litt. 2002). Consequently, had the May 2000 survey been conduced later (*e.g.* July or August) when the sea ice and the otters were more dispersed, it seems likely that fewer would have been in the Port Moller transect areas, which would have resulted in a lower count in the 2000 survey.

Offshore areas on the south side of the Alaska Peninsula (Figure 4B) were surveyed at three different time periods in 1986 (Brueggeman *et al.* 1988). Noting computational errors in the survey report, we re-analyzed the original 1986 survey data, resulting in estimates of 13,900–17,500 sea otters for the three surveys conducted in 1986 (Burn and Doroff in prep.). We replicated the survey in April 2001, when our estimate of 1,005 otters for the south Alaska Peninsula offshore area indicated a decline in abundance of at least 93 percent when compared with the minimum and maximum point estimates in this area from the 1986 surveys. Specific areas of high sea otter concentrations in 1986, such as Sandman Reefs, were almost devoid of sea otters in 2001 (Burn and Doroff in prep.).

Several island groups along the south side of the Alaska Peninsula (Figure 4C; Pavlof and Shumagin Islands, as well as Sanak, Caton, and Deer Islands) are another survey area. In 1962, Kenyon (1969) counted 1,900 otters along these islands. Twenty-four years later, in 1986, Brueggeman *et al.* (1988) counted 2,122 otters in the same survey area. In 1989, DeGange *et al.* (1995) counted 1,589 otters along the shorelines of the islands that had been surveyed in 1962 and 1986, which was approximately 16–28 percent fewer sea otters than were reported in the earlier counts. This decrease was the first indication of a sea otter population decline in the area of the Alaska Peninsula. When we counted sea otters in these island groups in 2001 we recorded only 405 individuals (Burn and Doroff in prep.), which is an 81-percent decline from the 1986 count reported by Brueggeman *et al.* (1988).

The shoreline of the Alaska Peninsula from False Pass to Cape Douglas (Figure 4D) is another survey area. In 1989, DeGange *et al.* (1995) counted 2,632 sea otters along this stretch of shoreline. In 2001 we counted 2,651 sea otters (Burn and Doroff in prep.), nearly the same as the 1989 count. When we subdivided and compared the results for the eastern and western components of the survey areas, we found that the count along the eastern end of the Peninsula, from Cape Douglas to Castle Cape, increased approximately 20 percent, from 1,766 in 1989 to 2,115 in 2001. For the western end of the Peninsula from False Pass to Castle Cape, however, there was evidence of a population decline, with 866 counted in 1989 as compared to 536 in 2001, a drop of almost 40 percent. (We also counted 42 sea otters along the shoreline of Unimak Island in 2001, but there is no suitable baseline data for comparison.) Based on what is known about sea otter movements and the distance between the eastern and western ends of the Peninsula, we believe that it is unlikely that these observations represent a change in distribution.

The results from the different survey areas along the Alaska Peninsula indicate various rates of change. Overall, the combined counts for the Peninsula have declined by 65–72 percent since the mid-1980s, based on the data presented in Table 1.

We have calculated an estimate of the current population for the entire Alaska Peninsula, including an adjustment for otters not detected by observers. In making this calculation, we first revised the combined total number of sea otters observed during the most recent surveys (8,789), to account for potential double-counting in an area of overlap between two of the study areas along the Peninsula. We then multiplied this revised number of otters (8,328) by the correction factor of 2.38 provided by Evans *et al.* (1997) for the type of aircraft used, to account for otters not detected by observers. The result is an adjusted estimate of 19,821 sea otters along the Alaska Peninsula as of 2001 (Burn and Doroff in prep.).

Kodiak Archipelago

One of the remnant sea otter colonies in southwest Alaska is thought to have occurred at the northern end of the Kodiak archipelago (Figure 4D), near Shuyak Island. In 1959, Kenyon (1969) counted 395 sea otters in the Shuyak Island area. Over the next 30 years, the sea otter population in the Kodiak archipelago grew in numbers, and its range expanded southward around Afognak and Kodiak Islands (Schneider 1976, Simon-Jackson *et al.* 1984, Simon-Jackson *et al.* 1985). DeGange *et al.* (1995) surveyed the Kodiak archipelago in 1989 and calculated an adjusted population estimate of 13,526 sea otters. In July and August 1994, we conducted an aerial survey using the methods of Bodkin and Udevitz (1999) and calculated an adjusted population estimate of 9,817, approximately 27 percent lower than the estimate for 1989 (Doroff *et al.* in prep.). Although both surveys corrected for animals not detected by observers, differences in survey methods led to questions about

the ability to compare results between the two surveys. In June 2001, we surveyed the Kodiak archipelago using the same observer, pilot, and methods as in 1994. The result was an adjusted population estimate of 5,893 sea otters for the archipelago in 2001 (Doroff *et al.* in prep.), which is a 40-percent decline in comparison to the 1994 estimate and a 56-percent decline from the 1989 estimate.

Kamishak Bay

Kamishak Bay is located on the west side of lower Cook Inlet, north of Cape Douglas (Figure 4D). In 1994, Kamishak Bay was included as part of a survey for marine birds and marine mammals in lower Cook Inlet (Agler *et al.* 1995). The unadjusted population estimate of 5,914 sea otters from the 1994 survey included sea otters from both the southwest Alaska and the southcentral Alaska stocks (*see* section on Distinct Vertebrate Population Segment, below), therefore an estimate for only the Kamishak Bay area is not available. In the summer of 2002, the U.S. Geological Survey (USGS), Biological Resources Division conducted an aerial survey of lower Cook Inlet and the Kenai Fiords area. This survey was designed, in part, to estimate sea otter abundance in Kamishak Bay. The method used was identical to that of the 2001 aerial survey of the Kodiak archipelago, which includes a correction factor for sea otters not detected by the observer (Bodkin and Udevitz 1999). Sea otters were relatively abundant within Kamishak Bay during the 2002 survey, with numerous large rafts of sea otters observed. The adjusted estimate for the current sea otter population size in Kamishak Bay is 6,918 (USGS in litt. 2002). As no previous estimates for Kamishak Bay exist, the population trend for this area is unknown.

Overall Comparison

The history of sea otters in southwest Alaska is one of commercial exploitation to near extinction (1742 to 1911), protection under the International Fur Seal Treaty (1911), and population recovery (post-1911). By the mid- to late-1980s, sea otters in southwest Alaska had grown in numbers and recolonized much of their former range. The surveys conducted in various areas, described above, provide information about the extent of declines within those areas. However, due to differences in the years of the various baseline surveys for different areas (1962, 1965, 1976, 1989), it is difficult to combine those surveys as a basis for estimating the overall size of the sea otter population throughout southwest Alaska at the onset of the decline. Therefore, as part of our effort to evaluate information reflecting the overall magnitude of the decline, we also have considered information provided by Calkins and Schneider (1985), who summarized sea otter population estimates worldwide based on data collected through 1976. Much of the information they present is from unpublished Alaska Department of Fish and Game survey results, and we include this information as it is the only comprehensive reference for estimating the overall magnitude of the sea otter decline in southwest Alaska.

Calkins and Schneider (1985) provided estimates as of 1976, adjusted for animals not detected by observers, for the Aleutian Islands (55,100–73,700), north Alaska Peninsula (11,700–17,200), south Alaska Peninsula (22,000–30,000) and Kodiak archipelago (4,000–6,000). They did not report a specific estimate for the Kamishak Bay area, which presumably was included within their estimate for the Kenai Peninsula and Cook Inlet area (2,500–3,500 otters), and we are assuming that half of the sea otters estimated for Kenai Peninsula and Cook Inlet occurred in Kamishak Bay (1,250–1,750). Combining these estimates, the sea otter population in the area encompassing the range of the southwest Alaska population was believed to have numbered between 94,050–128,650 animals as of 1976. As sea otters had not yet fully recolonized southwest Alaska or reached equilibrium density in all areas in 1976, additional population growth was expected. Therefore, the overall population prior to the onset of the decline in the 1980's probably was higher than the population estimate for 1976.

Our estimate for the current size of the southwest Alaska population of the northern sea otter is 41,474 animals (Table 2). This estimate is based on recent survey information, adjusted for animals not detected.

TABLE 2.—CURRENT POPULATION ESTIMATES FOR THE SEA OTTER IN SOUTHWEST ALASKA

[Alaska Peninsula and Unimak Island counts are adjusted using a correction factor of 2.38 for twin-engine aircraft surveys of sea otters according to Evans *et al.* (1997). Aleutian Islands, Kodiak Archipelago, and Kamishak Bay surveys are adjusted using survey-specific correction factors.]

Survey area	Year	Unadjusted count or estimate	Adjusted count or estimate	Reference
Aleutian Islands	2000	2,442	8,742	Doroff *et al.* (2003).
North Alaska Penninsula Offshore Areas	2000	4,728	11,253	Burn and Doroff (in prep.).
South Alaska Peninsula Offshore Areas	2001	1,005	2,392	Burn and Doroff (in prep.).
South Alaska Peninsula Shoreline	2001	[a] 2,190	5,212	Burn and Doroff (in prep.).
South Alaska Peninsula Islands	2001	405	964	Burn and Doroff (in prep.).
Unimak Island	2001	42	100	Burn and Doroff (in prep.).
Kodiak Archipelago	2001	.....	5,893	Doroff *et al.* (in prep.).
Kamishak Bay	2002	.....	6,918	USGS Unpublished data.
Total	.....	.....	41,474	

[a] Does not include a count of 461 sea otters from False Pass to Seal Cape, which was also surveyed as part of the south Alaska Peninsula Offshore Areas survey.

The 1976 population estimate based on the work of Calkins and Schneider (1985) is not directly comparable to our current estimate because of somewhat different survey approaches and estimation techniques. Nevertheless, the results provide a basis for at least a rough comparison of the overall extent of the decline of sea otters in southwest Alaska. When compared to the estimate of 94,050–128,650 from Calkins and Schneider (1985), our current estimate of approximately 41,500 sea otters is 53,000–87,000 lower, which is 56–68 percent lower than the estimate for 1976.

Translocated Sea Otter Populations

As part of efforts to re-establish sea otters in portions of their historical range, otters from Amchitka Island (part of the Aleutian Islands) were translocated to other areas outside the range of what we now recognize as the southwest Alaska distinct population segment, but within the range of *E. l. kenyoni* (Jameson *et al.* 1982). These translocation efforts met with varying degrees of success. From 1965 to 1969, 412 otters (89 percent from Amchitka Island, and 11 percent from Prince William Sound, which is in southcentral Alaska, outside the range of the southwest Alaska DPS) were translocated to six sites in southeast Alaska (Jameson *et al.* 1982). Since that time, these translocated populations have grown rapidly in numbers and expanded their range. The most recent surveys conducted between 1994 and 1996 estimated 12,632 otters in southeast Alaska (USFWS 2002b).

Sea otters from Amchitka Island also were translocated to Washington and Oregon, and to British Columbia, Canada, between 1969 and 1972 (Jameson *et al.* 1982). Sea otters translocated to British Columbia were captured at Amchitka Island and Prince William Sound; the otters translocated to Washington and Oregon were captured at Amchitka Island only. The British Columbia and Washington populations have grown in number and expanded their range, while the Oregon population disappeared. The most recent estimates of population size are 550 in Washington and 2,000 in British Columbia (Jameson and Jeffries 2001; Watson *et al.* 1997). Although these populations, as well as sea otters in southeast Alaska, are descended from sea otters at Amchitka Island, they are geographically isolated from the southwest Alaska population and their parent population by hundreds of kilometers (see section entitled Distinct Vertebrate Population Segment, below) and are not included in this proposed listing action.

The total number of otters removed from Amchitka as part of this translocation program was just over 600 animals (Jameson *et al.* 1982). Estes (1990) estimated that the sea otter population at Amchitka Island remained essentially stable at more than 5,000 otters between 1972 and 1986, and consequently there is no evidence that removals for the translocation program have been a contributing factor in the current population decline.

Previous Federal Action

Based on the results of the April 2000 sea otter survey in the Aleutian Islands, we added sea otters in the Aleutians to our list of candidate species in August of 2000 (65 FR 67343). On October 25, 2000, we received a petition from the Center for Biological Diversity (Center) in Berkeley, California, requesting that we list the Aleutian population of the northern sea otter as endangered. As we already had identified sea otters in the Aleutians as a candidate species, we considered the petition to be a second, redundant petition, and in accordance with our petition management guidance (61 FR 36075) did not make an additional 90-day or 12-month finding on this petition. On November 14, 2000, we received a Notice of Intent to sue from the Center challenging our decision not to propose to list sea otters in the Aleutians under the Act. We responded to the Center that funds were not available during Fiscal Year 2001 to prepare a proposed listing rule.

On August 21, 2001, we received a petition from the Center to designate the Alaska stock of sea otters (State-wide) as depleted under the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*). Under the MMPA, a marine mammal species or population stock is considered to be depleted when it is below its Optimum Sustainable Population (OSP) level. The OSP is defined in the MMPA as: "the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element." In accordance with the MMPA, we published a notice in the **Federal Register** on September 6, 2001, announcing the receipt of this petition (66 FR 4661). On November 2, 2001, we published our finding on the petition in the **Federal Register** (66 FR 55693). While we acknowledged the evidence of a population decline in the southwest Alaska stock, the best available information suggested that the southeast Alaska stock was increasing, and the southcentral Alaska stock was either stable or increasing. We found that the petitioned action was not warranted under the MMPA for the following reasons: (1) The best estimate of the population size for the entire state of Alaska was greater than the value presented in the petition; (2) based on the best estimate of population size, the Alaska stock of sea otters was above OSP level; and (3) recent information had identified the existence of three stocks of sea otters in Alaska: southwest, southcentral, and southeast (Gorbics and Bodkin 2001). The boundaries of these three stocks are depicted in Figure 5.

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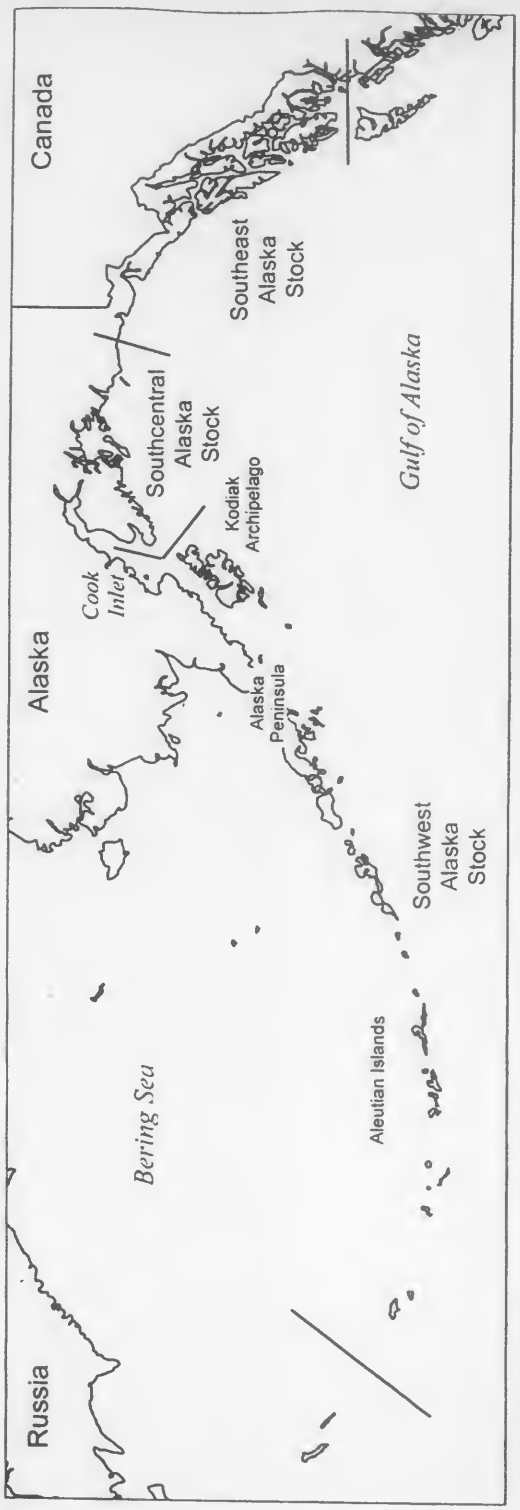

Figure 5. Northern sea otter stock boundaries in Alaska, from Gorbics and Bodkin (2001).

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We recently revised the MMPA stock assessment reports for sea otters in Alaska. Draft stock assessment reports identifying the three stocks of sea otters were made available for public review and comment from March 28 to June 26, 2002 (67 FR 14959). The sea otter stock assessment reports were finalized on August 20, 2002, and notice of their availability was published on October 9, 2002 (67 FR 62979).

On January 11, 2002, we received a petition from the Sea Otter Defense Initiative (SODI), a project of the Earth Island Institute, in Deer Isle, Maine. The petition requested that we emergency and permanently list the southwest Alaska stock of sea otters as endangered. We responded to SODI that, based on the best available population estimate that we prepared in response to the Center's petition to list the Alaska stock of sea otters as depleted under the MMPA, an emergency listing of the southwest Alaska stock was not warranted. We also notified SODI that we had begun the preparation of this proposed rule during Fiscal Year 2002.

Based on additional sea otter surveys along the Alaska Peninsula and Kodiak archipelago, and the identification of multiple stocks of sea otters in Alaska, we expanded the candidate species designation on June 3, 2002, to include the geographic range of the southwest Alaska stock of the northern sea otter. Notification of this change was included in our June 13, 2002, notice of review of candidate species (67 FR 40657).

Distinct Vertebrate Population Segment

Pursuant to the Act, we must consider for listing any species, subspecies, or, for vertebrates, any distinct population segment (DPS) of these taxa if there is sufficient information to indicate that such action may be warranted. To interpret and implement the DPS provision of the Act and Congressional guidance, the Service and the National Marine Fisheries Service published, on December 21, 1994, a draft Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act and invited public comments on it (59 FR 65885). After review of comments and further consideration, the Services adopted the interagency policy as issued in draft form, and published it in the **Federal Register** on February 7, 1996 (61 FR 4722). This policy addresses the recognition of DPSs for potential listing actions. The policy allows for more refined application of the Act that better reflects the biological needs of the taxon being considered, and avoids the inclusion of entities that do not require its protective measures.

Under our DPS policy, three elements are considered in a decision regarding the status of a possible DPS as endangered or threatened under the Act. These are applied similarly for additions to the list of endangered and threatened species, reclassification, and removal from the list. They are: (1) Discreteness of the population segment in relation to the remainder of the taxon; (2) the significance of the population segment to the taxon to which it belongs; and (3) the population segment's conservation status in relation to the Act's standards for listing (*i.e.*, is the population segment, when treated as if it were a species, endangered or threatened?). A systematic application of the above elements is appropriate, with discreteness criteria applied first, followed by significance analysis. Discreteness refers to the isolation of a population from other members of the species and we evaluate this based on specific criteria. We determine significance by using the available scientific information to determine the DPS's importance to the taxon to which it belongs. If we determine that a population segment is discrete and significant, we then evaluate it for endangered or threatened status based on the Act's standards.

Discreteness

Under our Policy Regarding the Recognition of Distinct Vertebrate Population Segments, a population segment of a vertebrate species may be considered discrete if it satisfies either one of the following conditions:

1. It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors. Quantitative measures of genetic or morphological discontinuity may provide evidence of this separation.

2. It is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the Act.

The focus of our DPS evaluation is the subspecies *E. l. kenyoni*, which occurs from the west end of the Aleutian Islands in Alaska, to the coast of the State of Washington (Wilson *et al.* 1991), as depicted in Figure 1. To the west of the Aleutian Islands, the sea otters in Russia are recognized as a separate subspecies, *E. l. lutris*. To the east of the Aleutians, a discontinuity in sea otter distribution occurs at Cook Inlet. This discontinuity also was specifically recognized during the process of identifying marine mammal stocks under the MMPA, and is reflected by the boundary separating the southwest Alaska stock of sea otters from the southcentral stock, as shown in Figure 4. Although sea otters inhabit both the eastern and western shores of lower Cook Inlet, their distribution around the Inlet is not contiguous because the presence of winter sea ice in upper Cook Inlet forms a natural break in sea otter distribution. This break in sea otter distribution in the upper portion of the Inlet persists throughout the ice-free portions of the year as well (Rotterman and Simon-Jackson 1988).

In the lower portion of Cook Inlet, a different type of barrier exists in the form of an expanse of deep water. The distance across lower Cook Inlet ranges from 50–90 km (31–56 miles). While sea otters are physically capable of swimming these distances, the water depths of up to 260 m (142 fathoms) and lack of food resources for sea otters in deep water areas makes such movements across this open water area quite unlikely.

Surveys conducted for sea otters and other species in the area of Lower Cook Inlet confirm the discontinuity of sea otters in this area. In the summer of 1993, Agler *et al.* (1995) conducted boat-based surveys of marine birds and mammals, including sea otters, in Lower Cook Inlet. During approximately 1,574 km (978 miles) of survey effort, only one sea otter was observed in the center of the Inlet. More recently, during an aerial survey of sea otters conducted in the summer of 2002, no otters were observed on 324 km (201 miles) of transects flown across the center of Cook Inlet (USGS in litt. 2002).

Information gathered incidental to surveys of other species also indicates that sea otters rarely occur in the offshore areas of lower Cook Inlet, further confirming the discontinuity of sea otters in this area. NMFS has conducted aerial surveys of beluga whales, *Delphinapterus leucas*, in Cook Inlet since 1993. In addition to beluga whales, observers recorded observations of other marine mammals, including sea otters. During these surveys, which covered a combined total of 11,583 km (7,197 miles) of systematic transects flown across the inlet over several years, no sea otters were observed in the deeper, offshore areas of Cook Inlet (Rugh *et al.* 2000). The NMFS also conducted a marine mammal observer program during the Cook Inlet salmon drift and set gillnet fisheries in 1999 and 2000 (Fadely and Merklein 2001). During this period with several thousand hours of observations, no sea otters were recorded in the offshore

areas of Cook Inlet. Given the amount of survey effort that has been expended, the almost complete lack of observations in deeper offshore waters indicates that there is little exchange of sea otters between the eastern and western shores of lower Cook Inlet.

The population of sea otters represented by the southwest Alaska stock is genetically different from both the southcentral and southeast Alaska stocks. Studies using mitochondrial DNA analysis identified ten different genotypes within the range of sea otters; six of these ten different genotypes are found in Alaska (Sanchez 1992, Bodkin *et al.* 1992, Cronin *et al.* 1996). Gorbics and Bodkin (2001) demonstrated that mitochondrial DNA haplotype frequencies (a descriptive genetic characteristic) differ significantly among sea otters from southwest Alaska (west of Cook Inlet) compared to those from southcentral Alaska (east of Cook Inlet) and southeast Alaska.

Additional genetic analysis of both mitochondrial and nuclear (microsatellite) DNA (these are two different approaches for examining genetic diversity) has shown similar patterns of genetic differentiation and supports the identification of multiple populations of sea otters in Alaska. As mitochondrial DNA is maternally inherited, it can only be used to assess gene flow in females. Analysis of nuclear genetic markers, such as microsatellite DNA, can be used to assess gene flow by both males and females and provide a better quantification of genetic differentiation than mitochondrial DNA alone (Cronin *et al.* 2002). Pairwise comparisons of both mitochondrial and nuclear DNA between individual sampling locations from southwest and southcentral Alaska had 40 significant differences out of 60 comparisons (67%). In addition, tests of heterogeneity between pooled sampling locations showed significant differences between sea otters in southwest and southcentral Alaska in three out of three tests (Cronin *et al.* 2002). These genetic differences are most likely the result of little or no movement of animals across stock boundaries (Gorbics and Bodkin 2001). The boundary between the southwest and southcentral stocks of sea otters is in the area of Cook Inlet, and the aforementioned genetic differences and lack of observations from the center of Cook Inlet indicate that sea ice and deep water constitute physical barriers that effectively limit animal movements between the southwest and southcentral Alaska stocks of sea otters.

Sea otters in southwest and southcentral Alaska also differ morphologically. Comparison of 10 skull characteristics between 26 adult sea otters from Amchitka Island and 42 sea otters from Prince William Sound showed numerous statistically significant differences, with the Amchitka otters being the larger of the two (Gorbics and Bodkin 2001).

These genetic and morphological differences were part of the basis for identification of sea otter population stocks under the MMPA (USFWS 2002a, USFWS 2002b, USFWS 2002c). The Service and NMFS have adopted the methods of Dizon *et al.* (1992), who outlined four criteria for consideration when identifying marine mammal population stocks: (1) Distribution; (2) population response; (3) morphology; and (4) genetics. Applying these criteria to the best available scientific information, Gorbics and Bodkin (2001) identified three stocks of sea otters in Alaska, the southwest, southcentral, and southeast stocks, with ranges as depicted in Figure 5.

In summary, sea otters from the Aleutians Islands to the middle of Cook Inlet are a population that differs from other sea otters in several respects. Sea otters to the west of the Aleutians are recognized as belonging to a different taxon, the subspecies *E. l. lutris*. Within the taxon *E. l. kenyoni*, there are physical barriers to movement across the upper and the lower portions of Cook Inlet, and there are morphological and genetic differences between sea otters that correspond to the southwest and southcentral Alaska stocks that we identified under the MMPA, with Cook Inlet being the boundary separating these stocks. The geographic separation between the southwest and southeast Alaska stocks is even greater than between the southwest and southcentral Alaska stocks. In addition, Bodkin *et al.* (1999) note that haplotype frequencies in southeast Alaska (a translocated population) differed significantly from both "parent" stocks.

Based on our consideration of the best scientific information available, we find that the southwest Alaska population of the northern sea otter that occurs from the Aleutian Islands to Cook Inlet, corresponding to the southwest Alaska stock as identified by us previously under the MMPA (Figure 5), is markedly separated from other populations of the same taxon as a consequence of physical factors, and there is genetic and morphological discontinuity that is evidence of this separation. Therefore, the southwest Alaska population of the northern sea otter meets the criterion of discreteness under our Policy Regarding the Recognition of Distinct Vertebrate Population Segments.

Significance

If we determine a population segment is discrete, we next consider available scientific evidence of its significance to the taxon to which it belongs. Our policy states that this consideration may include, but is not limited to, the following:

1. Persistence of the discrete population segment in an ecological setting unusual or unique for the taxon,
2. Evidence that loss of the discrete population segment would result in a significant gap in the range of the taxon,
3. Evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historic range, or
4. Evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics.

The sea otter population that corresponds to the southwest Alaska stock contains over 60 percent of the range for the subspecies *E. l. kenyoni*. Following protection from commercial exploitation in 1911, sea otters recovered quickly in southwest Alaska, which is a remote part of the State. In the mid-1980s, biologists believed that 94 percent of the subspecies *E. l. kenyoni*, and 84 percent of the world population, existed in southwest Alaska (Calkins and Schneider 1985). Despite the recent population decline, current information indicates that roughly half of all sea otters in the subspecies *E. l. kenyoni* exist in the southwest Alaska population. Thus, the loss of this population segment would result in a significant gap in the range of the taxon because it comprises 60 percent of the range and approximately half of the population of the subspecies. In addition, the best scientific information available demonstrates the southwest Alaska population differs significantly from the southcentral and southeast Alaska stocks in terms of genetic characteristics (Gorbics and Bodkin 2001). Therefore, we find that the southwest Alaska population segment is significant to the taxon to which it belongs because the loss of this segment would result in a significant gap in the range of the taxon, and because there is evidence that it differs markedly from other populations of the taxon in its genetic characteristics.

Summary of Discreteness and Significance Evaluations

Based on the above consideration of the southwest Alaska population of the northern sea otter's discreteness and its

significance to the remainder of the taxon, we find that it is a distinct population segment, or DPS, as described under our Policy Regarding the Recognition of Distinct Vertebrate Population Segments. The population's discreteness is due to its separation from other populations of the same taxon as a consequence of physical factors, and there are morphological and genetic differences from the remainder of the taxon that are evidence of this separation. The population segment's significance to the remainder of the taxon is due principally to the significant gap that its loss would represent in the range of the taxon, and also to the fact that it differs markedly from other populations of the species in its genetic characteristics. We refer to this population segment as the southwest Alaska DPS for the remainder of this proposed rule.

Conservation Status

Pursuant to the Act, we must consider for listing any species, subspecies, or, for vertebrates, any distinct population segment of these taxa, if there is sufficient information to indicate that such action may be warranted. We have evaluated the conservation status of the southwest Alaska DPS of the northern sea otter in order to make a determination relative to whether it meets the Act's standards for listing the DPS as endangered or threatened. Based on the definitions provided in section 3 of the Act, endangered means the DPS is in danger of extinction throughout all or a significant portion of its range, and threatened means the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Summary of Factors Affecting the Species

Section 4 of the Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal list. As defined in section 3 of the Act, the term "species" includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species or vertebrate fish or wildlife which interbreeds when mature. We may determine a species to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. These factors, and their application to the southwest Alaska DPS of the northern sea otter, are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Habitat destruction or modification are not known to be major factors in the decline of the southwest Alaska DPS of the northern sea otter. At present, no curtailment of range has occurred, as sea otters still persist throughout the range of the DPS, albeit at markedly reduced densities. However, as there is no evidence to suggest that the decline has abated, it is possible that additional losses may occur that would curtail the range of sea otters in southwest Alaska.

Human-induced habitat effects occur primarily in the form of removal of some of the prey species used by sea otters as a result of resource use such as commercial fishing, which occurs throughout southwest Alaska. While there are some fisheries for benthic invertebrates in southwest Alaska, there is little competition for prey resources due to the limited overlap between the geographic distribution of sea otters and fishing effort. In addition, the total commercial catch of prey species used by sea otters is relatively small (Funk 2003).

In studies of sea otters in the Aleutians, there was no evidence that sea otters are nutritionally stressed in that area, and foraging behavior, measured as percent feeding success, has increased during the 1990's (Estes *et al.* 1998).

Development of harbors and channels by dredging may affect sea otter habitat on a local scale by disturbing the sea floor and benthic invertebrates that sea otters eat. Typically, the number and size of these activities are small relative to the overall range of the DPS.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Following 170 years of commercial exploitation, sea otters were protected in 1911 under the International Fur Sea Treaty, which prohibited further hunting. In 1972, the Marine Mammal Protection Act (MMPA) established a moratorium on the take of all marine mammals in U.S. waters. Section 101(b) of the MMPA provides an exemption for Alaska Natives to take marine mammals for subsistence purposes. Although the Native exemption was established in 1972, subsistence harvest of sea otters did not begin in earnest until the mid-1980s (Simon-Jackson 1988). In October 1988, we initiated the marine mammal Marking, Tagging, and Reporting Program (MTRP) to monitor the harvest of sea otter, polar bear (*Ursus maritimus*), and Pacific walrus (*Odobenus rosmarus divergens*) in Alaska (50 CFR 18.23(f)). The majority of the sea otter harvest occurs in southeast and southcentral Alaska. Information from the MTRP estimates the subsistence harvest of sea otters from the southwest Alaska DPS averaged less than 100 sea otters per year during the 1990s (Burn and Doroff in prep.). Based on the magnitude of the current decline, the impact of the subsistence harvest is negligible.

Scientific research on sea otters occurs primarily as aerial and skiff surveys of abundance, and such surveys are conducted infrequently (once every few years) and when they occur, they last for very short durations of time. During the 1990s, 198 otters were captured and released as part of health monitoring and radio telemetry studies at Adak and Amchitka (T. Tinker, University of California at Santa Cruz, *in litt.* 2003). Based on the magnitude of the current decline, we do not believe that the impact of surveys, or the impact of capture/release activities, is a significant factor.

Translocations of sea otters from southwest Alaska to other areas also has occurred. These translocations took place from 1965 to 1972, and involved removal of a total of just over 600 sea otters from Amchitka Island (Jameson *et al.* 1982). Estes (1990) estimated that the sea otter population at Amchitka Island remained essentially stable at more than 5,000 otters between 1972 and 1986, and consequently there is no evidence that removals for the translocation program have resulted in overutilization.

C. Disease or Predation

Fish processing operations produce large quantities of organic waste, which can affect the health of sea otters on a local scale. In some areas of Alaska, sea otters have been observed consuming fish waste. Necropsies of carcasses recovered in Orca Inlet, Prince William Sound (which is not within the range of the southwest Alaska DPS), revealed that some otters in these areas had developed parasitic infections and fish bone impactions that contributed to the deaths of these animals (Ballachey *et al.* 2002, King *et al.* 2000). Measures such as heating and grinding waste materials, or barging it further offshore, have proven successful at eliminating these impacts. There is no evidence that the fish processing operations are resulting in disease on any substantial scope or scale for the southwest Alaska DPS of the northern sea otter.

The cause of the sea otter decline in the Aleutians has been explored by reviewing available data on sea otter

reproduction, survival, distribution, habitat, and environmental contaminants. Estes *et al.* (1998) concluded that the observed sea otter declines there were most likely the result of increased adult mortality. While disease, pollution, and starvation may all influence sea otter mortality, no evidence available at this time suggests these factors are contributing to the decline in the Aleutians.

The weight of evidence of available information suggests that predation by killer whales (*Orcinus orca*) may be the most likely cause of the sea otter decline in the Aleutian Islands (Estes *et al.* 1998). Data that support this hypothesis include: (1) A significant increase in the number of killer whale attacks on sea otters during the 1990s (Hatfield *et al.* 1998); (2) scarcity of beachcast otter carcasses that would be expected if disease or starvation were occurring; and (3) markedly lower mortality rates between sea otters in a sheltered lagoon (where killer whales cannot go) as compared to an adjacent exposed bay. Similar detailed studies have not yet been conducted in other areas within the southwest Alaska DPS, and the role of killer whale predation on sea otters outside of the Aleutians is unknown. (*See* the discussion of Factor E, below, for additional information concerning killer whales.)

Besides killer whales, other predators on sea otters include white sharks (*Carcharodon carcharias*), brown bears (*Ursus arctos*), and coyotes (*Canis latrans*) (Riedman and Estes 1990). Carcasses of sea otter pups have been observed in bald eagle (*Haliaeetus leucocephalus*) nests (Sherrod *et al.* 1975). Although there is anecdotal information regarding shark attacks on sea otters in Alaska, we believe that the impact of sharks and predators other than killer whales on the southwest Alaska DPS of the northern sea otter is negligible.

D. The Inadequacy of Existing Regulatory Mechanisms

The MMPA (16 U.S.C. 1361), enacted in 1972, is an existing regulatory mechanism that involves sea otters. The MMPA placed a moratorium on the taking of marine mammals in U.S. waters. Similar to the definition of "take" under section 3 of the ESA, "take" is defined under the MMPA as "harass, hunt, capture, or kill, or attempt to harass, hunt, capture or kill" (16 U.S.C. 1362). The MMPA does not include provisions for restoration of depleted species or population stocks, and does not provide measures for habitat protection.

Section 101(b) of the MMPA provides an exemption to allow Alaska Natives to take marine mammals for subsistence purposes. The MMPA does not allow any regulation of the subsistence harvest prior to a finding of depletion. By definition, a marine mammal species or stock that is designated as "threatened" or "endangered" under the Endangered Species Act is also classified as "depleted" under the MMPA. The converse is not true, however, as a marine mammal species or stock may be designated as depleted under the MMPA, but not be listed as threatened under the ESA. As stated earlier, current levels of subsistence harvest of sea otters, which amounted to fewer than 100 sea otters per year during the 1990s, are believed to have a negligible impact on this DPS, and is therefore not a cause for concern at this time.

Section 118 of the MMPA addresses the taking of marine mammals incidental to commercial fishing operations. This section, which was added to the MMPA in 1994, establishes a framework that authorizes the incidental take of marine mammals during commercial fishing activities. In addition, this section outlines mechanisms to monitor and reduce the level of incidental take. Information from monitoring programs administered by NMFS indicates that interactions between sea otters and commercial fisheries result in less than one instance of mortality or serious injury per year within the southwest Alaska DPS and are, therefore, not a cause for concern at this time (USFWS 2002a).

Northern sea otters are not on the State of Alaska lists of endangered species or species of special concern. Alaska Statutes sections 46.04 200–210 specify State requirements for Oil and Hazardous Substance Discharge and Prevention Contingency Plans. These sections include prohibitions against oil spills and provide for the development of contingency plans to respond to spills should they occur. The potential impacts of oil spills on sea otters are addressed in Factor E.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Sea otters are particularly vulnerable to contamination by oil (Costa and Kooyman 1981). As they rely solely on fur for insulation, frequent grooming is essential to maintain the insulative properties of the fur. Vigorous grooming bouts generally occur before and after feeding episodes and rest periods. Oiled sea otters are highly susceptible to hypothermia resulting from the reduced insulative properties of oil-matted fur. Contaminated sea otters also are susceptible to the toxic effects from oil ingested while grooming. In addition, volatile hydrocarbons may affect the eyes and lung tissues of sea otters in oil-contaminated habitats and contribute to mortality.

The sea otter's vulnerability to oil was clearly demonstrated during the *Exxon Valdez* oil spill in 1989, when thousands of sea otters were killed in Prince William Sound, Kenai Fiords, the Kodiak archipelago, and the Alaska Peninsula. Although the spill occurred hundreds of miles outside the range of the southwest Alaska DPS of the northern sea otter, an estimated 905 sea otters from this population segment died as a result of the spill (Handler 1990, Doroff *et al.* 1993, DeGange *et al.* 1994).

Although numerous safeguards have been established since the *Exxon Valdez* oil spill to minimize the likelihood of another spill of catastrophic proportions in Prince William Sound, vessels and fuel barges are a potential source of oil spills that could impact sea otters in southwest Alaska. Since 1990 in Alaska, more than 4,000 spills of oil and chemicals on water have been reported to the U.S. Coast Guard National Response Center. Of these, nearly 1,100 occurred within the range of the southwest Alaska DPS of the northern sea otter. Reported spills include a variety of quantities (from a few gallons to thousands of gallons) and materials (primarily diesel fuel, gasoline, and lubricating oils). Reports of direct mortality of sea otters as a result of these spills are lacking and the impact of chronic oiling on sea otters in general, or on the southwest Alaska DPS, is unknown. Also, despite the fact that locations such as boat harbors have higher occurrences of small spills than more remote areas, individual sea otters have been observed to frequent some harbors for years. The overall health, survivorship, and reproductive success of these otters is not known.

Currently, there is no oil and gas production within the range of the southwest Alaska DPS of the northern sea otter. Proposed Outer Continental Shelf (OCS) oil and gas lease sales are planned, however, for lower Cook Inlet. Based on a review of the draft Environmental Impact Statement for these lease sales, it is our opinion that the potential impacts of this development on the southwest Alaska DPS will be negligible as sea otters occur primarily in the nearshore zone and the lease sale area is at least three miles off shore. Therefore, sea otters do not significantly overlap with the lease sale area.

Contaminants may also affect sea otters and their habitat. Potential sources of contaminants include local sources at specific sites in Alaska, and remote sources outside of Alaska. One category of contaminants that has been studied are polychlorinated biphenyls (PCBs), which may originate from a wide variety of sources. Data from blue mussels collected from the Aleutian Islands in southwest Alaska through southeast Alaska indicate background concentrations of PCBs at most sampling locations, with "hot spots" of high PCB concentrations evident at Adak (Sweeper Cove), Dutch Harbor, and Amchitka. Notwithstanding these "hot spots," PCB levels in samples from southwest Alaska actually are lower than those in southeast Alaska sites. The PCB concentrations found in liver tissues of sea otters from the Aleutians were similar to or higher than those causing reproductive failure in captive mink (Estes *et al.* 1997, Giger and Trust 1997), but the toxicity of PCBs to sea otters is unknown. Population survey data for the Adak Island area indicates normal ratios of mothers and pups, which suggests that reproduction in sea otters is not being suppressed in sea otters in that area (Tinker and Estes 1996). As PCB's typically inhibit reproduction rather than cause adult mortality, these findings do not suggest a reproductive impact due to PCBs. Sample sizes were limited, however, and data needed to fully evaluate the potential role of PCBs and other environmental contaminants in the observed sea otter population decline are incomplete. In summary, a conclusive link between the sea otter decline and the effects of specific contaminants in their habitat has not been established.

Sea otters are sometimes taken incidentally in commercial fishing operations. Information from the NMFS list of fisheries indicates that entanglement leading to injury or death occurs infrequently in set net, trawl, and finfish pot fisheries within the range of the southwest Alaska DPS of the northern sea otter (67 FR 2410, January 17, 2002). During the summers of 1999 and 2000, NMFS conducted a marine mammal observer program in Cook Inlet for salmon drift and set net fisheries. No mortality or serious injury of sea otters was observed in either of these fisheries in Cook Inlet (Fadely and Merklein 2001). Similarly, preliminary results from an ongoing observer program for the Kodiak salmon set net fishery also report only four incidents of entanglement of sea otters, with no mortality or serious injury (M. Sternfeld, NMFS, in litt. 2003). Additional marine mammal observer programs will continue to improve our understanding of this potential source of sea otter mortality.

The hypothesis that killer whales may be the principal cause of the sea otter decline suggests that there may have been significant changes in the Bering Sea ecosystem (Estes *et al.* 1998). For the past several decades, harbor seals (*Phoca vitulina*) and Steller sea lions (*Eumetopias jubatus*), the preferred prey species of transient, marine mammal-eating killer whales, have been in decline throughout the western north Pacific. In 1990, Steller sea lions were listed under the Act as threatened under the ESA (55 FR 49204). Their designation was later revised to endangered in western Alaska, and threatened in eastern Alaska, with the dividing line located at 144 degrees west longitude (62 FR 24345). Estes *et al.* (1998) hypothesized that killer whales may have responded to declines in their preferred prey species, harbor seals and Stellar sea lions, by broadening their prey base to include sea otters. While the cause of sea lion and harbor seal declines is the subject of much debate, it is possible that changes in composition and abundance of forage fish as a result of climatic changes and/or commercial fishing practices may be contributing factors.

It also recently has been hypothesized that the substantial reduction of large whales from the North Pacific Ocean as a result of post-World War II industrial whaling may be the ultimate cause of the decline of several species of marine mammals in the north Pacific (Springer *et al.* 2003). Killer whales are considered to be the foremost natural predator of large whales. By the early 1970's, the biomass of large whales had been reduced by 95 percent, a result attributed to commercial harvesting. This reduction may have caused killer whales to begin feeding more intensively on smaller coastal marine mammals such as sea lions and harbor seals. As those species became increasing rare, the killer whales that preyed on them may have expanded their diet to include the even smaller and calorically less profitable, sea otter. The information supporting this theory is still under review. Although the proximate cause of the current sea otter decline may be predation by killer whales, the ultimate cause remains unknown.

Conclusion of Status Evaluation

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by the southwest Alaska DPS of the northern sea otter in determining to propose this rule. The Act defines an endangered species as one that is in danger of extinction throughout all or a significant portion of its range. A threatened species is one that is likely to become an endangered species in the foreseeable future throughout all or a significant portion of its range.

To date, investigations of the cause(s) of the sea otter decline have been limited to the Aleutian islands; little research has been conducted in other portions of the southwest Alaska DPS. Although killer whale predation has been hypothesized to be responsible for the sea otter decline in the Aleutian islands, the cause(s) of the decline throughout southwest Alaska are not definitively known.

At present, sea otters have not been extirpated from any portion of the range of the southwest Alaska DPS, however they have been reduced to markedly lower densities, particularly in the Aleutian Islands and south Alaska Peninsula areas. Recent survey information indicates that the southwest Alaska DPS has declined by at least 56–68 percent during the past 10–15 years. Estimated rates of decline have been as great as 17.5 percent per year in the Aleutian archipelago (Doroff *et al.* 2003). At present, we have no evidence to indicate that the decline has abated, and we have no reason to expect that the decline will cease. If the trend were to continue at the overall estimated decline rates for the southwest Alaska DPS, which range from 5.2–10.6 percent per year, the DPS would be further reduced from its current level by 66–89 percent in 20 years, and could become extirpated in portions of its range.

Regardless of its cause, the severity and widespread nature of the decline in the southwest Alaska sea otter DPS is quite serious. The decline may be due to predation by killer whales, which in turn may be the result of changes in the ecosystem. Also, regardless of what the reason for the decline may be, at present we have no evidence to indicate that the decline has abated, and we have no reason to expect that the decline will cease. Given the current population size and distribution, we do not believe the DPS is presently in danger of extinction throughout all or a significant portion of its range. Based on our evaluation of the best available scientific information, however, we believe it is likely to become an endangered species in the foreseeable future throughout all or a significant portion of its range. Therefore, we are proposing to list the

southwest Alaska DPS of the northern sea otter as threatened.

Critical Habitat

Critical habitat is defined in section 3 of the Act as: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" is defined in section 3 as meaning the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

The primary regulatory effect of critical habitat is the section 7(a)(2) requirement that Federal agencies shall insure that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat.

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, we designate critical habitat at the time a species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist—(1) the species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species. Our regulations (50 CFR 424.12(a)(2)) further state that critical habitat is not determinable when one or both of the following situations exist: (1) Information sufficient to perform required analysis of the impacts of the designation is lacking, or (2) the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

Delineation of critical habitat requires identification of the physical and biological habitat features that are essential to the conservation of the species. In general terms, critical habitat for the southwest Alaska DPS of the northern sea otter may be a function of several factors, including: (1) Water depth; (2) proximity to shore; and (3) sheltered areas that provide refuge from rough weather and/or aquatic predators. Unlike other marine mammal species such as seals and sea lions, sea otters do not occur at high-density focal areas such as rookeries and haulout sites. Although they are occasionally observed on land, sea otters are typically distributed at low densities throughout shallow, nearshore marine waters. In addition to nearshore foraging areas, sea otters may move from exposed, open-water areas, into protected bays, lagoons, and inlets when inclement weather produces large waves. These sheltered areas may be important resting areas for sea otters, especially mothers with dependent pups. In addition, some sheltered areas may provide refuge from aquatic predators, such as killer whales and sharks.

With respect to whether it is prudent to designate critical habitat for the southwest Alaska DPS of the northern sea otter at the time of listing, such a designation would not be expected to increase the threat to the DPS. However, information sufficient to perform the required analysis of the impacts of the designation of critical habitat is lacking at this time. Further, at this time the identification of specific physical and biological features and specific areas for consideration as critical habitat is complicated by uncertainty as to the extent to which habitat may or may not be a limiting factor for this DPS, resulting in uncertainty as to which specific areas might be essential to the conservation of the species and thus meet a key aspect of the definition of critical habitat. Consequently, the designation of critical habitat for the southwest DPS of the northern sea otter is not determinable at this time. In the Public Comments Solicited section of this proposed rule we specifically request information regarding critical habitat. If the listing of the DPS becomes final, we then will consider whether to propose the designation of critical habitat.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing results in public awareness and conservation actions by Federal, State, and local agencies, private organizations, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer informally with us on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us under the provisions of section 7(a)(2) of the Act.

Several Federal agencies are expected to have involvement under section 7 of the Act regarding the southwest Alaska DPS of the northern sea otter. The National Marine Fisheries Service may become involved through their permitting authority for crab and ground fisheries. The Environmental Protection Agency may become involved through their permitting authority for the Clean Water Act. The U.S. Corps of Engineers may become involved through its responsibilities and permitting authority under section 404 of the Clean Water Act and through future development of harbor projects. Minerals Management Service may become involved through administering their programs directed toward offshore oil and gas development. The Denali Commission may be involved through their potential funding of fueling and power generation projects. The U.S. Coast Guard may become involved through their development of docking facilities.

The listing of the southwest Alaska DPS of the northern sea otter would subsequently lead to the development of a recovery plan for this species. Such a plan will bring together Federal, State, local agency, and private efforts for the conservation of this species. A recovery plan establishes a framework for interested parties to coordinate activities and to cooperate with each other in conservation efforts. The plan will set recovery priorities, identify responsibilities, and estimate the costs of the tasks necessary to accomplish the

priorities. It will also describe site-specific management actions necessary to achieve the conservation of the southwest Alaska DPS of the northern sea otter. Additionally, pursuant to Section 6 of the Act, we would be able to grant funds to the State of Alaska for management actions promoting the conservation of the southwest Alaska DPS of the northern sea otter.

Section 9 of the Act prohibits take of endangered wildlife. The Act defines take to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect or to attempt to engage in any such conduct. However, the Act also provides for the authorization of take and exceptions to the take prohibitions. Take of listed species by non-Federal property owners can be permitted through the process set forth in section 10 of the Act. For federally funded or permitted activities, take of listed species may be allowed through the consultation process of section 7 of the Act. The Service has issued regulations (50 CFR 17.31) that generally apply to threatened wildlife the prohibitions that section 9 of the Act establishes with respect to endangered wildlife. Our regulations for threatened wildlife also provide that a "special rule" under section 4(d) of the Act can be tailored for a particular threatened species. In that case, the general regulations for some section 9 prohibitions do not apply to that species, and the special rule contains the prohibitions, and exemptions, necessary and appropriate to conserve that species. The Act provides for an exemption for Alaska Natives in section 10(e) that allows any Indian, Aleut, or Eskimo who is an Alaskan Native who resides in Alaska to take a threatened or endangered species if such taking is primarily for subsistence purposes. Non-edible by-products of species taken pursuant to section 10(e) may be sold in interstate commerce when made into authentic native articles of handicrafts and clothing. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Further, it is illegal for any person to commit, to solicit another person to commit, or cause to be committed, any of these acts. Certain exceptions to the prohibitions apply to our agents and State conservation agencies.

The Act provides for the issuance of permits to carry out otherwise prohibited activities involving threatened or endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 and 17.23. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in the course of otherwise lawful activities. Permits are also available for zoological exhibitions, educational purposes, or special purposes consistent with the purposes of the Act. Requests for copies of the regulations on listed species and inquiries about prohibitions and permits may be addressed to the Endangered Species Coordinator, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, Alaska 99503.

It is our policy, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not likely constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effects of the listing on proposed and ongoing activities within a species' range.

For the southwest DPS of the northern sea otter, we believe that, based on the best available information, the following activities are unlikely to result in a violation of section 9, provided these activities are carried out in accordance with existing regulations and permit requirements:

(1) Possession, delivery, or movement, including interstate transport of authentic native articles of handicrafts and clothing made from northern sea otters that were collected prior to the date of publication in the **Federal Register** of a final regulation adding the southwest Alaska DPS of the northern sea otter to the list of threatened species;

(2) Sale, possession, delivery, or movement, including interstate transport of authentic native articles of handicrafts and clothing made from sea otters from the southwest Alaska DPS that were taken and produced in accordance with section 10(e) of the Act;

(3) Any action authorized, funded, or carried out by a Federal agency that may affect the southwest Alaska DPS of the northern sea otter, when the action is conducted in accordance with an incidental take statement issued by us under section 7 of the Act;

(4) Any action carried out for the scientific research or to enhance the propagation or survival of the southwest Alaska DPS of the northern sea otter that is conducted in accordance with the conditions of a section 10(a)(1)(A) permit; and

(5) Any incidental take of the southwest Alaska DPS of the northern sea otter resulting from an otherwise lawful activity conducted in accordance with the conditions of an incidental take permit issued under section 10(a)(1)(B) of the Act. Non-Federal applicants may design a habitat conservation plan (HCP) for the species and apply for an incidental take permit. HCPs may be developed for listed species and are designed to minimize and mitigate impacts to the species to the greatest extent practicable.

We believe the following activities could potentially result in a violation of section 9 and associated regulations at 50 CFR 17.3 with regard to the southwest DPS of the northern sea otter; however, possible violations are not limited to these actions alone:

(1) Unauthorized killing, collecting, handling, or harassing of individual sea otters;

(2) Possessing, selling, transporting, or shipping illegally taken sea otters or their pelts;

(3) Unauthorized destruction or alteration of the nearshore marine benthos that actually kills or injures individuals sea otters by significantly impairing their essential behavioral patterns, including breeding, feeding or sheltering; and,

(4) Discharge or dumping of toxic chemicals, silt, or other pollutants (*i.e.*, sewage, oil, pesticides, and gasoline) into the nearshore marine environment that actually kills or injures individuals sea otters by significantly impairing their essential behavioral patterns, including breeding, feeding or sheltering.

We will review other activities not identified above on a case-by-case basis to determine whether they may be likely to result in a violation of section 9 of the Act. We do not consider these lists to be exhaustive and provide them as information to the public. You may direct questions regarding whether specific activities may constitute a violation of section 9 to the Field Supervisor, U.S. Fish and Wildlife Service, Anchorage Ecological Services Field Office, 605 West 4th Avenue, Room G–62, Anchorage, Alaska 99501.

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we request comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this DPS;

(2) The location of any additional populations of this DPS;

(3) The specific physical and biological features to consider, and specific areas that meet the definition of critical habitat and that should or should not be considered for critical habitat designation as provided by section 4 of the Act;

(4) Additional information concerning the range, distribution, and size of this DPS; and

(5) Current or planned activities in the subject area and their possible impacts on this DPS.

If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods, as listed above in **ADDRESSES.** If you submit comments by e-mail, please submit them as an ASCII file format and avoid the use of special characters and encryption. Please include "Attn: [RIN 1018–AI44]" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, contact us directly by calling our Marine Mammals Management Office at phone number 907/786–3800. Please note that this e-mail address will be closed out at the termination of the public comment period.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. Anonymous comments will not be considered. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

We will take into consideration your comments and any additional information received on this DPS when making a final determination regarding this proposal. The final determination may differ from this proposal based upon the information we receive.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will solicit the expert opinions of at least three appropriate and independent specialists for peer review of this proposed rule. The purpose of such review is to ensure that listing decisions are based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed listing of this species. We will summarize the opinions of these reviewers in the final decision document, and we will consider their input as part of our process of making a final decision on the proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. You may request a public hearing on this proposed rule. Your request for a hearing must be made in writing and filed at least 15 days prior to the close of the public comment period. Address your request to the Supervisor (see **ADDRESSES** section). We will schedule at least one public hearing on this proposal, if requested, and announce the date, time, and place of any hearings in the **Federal Register** and local newspapers at least 15 days prior to the first hearing.

Clarity of the Rule

Executive Order 12866 requires agencies to write regulations that are easy to understand. We invite your comments on how to make this proposal easier to understand including answers to questions such as the following: (1) Is the discussion in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposal? (2) Does the proposal contain technical language or jargon that interferes with its clarity? (3) Does the format of the proposal (groupings and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? What else could we do to make the proposal easier to understand? Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C. Street NW., Washington, DC 20240. You may also e-mail the comments to this address: *Exsec@ios.doi.gov.*

Executive Order 13211

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This rule is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

National Environmental Policy Act

We have determined that we do not need to prepare an Environmental Assessment and/or an Environmental Impact Statement as defined under the authority of the National Environmental Policy Act of 1969, in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Paperwork Reduction Act

This rule does not contain any new collections of information that require approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*). This proposed rule will not impose new recordkeeping or reporting requirements on State or local governments, individuals, business, or organizations. We 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.

References Cited

A complete list of all references cited in this proposal is available upon request. You may request a list of all references cited in this document from the Supervisor, Marine Mammals Management Office (*see* **ADDRESSES**).

Author

The primary author of this proposed rule is Douglas M. Burn, Marine Mammals Management Office (*see* **ADDRESSES**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Section 17.11(h) is amended by adding the following, in alphabetical order under MAMMALS, to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
MAMMALS							
*	*	*	*	*	*		*
Otter, northern sea	*Enhydra lutris kenyoni.*	U.S.A. (AK, WA, OR, CA).	Southwest Alaska, from Attu Island to Western Cook Inlet, incuding Bristol Bay, the Kodiak Archipelago, and the Barren Islands.	T	.....	NA	NA
*	*	*	*	*	*		*

Dated: December 9, 2003.

Steve Williams,

Director, Fish and Wildlife Service.

[FR Doc. 04–2844 Filed 2–10–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 635

[Docket No. 040202035–4035–01; I.D. 112403A]

RIN 0648–AR80

Atlantic Highly Migratory Species (HMS); Pelagic Longline Fishery

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

ACTION: Proposed rule; request for comments; public hearings.

SUMMARY: This proposed rule would reduce bycatch and bycatch mortality of sea turtles caught incidentally in the Atlantic and Gulf of Mexico HMS pelagic longline fisheries, consistent with the requirements of the Endangered Species Act (ESA). Based upon the results of an experiment in the Northeast Distant (NED) statistical reporting area and information indicating that the level of incidental takes of sea turtles established for the HMS pelagic longline fishery has been exceeded, NMFS proposes to implement new sea turtle bycatch mitigation measures throughout the fishery, including the NED statistical reporting area, and to reopen the NED closed area. Through experimentation in the NED, certain hook and bait measures have proven to be effective at reducing sea turtle bycatch, and are expected to reduce bycatch mortality and interactions with these species. The proposed bycatch mitigation measures include mandatory pelagic longline circle hook and bait requirements, and mandatory possession and use of onboard equipment to reduce sea turtle bycatch mortality. The intent of this proposed action is to reduce interactions with, and post-release mortality of, threatened and endangered sea turtles in HMS pelagic longline fisheries to comply with the ESA and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments on the proposed rule must be received no later than 5 p.m., eastern standard time, on March 15, 2004. NMFS will hold public hearings from March 2, 2004, through March 9, 2004. *See* **ADDRESSES** for specific locations, dates, and times.

ADDRESSES: The public hearing locations, dates and times are:

1. Tuesday, March 2, 2004 - North Dartmouth, MA, 7 - 9 p.m. University of Massachusetts at Dartmouth, 285 Old Westport Road, Deon Building, Room 105, North Dartmouth, MA 02747–2300;

2. Thursday, March 4, 2004 - New Orleans, LA, 7 - 9 p.m. New Orleans Airport Hilton Hotel, 901 Airline Drive, Kenner, LA 70062; and

3. Tuesday, March 9, 2004 - Manteo, NC, 7 - 9 p.m. North Carolina Aquarium on Roanoke Island, 374 Airport Road, Manteo, NC 27954–0967.

Written comments on the proposed rule should be submitted to Christopher Rogers, Chief, Highly Migratory Species (HMS) Management Division (SF/1), National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. Comments may be sent via facsimile (fax) to 301–713–1917. Comments on this proposed rule may also be submitted by e-mail. The mailbox address for providing e-mail comments is: *0648AR80.PROPOSED@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: 0648–AR80. For copies of the Draft Supplemental Environmental Impact Statement/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (DSEIS/RIR/IRFA), contact Russell Dunn at (727) 570–5447.

FOR FURTHER INFORMATION CONTACT: Russell Dunn, Greg Fairclough, or Richard A. Pearson at (727) 570–5447 or fax (727) 570–5656.

SUPPLEMENTARY INFORMATION: The Atlantic tuna and swordfish fisheries are managed under the authority of the Magnuson-Stevens Act and the Atlantic Tunas Convention Act (ATCA). Atlantic sharks are managed under the authority of the Magnuson-Stevens Act. The Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP), finalized in 1999, is implemented by regulations at 50 CFR part 635. The Atlantic pelagic longline fishery is also subject to the requirements of the ESA and the Marine Mammal Protection Act (MMPA).

Management History of Sea Turtle Bycatch Reduction

Under the ESA, Federal agencies must consult with either the U.S. Fish and Wildlife Service or NMFS whenever they authorize, fund, or carry out an action that may adversely affect a threatened or endangered species or its designated critical habitat. In the case of marine fisheries, the NMFS Office of Sustainable Fisheries consults with its Office of Protected Resources. After consultation, NMFS issues a Biological

Opinion (BiOp) that determines whether a fishery management action is likely to jeopardize the continued existence of threatened or endangered populations of marine species, including sea turtles. If the determination is that the action is likely to jeopardize a listed species, NMFS provides one or more reasonable and prudent alternatives (RPA) that would permit the activity to proceed without creating jeopardy. NMFS then identifies the amount or level of incidental take of endangered species (incidental take statement (ITS)), and specifies the terms and conditions which must be met in order to mitigate impacts on a listed species. ESA consultation must be reinitiated when a regulated action exceeds the level of take previously identified in an existing ITS; if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; or if the action is subsequently modified in a manner that causes an effect that was not considered in an existing BiOp.

Since 1999, three BiOps have been issued that address the HMS pelagic longline fishery (April 23, 1999; June 30, 2000; June 14, 2001). In November, 1999, NMFS reinitiated ESA consultation based upon information indicating that the number of sea turtles taken in the pelagic longline fishery had exceeded the ITS established by the April 23, 1999, BiOp. Also, proposed regulations (64 FR 69982, December 15, 1999) to reduce bycatch in the HMS pelagic longline fishery triggered the need to reinitiate consultation. The resulting June 30, 2000, BiOp concluded that the pelagic longline fishery was likely to jeopardize the continued existence of loggerhead and leatherback sea turtles.

To implement the RPA in June 30, 2000, BiOp, NMFS issued emergency regulations (65 FR 60889, October 13, 2000) that closed a 55,970–square nautical mile, L-shaped portion of the NED area to pelagic longline fishing from October 10, 2000, through April 9, 2001, and required the possession and use of line clippers and dipnets for all HMS-permitted pelagic longline vessels. NMFS published an interim final rule on March 30, 2001 (66 FR 17370), continuing the requirement to possess and use dipnets and line clippers on all vessels in the pelagic longline fishery.

On June 14, 2001, NMFS issued a new BiOp incorporating information obtained from a January 2001 technical gear workshop, and a February 2001 report entitled "Stock Assessment of Loggerhead and Leatherback Sea Turtles and an Assessment of the Impact of the Pelagic Longline Fishery on Loggerhead and Leatherback Sea Turtles of the Western North Atlantic." The June 14, 2001, BiOp determined that the FMP was likely to jeopardize loggerhead and leatherback sea turtles. The BiOp included an RPA that required, among other measures, closure of the NED. After implementation of the RPA, the anticipated incidental take levels (i.e., interactions) established for the HMS pelagic longline fishery in the June 14, 2001, BiOp were: leatherback sea turtles - 438 estimated captured per calendar year; loggerhead sea turtles - 402 estimated captured per calendar year; green, hawksbill, and Kemps ridley sea turtles (combined) - 35 estimated captured per calender year. If these incidental take levels were exceeded, the BiOp required reinitiation of consultation and a review of the RPA that was provided.

NMFS issued an emergency rule on July 13, 2001, (66 FR 36711; revised on September 24, 2001 (66 FR 48812)) to implement the RPA, including a closure of the NED area to pelagic longline vessels through January 9, 2002, gear modifications outside the NED area, and a requirement to post sea turtle handling and release guidelines on HMS-permitted vessels. The emergency rule was later extended for an additional 180 days through July 8, 2002. A final rule, published on July 9, 2002 (67 FR 45393), implemented the RPA required by the June 14, 2001, BiOp.

The RPA recognized that developing gear technologies or fishing strategies capable of significantly reducing the likelihood of capturing sea turtles or dramatically reducing mortality rates of captured sea turtles was necessary to minimize the effects of domestic and international longline fishing activities on sea turtle populations. NMFS undertook a 3–year research experiment (2001–2003) in the NED to develop or modify fishing gear and techniques to reduce sea turtle interactions and the mortality associated with such interactions. Upon successful completion of the gear research experiment and its final analysis, the BiOp required that NMFS implement a rule to require the adoption of complementary bycatch reduction measures. The rule would be required before pelagic longline vessels could fish again within the NED area.

Estimated 2002 Bycatch of Sea Turtles in the U.S. Atlantic HMS Pelagic Longline Fishery

Pelagic longline gear consists of a mainline, often many miles long, suspended in the water column by floats and from which baited hooks are attached on leaders (gangions). It is often used to target HMS. Though not completely selective, pelagic longline gear can be modified through gear configuration, hook depth, and timing of sets to target swordfish, yellowfin tuna, or bigeye tuna.

Due to interactions with protected resources and bycatch of recreationally-important finfish, the pelagic longline fishery has had a fishery observer program in place since 1992 to document finfish bycatch, characterize fishery behavior, and quantify interactions with protected species. In addition, a mandatory fishery logbook system has been in place since 1992 requiring boat captains to report fishing effort, gear characteristics, and commercial catch. Thus, there is information available on both the absolute level of effort in this fishery and bycatch rates of protected species.

These data are used to generate annual estimates of sea turtle bycatch. Bycatch rates (catch-per-hook) of protected species are quantified based upon observer data by year, fishing area, and quarter. The estimated bycatch rate is then multiplied by the total fishing effort (number of hooks), as reported to the mandatory fishery logbook program, to obtain estimates of total interactions with protected species. These methods, as well as a description of any sources of bias or uncertainty, are detailed in a report entitled, "Estimated Bycatch of Marine Mammals and Turtles in the U.S. Atlantic Pelagic Longline Fleet During 2001 - 2002" (NOAA Technical Memorandum NMFS-SEFSC 515 (2003)).

In 2002, 9,614 sets were reported and 856 sets were observed, for an average total observer coverage rate of 8.9 percent. The 2002 total reported pelagic longline fishing effort, including the NED area research experiment, was 7.15 million hooks. There were 335 observed interactions with marine turtles. Many of these interactions occurred during the NED experimental fishery, but are not counted against the ITS because the experimental fishery had a separate ITS. As described below, the greatest number of turtle takes during fishing occurred in 2002 in the Gulf of Mexico (GOM) in the 2nd and 3rd quarters. One leatherback turtle was observed dead during 2002. The vast majority of the remaining turtles were reported as being released alive and injured. Most of these were hooked. Leatherback turtles were most typically hooked in the front shoulder, armpit, or flipper, while loggerhead turtles more often swallowed the hook or were hooked in the mouth. In the NED gear experiment, the majority of fishing gear was removed prior to release, with the exception of sea turtles

that swallowed hooks. For turtles that swallowed hooks, the trailing line was generally removed before releasing the turtle.

A total of 962 leatherback sea turtle interactions and 575 loggerhead sea turtle interactions were estimated for 2002. Interactions with leatherback sea turtles occurred predominantly in the GOM area (695 animals), while loggerhead interactions were distributed across the GOM area (170 animals), the Northeast coastal (NEC) area (147 animals), the Florida east coast (FEC) area (99 animals), and the mid-Atlantic bight (MAB) area (94 animals). These estimates indicate that the current ITS established for leatherback and loggerhead sea turtles in the June 14, 2001, BiOp has been exceeded. Accordingly, NMFS has reinitiated consultation on the Atlantic HMS pelagic longline fishery, as required by the ESA.

Results of the NED Gear Experiment

In cooperation with the U.S. Atlantic pelagic longline fleet, NMFS recently completed a 3–year gear experiment permitted pursuant to section 10 of the ESA in the NED statistical reporting area to develop and test methods to reduce bycatch, and bycatch mortality, of sea turtles caught incidentally while commercial pelagic longline fishing. A key objective of the research experiment was to develop and verify techniques to reduce sea turtle interactions that could be "exported" and applied throughout the range of the domestic and international pelagic longline fishery in the Atlantic basin, and possibly the Pacific Ocean.

The experiment identified various sea turtle bycatch mitigation techniques, primarily involving hook and bait combinations, that reduced sea turtle interactions. In 2002, the experimental design evaluated the effects of an 18/0 non-offset circle hook, an 18/0 offset circle hook (10°) with squid bait, and the use of whole mackerel bait on both offset "J" hooks (control) and 18/0 offset circle hooks in reducing sea turtle interactions with pelagic longline gear. In 2003, the experimental design evaluated the effects of an 18/0 non-offset circle hook with squid bait, an 18/0 offset circle hook (10°) with mackerel bait, and a 20/0 circle hook with mackerel bait. The experiment further tested three hook treatments to examine their impacts on tuna catches.

A "J" hook is generally "J"-shaped with the barb pointing upward. Unlike a "J" hook, a circle hook possesses a barb pointing perpendicularly back to the shank. An offset circle hook is a circle hook in which the barbed end of the hook is displaced relative to the parallel plane of the eyed-end, or shank, of the hook when laid on its side

Both loggerhead and leatherback sea turtle catch rates were significantly reduced for the 18/0 non-offset circle hook with squid bait, as compared to the "J" hook with squid bait. Combined data for years 2002 and 2003 of the experiment provided a reduction rate of 74.03 percent for loggerhead sea turtle interactions. The reduction rate for leatherback sea turtles was 75.38 percent. There was a loss of swordfish by weight of 30.35 percent. There was a nominal increase in bigeye tuna catch by weight of 25.23 percent, but this was not found to be statistically significant.

Loggerhead and leatherback sea turtle catch rates were also significantly reduced with the 18/0 offset circle hook with squid bait, as compared to the "J" hook with squid bait. The mean reduction rate for loggerhead sea turtles was 85 percent. The mean reduction rate for leatherback sea turtles was 50 percent. There was a mean loss of swordfish by weight of 29 percent. There was also a nominal increase in bigeye tuna catch, which was not found to be statistically significant. This hook treatment was not tested during 2003.

Loggerhead and leatherback sea turtle catch rates were also significantly reduced by using whole mackerel bait, rather than squid bait, on "J" hooks. The mean reduction rate for loggerhead sea turtles was 75 percent. For leatherback sea turtles, there was a mean reduction rate of 67 percent. There was a 63–percent mean increase of swordfish by weight. However, there was a 90–percent reduction in bigeye tuna catch by weight. This hook treatment was not tested during 2003.

The best reduction rate for loggerhead sea turtles was achieved by using a combination of whole mackerel bait with an 18/0 offset circle hook. Combined data for years 2002 and 2003 of the experiment provided a reduction rate of 90.58 percent for loggerhead sea turtle interactions. The reduction rate for leatherback turtles was 67.25 percent. There was an increase in swordfish catch by weight of 15.62 percent. However, there was a loss of 83.84 percent for bigeye tuna by weight.

The results of the experimental research indicate that loggerhead and leatherback sea turtle interactions associated with the Western Atlantic HMS pelagic longline fishery can be significantly reduced by employing 18/0 offset (10°) circle hooks with whole mackerel, rather than squid, as bait. When the two treatments are used together, reductions in turtle interactions can be obtained without negatively impacting swordfish catch. Benefits associated with swordfish (increased catches) may be less certain when fishing occurs in warmer ocean temperatures and may decline to zero, or even result in declining catches. This same combination, specifically the use of whole mackerel bait, could negatively impact bigeye tuna catches. In general, treatments that are effective at minimizing turtle interactions, and that have positive impacts on swordfish catches, have negative impacts on tuna catches and vise-versa.

Proposed Commercial Management Measures

The intent of this proposed rule is to reduce the incidental take of threatened and endangered sea turtles, and to reduce post-release mortality of incidentally-captured sea turtles, in the HMS pelagic longline fishery to comply with the ESA, and in accordance with the M-S Act and other applicable Federal law. To achieve these reductions, results from the NED gear experiment are proposed to be applied to the HMS pelagic longline fishery as a whole.

As previously discussed, the measures in this proposed rule were first developed and tested during the NED gear experiment. Because of their effectiveness at reducing sea turtle bycatch without negatively impacting swordfish catch, implementation of the proposed management measures (e.g., circle hook and bait requirements, possession and use of sea turtle release gear, and adherence to sea turtle handling protocols) will mitigate the need for a year-round closure of the NED area. However, management measures for the entire HMS pelagic longline fishery are necessary because, based upon available information, the sea turtle ITS established in the June 14, 2001, BiOp has been exceeded as a result of fishing activity occurring outside of the NED. Reopening the NED is expected to result in between 18 - 46 additional loggerhead interactions, and between 36 - 54 additional leatherback interactions under the preferred alternatives. The proposed management measures, described below, are projected to reduce sea turtle interactions for the entire HMS pelagic longline fishery to levels that will be in compliance with the ESA.

A. Proposed Sea Turtle Bycatch Release Equipment and Careful Release Protocols

Currently, to reduce injuries and mortalities associated with sea turtle interactions, all Atlantic vessels that have pelagic longline gear onboard and

have been issued, or are required to have, Federal HMS limited access permits, must possess onboard sea turtle release gear, including line clippers and dipnets that meet minimum design standards. Dipnets are required to boat sea turtles, when practicable, and line clippers are required to disengage any hooked or entangled sea turtles by cutting the line as close as possible to the hook. Pelagic longline vessels are also currently required to post, inside the wheelhouse, a plastic placard provided by NMFS describing careful handling and release guidelines for incidentally-captured sea turtles. Turtles that are brought on board are also currently required to be handled in accordance with procedures specified by NOAA's Office of Protected Resources at § 223.206(d)(1).

The proposed sea turtle bycatch release equipment requirements, described below, would similarly apply to all Atlantic vessels that have pelagic longline gear onboard and have been issued, or are required to have, Federal HMS limited access permits. The requirement to possess and utilize line clippers and dipnets would remain in effect. However, the design standards for this equipment are proposed to be slightly modified. The modified design standards for line cutters may still be represented by the Arceneaux line clipper, as well as the NOAA/LaForce Line Cutter model. Line cutters may also be fabricated using available materials. The minimum design standards for dipnets are largely unchanged, except that the extended reach handle is proposed to be amended by specifying that its length must be a minimum of 150–percent of the vessel's freeboard, or 6–feet (1.83 m), whichever is greater. Several additional pieces of required equipment to facilitate the removal of fishing hooks from incidentally-captured sea turtles are being proposed in this rule. Diagrams for several of the proposed pieces of equipment are provided in Appendix B1 to the DSEIS prepared for this proposed rule in a draft document entitled, "Requirements and Equipment Needed for the Careful Release of Sea Turtles Caught in Hook and Line Fisheries." This document is also available on the HMS website at *http://www.nmfs.noaa.gov/sfa/hms.* Minimum design standards for the pieces of equipment are provided in the proposed regulations.

The following new, or newly-revised, gears are proposed to be required: (A) a long-handled line clipper or cutter; (B) a long-handled dehooker for ingested hooks; (C) a long-handled dehooker for external hooks; (D) a long-handled device to pull an "inverted V"; (E)a dipnet; (F) a standard automobile tire; G) a short-handled dehooker for ingested hooks; (H) a short-handled dehooker for external hooks; (I) long-nose or needle-nose pliers; (J) a bolt cutter; (K) a monofilament line cutter; and, (L) two different types of mouth openers and mouth gags (including either a block of hard wood, a set of three canine mouth gags, a set of two sturdy dog chew bones, a set of two rope loops covered with hose, a hank of rope, a set of four PVC splice couplings, or a large avian oral speculum).

Items A - D above are intended to be used for turtles that are not boated. Items E - L above are intended to be used for turtles that are brought onboard. The long-handled dehooker for ingested hooks required in Item B would also satisfy the requirement for Item C. If a 6–foot (1.83 m) J-style dehooker is used for Item C, it would also satisfy the requirement for Item D. Similarly, the short-handled dehooker for ingested hooks required for Item G would also satisfy the requirement for Item H. NMFS recommends, but has not proposed a requirement, that one type of mouth opener/mouth gag allow for hands-free operation of the dehooking device or other tool, after the mouth gag is in place. Only a canine mouth gag would satisfy this recommendation. Also, as described in Appendix B1 of the DSEIS prepared for the proposed rule, a "turtle tether" and a "turtle hoist" are recommended by NMFS, but are not being proposed as requirements.

Table 1 provides an initial list of sea turtle bycatch release equipment that is approved as meeting the minimum design standards. At this time, NMFS is aware of only one manufacturer of long-handled and short-handled dehookers for ingested hooks that meet the minimum design standards. However, this proposed rule would allow for approval of other devices, as they become available, if they meet the minimum design standards. Line cutters or line clippers (items A and K) and dehookers (items B, C, G, H) not included on the initial list must be NMFS-approved before being used. NMFS would publish a notice in the **Federal Register** of any new items approved as meeting the design standards.

TABLE 1. NMFS-APPROVED MODELS FOR EQUIPMENT NEEDED FOR THE CAREFUL RELEASE OF SEA TURTLES CAUGHT IN HOOK AND LINE FISHERIES

Required Item	NMFS-Approved Models
(A) Long-handled line cutter	LaForce Line Cutter; or Arceneaux Line Clipper
(B) Long-handled dehooker for ingested hooks	ARC Pole Model Deep-Hooked Dehooker (Model BP11)
(C) Long-handled dehooker for external hooks	ARC Model LJ6P (6 ft (1.83 m)); or ARC Model LJ36; or ARC Pole Model Deep-Hooked Dehooker (Model BP11); or ARC 6 ft. (1.83 m) Pole Big Game Dehooker (Model P610)
(D) Long-handled device to pull an "inverted V"	ARC Model LJ6P (6 ft.); or Davis Telescoping Boat Hook to 96 in. (2.44 m) (Model 85002A); or West Marine # F6H5 Hook and # F6-006 Handle
(E) Dipnet	ARC 12–ft. (3.66–m) Breakdown Lightweight Dip Net Model DN6P (6 ft. (1.83 m)); or ARC Model DN08 (8 ft.(2.44 m)); or ARC Model DN 14 (12 ft. (3.66 m)); or ARC Net Assembly & Handle (Model DNIN); or Lindgren-Pitman, Inc. Model NMFS Turtle Net
(F) Standard automobile tire	Any standard automobile tire free of exposed steel belts
(G) Short-handled dehooker for ingested hooks	ARC 17–inch (43.18–cm) Hand-Held Bite Block Deep-Hooked Turtle Dehooking Device (Model ST08)
(H) Short-handled dehooker for external hooks	ARC Hand-Held Large J-Style Dehooker (Model LJ07); or ARC Hand-Held Large J-Style Dehooker (Model LJ24); or ARC 17–inch (43.18–cm) Hand-Held Bite Block Deep-Hooked Turtle Dehooking Device (Model ST08); or Scotty's Dehooker
(I) Long-nose or needle-nose pliers	12–in. (30.48–cm) S.S. NuMark Model #030281109871; or any 12–inch (30.48–cm) stainless steel long-nose or needle-nose pliers
(J) Bolt cutter	H.K. Porter Model 1490 AC

TABLE 1. NMFS-APPROVED MODELS FOR EQUIPMENT NEEDED FOR THE CAREFUL RELEASE OF SEA TURTLES CAUGHT IN HOOK AND LINE FISHERIES—Continued

Required Item	NMFS-Approved Models
(K) Monofilament line cutter	Jinkai Model MC-T
(L) Two of the following Mouth Openers and Mouth Gags	
(L1) Block of hard wood	Any block of hard wood meeting design standards (e.g., Olympia Tools Long-Handled Wire Brush and Scraper (Model 974174))
(L2) Set of (3) canine mouth gags	Jorvet Model #4160, 4162, and 4164
(L3) Set of (2) sturdy dog chew bones	Nylabone® (a trademark owned by T.F.H. Publications, Inc.); or Gumabone® (a trademark owned by T.F.H. Publications, Inc.); or Galileo® (a trademark owned by T.F.H. Publications, Inc.)
(L4) Set of (2) rope loops covered with hose	Any set of (2) rope loops covered with hose meeting design standards
(L5) Hank of rope	Any size soft braided nylon rope is acceptable, provided it creates a hank of rope approximately 2 - 4 inches (5.08 cm - 10.16 cm) in thickness
(L6) Set of (4) PVC splice couplings	A set of (4) Standard Schedule 40 PVC splice couplings (1–inch (2.54–cm), 1 1/4–inch 3.175–cm), 1 1/2 inch (3.81–cm), and 2–inch (5.08–cm)
(L7) Large avian oral speculum	Webster Vet Supply (Model 85408); or Veterinary Specialty Products (Model VSP 216–08); orJorvet (Model J–51z); or Krusse (Model 273117)

The proposed measures regarding sea turtle handling and careful release protocols, described below, would apply to all Atlantic vessels that have pelagic longline gear onboard and have been issued, or are required to have, Federal HMS limited access permits. The existing requirement to post a plastic placard inside the wheelhouse describing sea turtle handling and release guidelines would remain in effect, as would the requirement to adhere to existing sea turtle handling and resuscitation procedures specified by NOAA's Office of Protected Resources at § 223.206(d)(1). Additional sea turtle handling requirements at § 635.21(c)(5)(ii) are being proposed in this rule to improve the care of sea turtles on deck, and to facilitate the removal of fishing line and hooks from incidentally-captured sea turtles. The newly proposed procedures for hook removal and careful release of sea turtles are described in detail in a document entitled, "Careful Release Protocols for Release with Minimal Injury," which is provided in Appendix B2 of the DSEIS prepared for this proposed rule, and which is proposed to be required onboard all HMS pelagic longline vessels. This document is also available on the HMS website at *http://www.nmfs.noaa.gov/sfa/hms.*

This proposed rule also makes a minor revision to the regulatory text at § 223.206(d)(1)(ii) to clarify that the turtle handling and resuscitation provisions of § 223.206(d)(1)(i) are in addition to the turtle handling requirements in 50 CFR 635.21.

B. Proposed HMS Pelagic Longline Gear Modifications

This proposed rule would require that vessels which have pelagic longline gear on board and that have been issued, or are required to have, a limited access swordfish, shark, or tuna longline category permit for use in the Atlantic Ocean including the Caribbean Sea and the Gulf of Mexico would be limited, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i) 18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait only; or, (ii) 18/0 or larger non-offset circle hooks and squid bait only. Only one of these two types of hook and bait combinations would be allowed to be possessed onboard and/or used on a pelagic longline vessel during a trip. A "circle hook" is proposed to be defined as a fishing hook with the point turned perpendicularly back to the shank. The "offset" is proposed to be measured from the barbed end of the hook and is relative to the parallel plane of the eyed-end, or shank, of the hook when laid on its side. The outer diameter of an 18/0 circle hook at its widest point must be no smaller than 1.97 inches (50 mm), when measured with the eye of the hook on the vertical axis (y-axis) perpendicular to the horizontal axis (x-axis). Pictures of these two types of circle hooks and a diagram explaining how to measure the offset are provided in the DSEIS prepared for this proposed rule.

Whole mackerel bait is proposed to be defined as whole Atlantic mackerel (*Scomber scombrus*), and not pieces or chunks of the fish. NMFS is specifically proposing to require whole Atlantic mackerel bait for use with 18/0 or larger offset circle hooks, because the NED gear research experiment documented the effects of this hook and bait combination on catches of swordfish, tunas and sea turtles. However, NMFS recognizes that whole Atlantic mackerel may not be traditionally used in some regions of the country or, at times, may be difficult to obtain. Therefore, NMFS is requesting comment on the availability and feasibility of requiring the use of whole Atlantic mackerel bait.

These management measures are being proposed to reduce interactions with sea turtles and to assure compliance with the ESA, while minimizing, to the extent practicable, adverse economic impacts on commercial fishing vessels. Based upon data obtained from the NED gear experiment, the deployment of 18/0 or larger offset circle hooks and whole mackerel bait is expected to reduce loggerhead sea turtle interactions by 90.58 percent and leatherback sea turtle interactions by 67.26 percent, while increasing swordfish catches by 15.62 percent. Increased catches of swordfish, by weight, may be less certain when fishing in warmer ocean temperatures and may decline to zero, or even result in declining catches.

The NED gear experiment results also indicate that using 18/0 or larger non-offset circle hooks with squid bait will reduce loggerhead sea turtle interactions by 74.03 percent and leatherback sea turtle interactions by 75.38 percent, without negatively impacting bigeye tuna catches. While both hook and bait treatments are effective at reducing turtle interactions, the treatment that increased swordfish catches (i.e., option

i - 18/0 or larger offset circle hooks and whole mackerel bait) generally reduced tuna catches, and vice versa.

Based upon the successful results of the NED gear experiment, NMFS proposes to remove the current prohibition on pelagic longline fishing in the NED statistical reporting area, because the proposed hook and bait regulations will reduce sea turtle interactions throughout the fishery to the extent that the fishery management action will not be likely to jeopardize sea turtles.

Request For Specific Comments

In addition to comments on the proposed measures described above, NMFS is specifically requesting public comment on six items. First, NMFS requests information on the current availability of 18/0 offset and non-offset circle hooks, and the amount of time that would be needed to fill orders for vessels required to use these hooks, as well as information on the amount of time needed for vessels to come into compliance after final regulations are published. NMFS recognizes that vessel owners may want to fish in the NED, or elsewhere, as soon as possible, but NMFS may need to delay the effective date of final regulations to allow time for affected entities to comply with the new requirements. Second, NMFS is interested in receiving comments on the proposed definition of a circle hook. NMFS recognizes that hook shape is critical to achieving the conservation goals of this rulemaking. The lay definition of a circle hook, in which the point of the hook is turned back perpendicular to the shank of the hook, allows for a wide range of hook shapes, some of which more closely resemble traditional "J" hooks than true circles. More "J"-shaped circle hooks, where only the very tip of the barb is turned back perpendicular to the shank of the hook, may reduce the conservation benefit attributable to more circular-shaped circle hooks. Third, NMFS recognizes that there is no industry-standard definition of 16/0, 18/0 or 20/0 circle hooks. As such, hooks labeled 16/0, 18/0, or 20/0 may vary in size significantly from one manufacturer to another. NMFS seeks informed comment to better assist in developing minimum technical specifications to define the gauge of circle hooks and ensure that the intended ecological goals of this rulemaking are achieved. Fourth, NMFS is interested in receiving comments on the feasibility of requiring whole Atlantic mackerel (*Scomber scombrus*) bait versus whole finfish bait in terms of availability, practicality, and economic impacts, as well as the efficacy of whole Atlantic mackerel bait versus whole finfish bait in terms of maintaining catches of target species and reducing sea turtle interactions. Because the NED gear experiment documented the biological effects of using whole mackerel bait with an 18/0 offset circle hook, that requirement is being proposed. Fifth, NMFS is requesting public comment on the potential impacts on tuna catches of the proposed regulations requiring the use of 18/0 or larger circle hooks. The NED gear experiment provided much information on the impacts of an 18/0 circle hook on swordfish catches, but not as much information on tuna catches, particularly yellowfin tuna. Finally, NMFS recognizes that an important component of reducing the mortality associated with the incidental capture of sea turtles is the removal of fishing gear, specifically hooks and line, in a manner that minimizes further trauma to the animals. As such, NMFS requests specific comment on the proposed possession and use requirements of release gear and handling protocols identified in the preferred alternatives and further detailed under Appendices B1 and B2 of the Draft Supplemental Environmental Impact Statement.

Alternative NEPA Procedures

To more rapidly reduce sea turtle interactions and to mitigate the economic impact of sea turtle bycatch mitigation measures, NMFS has requested and been authorized to execute alternative procedures for the preparation and completion of an SEIS. The Council on Environmental Quality has authorized a waiver of 14 of the standard 45 days for the DSEIS comment period, and 4 of the standard 30 days for the waiting period before the record of decision on this action can be finalized. The public comment period on the DSEIS and this proposed rule will remain open until 5 P.M. on March 15, 2004.

Classification

This proposed rule is published under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.*, and ATCA, 16 U.S.C. 971 *et seq.*

As required under the Regulatory Flexibility Act, NMFS has prepared an initial regulatory flexibility analysis (IRFA) that examines the impacts of the preferred alternatives and any significant alternatives to the proposed rule that could minimize significant economic impacts on small entities. A summary of the information presented in the IRFA is provided below. The Draft Supplemental Environmental Impact Statement (DSEIS) prepared for this proposed rule provides further discussion of the biological, social, and economic impacts of all the alternatives considered.

This proposed rule would apply to all Atlantic vessels that have pelagic longline gear onboard and have been issued, or are required to have, Federal HMS limited access permits. NMFS considers all commercial permit holders to be small entities. NMFS estimates that, as of November 2003, approximately 235 tuna longline limited access permits had been issued. In addition, approximately 203 directed swordfish limited access permits, 100 incidental swordfish limited access permits, 249 directed shark limited access permits, and 357 incidental shark limited access permits had been issued. Because vessels authorized to fish for swordfish and tunas with pelagic longline gear must also possess a tuna longline permit, a swordfish permit (directed or incidental), and a shark permit (directed or incidental), the maximum number of vessels potentially affected by this proposed rule is 235 (i.e., the number of tuna longline permits issued), although only about 60 percent of these permit holders are considered active (i.e., reported logbook landings) in the fishery. The addresses of these permit holders range from Texas through Maine, with Florida (74), Louisiana (42), New Jersey (33), New York (17), North Carolina (11), and Texas (10) representing the states with the most permitted HMS pelagic longline vessels.

Other sectors of HMS fisheries such as dealers, processors, bait houses and gear manufacturers might be indirectly affected by the proposed alternatives, particularly the shift to required circle hooks and bait types, and the required turtle bycatch mitigation gears. However, the proposed rule does not apply directly to them. Rather it applies only to permit holders and fishermen. As such, economic impacts on these other sectors are discussed in the DSEIS, but were not the focus of the IRFA.

The proposed regulations do not contain additional reporting or record-keeping requirements, but will result in additional compliance requirements, including the possession and use of specific hook types, baits, and sea turtle release equipment. In addition, certain specific protocols regarding the proper use of sea turtle release equipment and onboard turtle handling procedures are proposed to be implemented. A document containing the sea turtle careful release protocols will be issued, and will be required to be onboard. NMFS does not believe that the

proposed regulations would conflict with any other relevant regulations, Federal or otherwise (5 U.S.C. 603(b)(5)).

NMFS considered 16 alternatives in developing the DSEIS. The alternatives included: no action (Alternative A1), hook and bait modifications outside the NED (Alternatives A2 - A5), reopening the NED without hook and bait restrictions (Alternative A6), reopening the NED with hook and bait modifications (Alternatives A7 - A10), a total prohibition on pelagic longline gear in Atlantic HMS fisheries (Alternative A11), pelagic longline time and area closures (Alternatives A12 - A15), and sea turtle careful handling protocols and release gear design standards (Alternative A16).

The following alternatives are currently preferred: Alternative A3 (limit pelagic longline vessels fishing outside the NED, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i)18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait; or, (ii) 18/0 or larger non-offset (flat) circle hooks and squid bait); Alternative A10 (reopen the NED to pelagic longline fishing and limit pelagic longline vessels fishing in the NED, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i) 18/0 or larger circle hook with an offset not to exceed 10 degrees with whole mackerel bait; or, (ii) 18/0 or larger non-offset (flat) circle hook with squid bait); and Alternative A16 (require pelagic longline vessels to possess and use dipnets and line clippers meeting newly revised design standards, require additional sea turtle release equipment meeting minimum design standards, and require compliance with new sea turtle handling and release protocols).

For the purpose of this analysis, NMFS assumed that industry would choose to fish with an 18/0 hook (either offset or non-offset), and not with a larger hook, although that would be allowed. NMFS expects that the proposed circle hook and bait requirements (Alternatives A3 and A10) will increase compliance costs initially, but will result in long-term cost savings through lower replacement costs and, possibly, fewer lost hooks. An informal survey of gear suppliers indicated that large commercial grade 18/0 circle hooks cost approximately $0.26 to $0.66 per hook, with an average of $0.42 per hook. Assuming an average of 2,500 hooks per vessel are needed for one trip to initially comply with the proposed hook requirement, the compliance cost, on a per vessel basis, would range from $657.25 to $1,650.00, with an anticipated average per vessel cost of approximately $1,044.00. While fishermen will incur additional costs initially to purchase new hooks, long-term savings are anticipated because, on average, traditional "J"-hooks are more expensive than circle hooks ($0.57 per hook). Assuming that vessels do not already possess the required hook type, a high-end estimate of the cost (every hook lost on every set, no hook used more than once during the year) to re-rig the entire Atlantic pelagic longline fleet is $2.98 million (7,150,602 hooks fished in 2002 x $0.4176 per hook). The cost per vessel would be approximately $20,176 per vessel for a year's worth of hooks ($2,986,091/148 vessels). This, however, is likely to be an overestimate of the true costs because not every hook is expected to be lost on every set. Further, NMFS anticipates a cost savings of approximately 27 percent annually versus rigging with the same number of "J"-hooks.

The proposed circle hook and bait alternatives (A3 and A10) are not expected to increase the needed skill level required for HMS fisheries, as the physical act of switching hook types is a normal aspect of commercial fishing operations. However, using the new circle hooks will likely require some adaptations to existing skills.

The proposed management measures also require the use of certain baits. Traditionally, bait accounts for between 16 to 26 percent of the total costs per trip. Any fluctuations in price and availability of whole mackerel bait or squid bait could have a substantial impact on profitability, either positive or negative. There could also be unquantifiable compliance costs as fishing crews that have not traditionally fished with a particular hook and bait combination familiarize themselves with the most efficient techniques. Atlantic mackerel and squid are generally abundant, but price and availability will likely depend upon available domestic harvesting and distributional capacities.

The proposed requirements to possess sea turtle handling and release equipment, and to use the equipment in accordance with careful release protocols provided by NMFS (Alternative A16), will impose initial compliance costs and could require additional skills on behalf of fishermen. NMFS estimates that the full suite of sea turtle release gear could cost between $589.00 and $1048.80. Fishermen would be required to use NMFS-approved gear. *See* Table 1 for an initial list of approved gear. However, the design standards would allow fishermen to construct some of the equipment from material that is readily available and using skills that most fishermen likely possess. This could potentially reduce some of the costs. Further, the design standards were developed in cooperation with the fishing industry during the NED experiment.

Preferred Alternative A10 (open the NED area to pelagic longline fishing and limit pelagic longline vessels in that area, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i) 18/0 or larger circle hook with an offset not to exceed 10 degrees with whole mackerel bait; or, (ii) 18/0 or larger non-offset (flat) circle hook with squid bait) is expected to produce positive economic impacts for vessels that have historically fished in the NED. Given that pelagic longline vessels cannot currently fish in the NED, any income derived from future NED trips would result in positive economic impacts, regardless of any hook and bait restrictions that vessels may have to comply with in that area.

Based upon traditional levels of effort in the area, NMFS projects that 12 vessels would likely return to the NED if it is reopened. Preferred Alternative A10 provides vessels with the flexibility to select a hook and bait combination, prior to departing on a trip, that is effective at catching either swordfish or tunas. Based upon the results of the NED area research experiment, fishermen in the NED may realize a change in swordfish catches of +15.62 to -30.35 percent (by weight), depending upon whether they choose to equip and deploy the 18/0 offset circle hook with whole mackerel bait, or the 18/0 non-offset circle hook with squid, respectively. Increased catches of swordfish by weight may be less certain when fishing occurs in warmer ocean temperatures and may decline to zero, or even result in declining catches.

Results of the experiment also indicate that fishermen operating in the NED could experience changes in tuna catches of -83.84 to possibly as much as +25.26 percent (by weight), depending upon whether they choose to fish with 18/0 offset circle hook with whole mackerel bait, or an 18/0 non-offset circle hook with squid, respectively. However, these potential tuna increases are less certain, based on the limited tuna catch data obtained during the NED experiment. The experimental results indicate that when the tested hook and bait combinations have a positive impact on swordfish catches, they tend to have a negative impact on tuna catches, and vice versa. To

maximize revenues, given the impacts of these hook and bait combinations on swordfish and tuna catches, fishermen operating in the NED will have to make a decision prior to departing port about which species they will target, and which hook and bait they will deploy.

If fishermen choose to equip and deploy 18/0 offset circle hooks with whole mackerel bait in the NED area (Preferred Alternative A10- option i) to target swordfish, substantial positive economic impacts are anticipated. Assuming a steady state in all other aspects, including catches of other species and prices, the proportion of total landings historically attributable to swordfish could increase from 88.54 percent to the equivalent of 102.37 percent. Assuming that the projected 15.62–percent increase in the weight of swordfish landed would result in a 15.62–percent increase in revenues attributable to swordfish, NMFS believes that overall gross revenues of vessels may increase by 13.77 percent ($25,753) overall from $187,074 (average annual vessel gross revenue) to $212,827.

In the IRFA, hook and bait impacts on bigeye tuna catches, as documented during the NED experiment, are used as a proxy for impacts on all tuna catches. Assuming a steady state in all other aspects, including catches of other species and prices, NMFS projects that the portion of total historical landings attributable to tuna using an 18/0 offset circle hook and whole mackerel bait would decline from 9.85 percent (by weight) to 1.82 percent. Assuming that the projected 84–percent decrease in the weight of tuna landed would result in an 84–percent decrease in revenues attributable to tuna, NMFS believes that overall gross revenues of vessels may decrease by 9.45 percent (-$17,677) to $169,397. However, tuna catches have traditionally represented only a limited portion of total gross revenues for vessels fishing in the NED.

In summary, combining increased swordfish revenues with decreased tuna revenues, vessels fishing in the NED using an 18/0 offset circle hook and whole mackerel bait (Preferred Alternative A10 - option i) and engaging on a mixed target trip could see a total increase in gross vessel revenues of $8,076, from $187,074 to $195,150. The impact of this hook and bait combination on shark, dolphin and wahoo catches is unknown.

If fishermen choose to equip and deploy 18/0 non-offset circle hooks with squid bait in the NED (Preferred Alternative A10 - option ii), there would likely be some small positive impact relative to the status quo, but overall negative economic impacts from a historical perspective would be expected for fishermen targeting swordfish, or embarking upon a mixed target species trip in the NED. Fishermen would likely experience minor increases in revenues associated with tuna catches from a historical perspective, but these tuna revenue increases would not be expected to offset overall historical revenue losses stemming from decreased swordfish landings.

Under Preferred Alternative A10 (option ii), using an 18/0 non-offset circle hook with squid in the NED, and assuming a steady state in all other aspects, including catches of other species and prices, NMFS projects that the portion of landings historically attributable to swordfish would decline from 88.54 percent (by weight) to 61.67 percent. Assuming that the projected 30.35–percent decrease in the weight of swordfish landed results in a 30.35–percent decrease in revenues attributable to swordfish, NMFS believes that overall gross revenues of vessels may decrease by as much as 26.75 percent ($50,043) to $137,031.

Assuming a steady state in all other aspects, including catches of other species and prices, NMFS projects that under Preferred Alternative A10 (option ii), using an 18/0 non-offset circle hook with squid, the portion of vessel landings historically attributable to tuna by weight would increase from 9.85 percent to as much as 12.33 percent. Assuming that the potential 25.23–percent increase the weight of tuna landed results in a possible 25.23–percent increase in revenues attributable to tuna, NMFS believes that overall gross revenues of vessels may increase by 2.8 percent ($5,318) to $192,392.

In summary, NMFS projects that the overall impact on vessel revenues of selecting the 18/0 non-offset circle hook and squid bait combination (Preferred Alternative A10, option ii), and engaging in a mixed trip in the NED, would result in a loss of gross revenues of approximately $44,725, thereby reducing annual gross vessel revenues to $142,394. The impact of this hook and bait combination on shark, dolphin, and wahoo catches is unknown.

NMFS anticipates that most fishermen will select an 18/0 offset circle hook with whole mackerel bait (option i) under Preferred Alternative A10, for trips in the NED area, because most of the fishing effort in that area has historically targeted swordfish. This preferred alternative, however, provides fishermen with the additional flexibility to select gear, prior to departing port, that is effective at catching tunas, if they choose to engage on a directed tuna trip in the NED.

Preferred Alternative A10 (both options) is not expected to cause noticeable changes in the practices or behavior of fishermen, but there could be minor unquantifiable lost opportunity costs, as compared to pre-NED closure trips, because fishing crews which have not traditionally fished with these types of hooks and baits would need to familiarize themselves with the most efficient techniques. This alternative would be expected to have positive economic impacts for fish processors and dealers in the Northeast by providing them with additional swordfish product. From 1998 to 2000, NED area vessels landed 21 percent of all swordfish landed by the U.S. Atlantic pelagic longline fishery.

Preferred Alternative A3 (limit pelagic longline vessels in all areas open to pelagic longline fishing, excluding the NED, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i) 18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait; or, (ii) 18/0 or larger non-offset (flat) circle hooks and squid bait) could produce widely varying impacts, either positive or negative, depending upon the hook and bait combination that is deployed and the target species chosen by fishermen.

Preferred Alternative A3 provides flexibility to select a hook and bait combination, prior to departing port, that is effective at catching either swordfish or tunas, but not both. Based upon the results of the NED experiment, NMFS projects that fishermen operating outside the NED may realize a change in swordfish catches of - 30.35 to +15.62 percent (by weight), depending upon whether they choose to deploy an 18/0 non-offset circle hook with squid bait, or an 18/0 offset circle hook with whole mackerel bait, respectively. Increased catches of swordfish by weight may be less certain when fishing occurs in warmer ocean temperatures and may decline to zero, or even result in declining catches. Experimental results also indicate that fishermen operating outside the NED could experience changes in tuna catches ranging from -83.84 to +25.23 percent (by weight), depending upon whether they choose to deploy an 18/0 offset circle hook with whole mackerel bait, or an 18/0 non-offset circle hook with squid bait, respectively. The potential tuna increases are less certain based on the limited tuna catch data obtained during the NED experiment. As mentioned earlier, the experimental results indicate that when the tested hook and bait

combinations have a positive impact on swordfish catches they tend to have a negative impact on tuna catches, and vice-versa. To maximize revenues, given the impacts of these hook and bait combinations on swordfish and tuna catches, fishermen will have to make a decision prior to departing port about which species they will target, and which gear they will deploy.

If fishermen operating outside the NED choose to deploy 18/0 offset circle hooks and whole mackerel bait (option i) under Preferred Alternative 3, positive economic impacts are anticipated for vessels that are able to successfully target swordfish outside of the NED, and negative economic impacts are anticipated for those vessels targeting tunas or engaging in mixed trips outside the NED. As mentioned above, NED experimental results indicate that this hook and bait combination may increase swordfish landings by 15.62 percent (weight) and decrease tuna landings by 83.84 percent (weight), with increased swordfish catches being less certain in warmer waters.

Using similar assumptions and analyses as set forth for Alternative A10, NMFS estimates that use of an 18/0 offset circle hook and whole mackerel bait outside the NED is expected to boost the proportion of total landings attributable to swordfish, by weight, from 36.22 percent to 41.88 percent as compared with traditional landings. Assuming that the estimated 15.6–percent increase in the weight of swordfish landed will result in a 15.6–percent increase in revenues attributable to swordfish, NMFS projects that overall gross revenues of vessels may to increase by 6.8 percent ($12,724) overall to $199,798.

In addition, using a similar analytical approach as with Alternative A10, NMFS projects that the proportion of total landings attributable to tuna (weight) outside the NED may decline from 58.63 percent to 9.47 percent using an 18/0 offset circle hook and whole mackerel bait (option i). Assuming that the estimated 84–percent decrease in the weight of tuna landed results in an 84–percent decrease in revenues attributable to tunas, overall annual gross vessel revenues could decrease by 45.13 percent ($84,430) to $102,644. Given that the average ex-vessel price for swordfish is higher than for tunas (except for bluefin) in all areas except the Mid-Atlantic Region (which represents only 1.08 percent of non-NED landings, by weight), choosing to fish with an 18/0 offset circle hook with whole mackerel bait outside of the NED could have positive economic impacts for vessels that are able to successfully target swordfish. However, many vessels may not be able to successfully catch swordfish in numbers that are sufficient to offset lost tuna revenues, particularly in the Gulf of Mexico where yellowfin tuna landings dominate catches. For these vessels, negative economic impacts would be expected. The impact of this hook and bait combination on shark, dolphin, and wahoo catches is unknown, and, therefore, unquantifiable.

In aggregate, under Preferred Alternative A3 (option i), vessels fishing with an 18/0 offset circle hook with whole mackerel bait outside the NED could see a possible change in total revenues ranging from -$84,430 to +$12,724, depending upon target species, with an average total estimated change for mixed trips of -$71,706, with annual vessel gross revenues declining from $187,074 to $115,368.

If fishermen outside the NED choose to deploy 18/0 non-offset circle hooks with squid bait, under Preferred Alternative A3 (option ii), there would likely be negative economic impacts for fishermen targeting swordfish, negative economic impacts for vessels undertaking mixed target (tunas and swordfish) trips, and positive economic impacts for vessels specifically targeting tunas.

Using similar assumptions and analyses as Alternative A10, NMFS expects that Alternative A3 (option ii - 18/0 non-offset circle hooks with squid bait) could reduce the percentage of landings historically attributable to swordfish by 30.35 percent, from 36.22 percent down to 25.23 percent. If this 30.35–percent decline in the weight of swordfish landed results in a 30.35-percent decline in revenues attributable to swordfish, NMFS projects that overall gross vessel revenues would decrease by 13.22 percent ($24,726) to $162,347.

With regard to tunas, NMFS projects that using 18/0 non-offset circle hooks with squid bait outside the NED would potentially increase the portion of landings historically attributable to tuna by as much as 25.23 percent (by weight), from 58.63 percent to 73.42 percent, thus resulting in an increase in overall gross vessel revenues of 13.77 percent ($25,757) to $212,831.

In summary, combining projected changes in swordfish and tuna landings and their associated revenues outside the NED under Preferred Alternative A3, option ii (18/0 non-offset circle hooks with squid bait), NMFS projects total vessel gross revenue changes of between -$24,726 to +$25,757, with an average total estimated change for mixed trips (under option ii, Alternative 3) of approximately +$1,031. This would result in an increase in total annual gross vessel revenues to $188,105.

Under Alternative A3 (both options i and ii, in aggregate), for those vessels outside the NED that are able to successfully target swordfish or tunas, and which equip and deploy with the most efficient hook and bait combination available for a chosen target species, average gross vessel revenues may increase between $12,724 and $25,757, respectively. These potential increases are likely to be overestimates, but they provide an estimated range of annual gross vessel revenues of between $199,798 and $212,831, respectively. For vessels that are not able to specifically target swordfish or tunas and which engage in mixed species trips outside the NED, NMFS estimates that the aggregate impact of Alternative A3 would be to change annual gross vessel revenues by between -$71,706 (18/0 offset circle hook with mackerel bait) and +$1,031 (18/0 non-offset circle hook with squid), thereby providing a range of annual gross vessel revenues of between $115,368 and $188,105. The actual impacts are most likely to fall between these ranges, because some vessels would be able to target specific species and not every vessel would choose the same hook and bait combination for every trip. The impacts of these hook and bait combinations on shark, dolphin, and wahoo catches are unknown and, thus, cannot be quantified.

In summary, Preferred Alternative A3 (both options) could cause some HMS pelagic longline vessels, operating outside of the NED, to change fishing practices and to target either swordfish specifically in some areas, or tunas specifically in other areas. NMFS expects that vessels would likely avoid mixed tuna-swordfish trips, to the extent practicable, where profits are most likely to be reduced. As a result, there could be changes in the geographic distribution of the HMS pelagic longline fleet, and some vessels may choose to exit the fishery altogether. Changes in fishing patterns could result in vessels having to travel greater distances to reach more favorable fishing grounds, thereby resulting in increased fuel, bait, ice, and labor costs. A potential shift in fishing grounds, should it occur, could also result in fishermen selecting new ports for offloading. The economic impact resulting from changes in fishing locations on fishermen, ports of landing, dealers, processors, and suppliers could be detrimental to some areas. Also, changes in hook and bait costs could occur, either positive or negative,

depending upon prices and availability. There could also be unquantifiable lost opportunity costs as fishing crews become familiar with the most efficient techniques for using new gear.

One of the requirements of an IRFA is to describe any alternatives to the proposed rule which accomplish the stated objectives and which minimize any significant economic impacts (5 - U.S.C. 603 (c)). Additionally, the Regulatory Flexibility Act (5 U.S.C. 603 (c)(1) - (4)) lists four categories for alternatives that should be discussed. These categories are: (1) establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and (4) exemptions from coverage of the rule for small entities.

As noted earlier, NMFS considers all permit holders to be small entities. In order to meet the objectives of this proposed rule, consistent with the Magnuson-Stevens Act, ATCA, and the ESA, NMFS cannot exempt small entities or change the reporting requirements only for small entities. Additionally, many of the proposed measures, such as circle hook and bait requirements, and sea turtle release gear requirements, would not be as effective with different compliance requirements. Moreover, the physical act of changing hook types is not expected to impose a significant compliance burden, as this is a normal aspect of commercial fishing operations. The initial compliance cost to purchase new hooks is expected to be approximately $1,044.00. The requirement to possess and utilize sea turtle release equipment according to prescribed design standards and usage protocols (Preferred Alternative A16) will also impose a compliance burden. Compliance costs for the required release gear are expected to range from approximately $589.00 to $1048.80. However, as noted above, the design standards would allow fishermen to construct some of the equipment from material that is readily available and using skills that most fishermen likely possess, thus potentially reducing some of the costs. Such gear is necessary to release sea turtles effectively with minimal harm or injury.

In summary, the management measures would not be as effective with different compliance requirements or exemptions for small entities. Thus, there are no alternatives discussed which fall under the first and fourth categories described above. Alternatives under the second and third categories, and other alternatives considered in the DSEIS, are discussed below.

The preferred alternatives for bycatch reduction and bycatch mortality mitigation (A3, A10 and A16) were designed to reduce sea turtle interactions and the mortality associated with such interactions to levels that will allow compliance with the ESA, while minimizing adverse economic impacts to the extent practicable. The economic impacts of the preferred alternatives were previously discussed above.

Alternative A1 (no action) would not achieve the biological goals of the proposed rule or ensure compliance with the ESA. Further, the no-action alternative would allow the full adverse economic impacts of the NED closure to be realized, given the termination of the NED research experiment and its attendant economic benefits.

Alternative A2 (limit pelagic longline vessels in all areas open to pelagic longline fishing, excluding the NED, at all times, to possessing on board and/or using only 18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait) would increase adverse economic impacts on fishermen, as compared to the proposed measures, because it would limit their flexibility in selecting a more efficient hook and bait treatment for use in targeting tunas. As such, those fishermen operating outside the NED that are not able to successfully target swordfish would be adversely impacted to a greater extent, compared to the proposed measures, because of losses in tuna revenues that are anticipated with this hook and bait treatment.

Alternative A4 (limit pelagic longline vessels in all areas open to pelagic longline fishing, excluding the NED, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait: (i) 18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait; or, (ii) 18/0 or larger non-offset circle hooks and squid bait; or, (iii) 9/0 "J"-hooks with an offset not to exceed 25 degrees and whole mackerel bait) would have either greater or lesser adverse economic impacts than the preferred alternatives, depending upon the hook and bait combination chosen and the target species. However, this alternative would not achieve the biological objective of reducing the mortality of incidentally-caught sea turtles. As discussed in the DSEIS, interactions with "J"-hooks have a higher incidence of deep hooking, and tend to result in more serious injuries of sea turtles. This alternative would likely result in a higher post-release mortality rate of sea turtles, because it would allow the use of "J"-hooks.

Alternative A5 (limit vessels with pelagic longline gear onboard, at all times, in all areas open to pelagic longline fishing excluding the NED, to possessing onboard and/or using only 16/0 or larger circle hooks with an offset not to exceed 10 degrees) would not, by itself, achieve the biological objectives of the proposed rule. Alternative A5 would likely have minor to moderate adverse economic impacts on fishermen, given potential decreases in swordfish catch.

Alternative A6 (allow pelagic longline fishing for Atlantic HMS in the NED), would be expected to have positive economic benefits, but would not meet the biological objectives of this rulemaking, or ensure compliance with the ESA.

Alternative A7, which would reopen the NED to pelagic longline fishing and limit vessels in that area, at all times, to possessing on board and/or using only 18/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait, would have positive social and economic effects, as compared to the status quo or historical economic impacts. However, compared to Preferred Alternative A10, it would limit the ability of fishermen to efficiently target swordfish or tunas because it would allow only a single hook and bait in the area. Also, this alternative, by itself, would not achieve the biological objective of the proposed rule.

Alternative A8, which would reopen the NED to pelagic longline fishing and limit pelagic longline vessels in that area, at all times, to possessing on board and/or using only 20/0 or larger circle hooks with an offset not to exceed 10 degrees and whole mackerel bait, would be effective at reducing sea turtle interactions and would have positive social and economic benefits over the status quo, but would have minor adverse economic impacts when viewed historically. Alternative A8, if selected, would have a greater adverse impact on revenues associated with landings of tuna and a less positive impact on revenues associated with landings of swordfish than Preferred Alternative A10.

Alternative A9 (reopen the NED to pelagic longline fishing and limit pelagic longline vessels in that area, at all times, to possessing on board and/or using only one of the following hook and bait combinations at anytime: (i) 9/0 "J"-hook with an offset not to exceed 25 degrees and whole mackerel bait; or, (ii) 18/0 or larger circle hook with an offset not to exceed 10 degrees with

whole mackerel bait) could provide greater positive economic impacts than the proposed measures in Alternative A10, however, as with Alternative A4, allowing the use of "J"-hooks under this alternative would not achieve the biological objective of reducing the mortality of incidentally-caught sea turtles.

Alternative A11 (prohibit the use of pelagic longline gear in all Atlantic HMS fisheries) would achieve the biological objectives of this proposed rulemaking. However, this alternative would impose the most adverse economic impacts of all the alternatives considered.

Alternative A12 (close the Gulf of Mexico west of 88 degrees W. Long., year-round) would have adverse economic impacts on a distinct geographic segment of the fishery, and would not, by itself, achieve the biological goals of this proposed rulemaking.

Alternative A13 (prohibit the use of pelagic longline gear in an area of the central Gulf of Mexico, year-round) would likely have substantial economic impacts on a large and distinct geographic segment of the U.S. pelagic longline fleet, communities, buyers, and dealers in the Gulf of Mexico. Available data indicate that potential increases in catches of swordfish and bigeye tuna of 17 and 32 percent (numbers of fish), respectively, and a decrease in swordfish catches of two percent (numbers of fish) could occur a result of this closure. However, the actual impacts are unknown because potential changes in weight of landings are unknown. Nevertheless, NMFS anticipates that the overall economic impacts of a closure of this size would likely be adverse. Because a high percentage of historical fishing effort has been located in this alternative's closure area, a substantial number of fishing vessels would likely have to adjust their fishing practices. Because of a projected increase in loggerhead sea turtle interactions associated with a relocation of fishing effort, Alternative A13 would not, by itself, achieve the biological goals of the proposed rule.

Alternative A14 (prohibit the use of pelagic longline gear in HMS fisheries in areas of the Central Gulf of Mexico and the Northeast Coastal (NEC) statistical reporting areas, year-round) would likely have substantial adverse economic impacts on a large and distinct segment of the U.S. pelagic longline fleet that fishes in the GOM and NEC, as well as associated communities, buyers, and seafood dealers. NMFS' analysis indicates that swordfish and bigeye tuna catches could potentially increase 18 and 33 percent (numbers of fish), respectively, and catches of yellowfin tuna could potentially decrease by two percent (numbers of fish). However, the actual impacts are unknown because changes in the weight of landings are unknown. Because a high percentage of the fishing effort has been located in these potential closure areas, a substantial number of fishing vessels would have to adjust their fishing practices accordingly. Further, this alternative by itself would not achieve the biological objectives of this proposed rule.

Alternative A15 (prohibit the use of pelagic longline gear in HMS Fisheries in areas of the central GOM and NEC, from May through October), similar to Alternative A14, would likely also have substantial adverse economic impacts on a large and distinct segment of the U.S. pelagic longline fleet that fishes in the GOM and NEC, as well as associated communities, buyers, and dealers. NMFS' analysis indicates, as a result of the closure in this alternative, swordfish, yellowfin tuna, and bigeye tuna catches could potentially increase five percent, three percent, and 17 percent (numbers of fish), respectively. However, the actual impacts are unknown because potential changes in the weight of landings are not known. Because a high percentage of the fishing effort has been located in the areas considered for the time/area closures, a substantial number of fishing vessels would have to adjust their fishing practices accordingly. Further, this alternative by itself would not achieve the biological objectives of proposed rule.

Although Alternatives A5, A7, A14, and A15 would not, independent of one another, sufficiently reduce sea turtle interactions to ensure compliance with the ESA, a suite of these alternatives (A5, A7, and A14; or A5, A7, and A15) would achieve the necessary sea turtle reductions, if combined. The combined economic impacts of these suites of alternatives, however, would be expected to impose greater adverse economic impacts than the alternatives being proposed.

This proposed rule does not contain any new reporting or recordkeeping requirements.

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

List of Subjects

50 CFR Part 223

Endangered and threatened species, Fisheries, Fishing, Fishing vessels.

50 CFR Part 635

Endangered and threatened species, Fisheries, Fishing, Fishing vessels, Foreign relations, Intergovernmental relations, Penalties, Statistics, Treaties.

Dated: February 5, 2004.

Rebecca J. Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 223 and 635 are proposed to be amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

2. In § 223.206, paragraph (d)(1)(ii) is revised to read as follows:

§ 223.206 Exceptions to prohibitions relating to sea turtles.

* * * * *

(d) * * *

(1) * * *

(ii) In addition to the provisions of paragraph (d)(1)(i) of this section, a person aboard a pelagic longline vessel in the Atlantic issued an Atlantic permit for highly pelagic species under 50 CFR 635.4, must follow the handling requirements in 50 CFR 635.21.

* * * * *

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.*; 16 U.S.C. 1801 *et seq.*

2. In § 635.2, the definition for "Northeast Distant closed area" is removed, and new definitions for "Circle hook" and "Offset circle hook" are added alphabetically to read as follows:

§ 635.2 Definitions.

* * * * *

Circle hook means a fishing hook with the point turned perpendicularly back to the shank.

* * * * *

Offset circle hook means a circle hook in which the barbed end of the hook is displaced relative to the parallel plane of the eyed-end, or shank, of the hook when laid on its side.

* * * * *

3. In § 635.21, paragraph (c)(2)(v) is removed; paragraphs (a)(3), (c)(5)(i), and (c)(5)(ii) are revised; and paragraphs (c)(5)(iii)(C) and (c)(5)(iv) are added to read as follows:

§ 635.21 Gear operation and deployment restrictions.

(a) * * *

(3) Operators of all vessels that have pelagic or bottom longline gear on board and that have been issued, or are required to have, a limited access swordfish, shark, or tuna longline category permit for use in the Atlantic Ocean including the Caribbean Sea and the Gulf of Mexico must possess, inside the wheelhouse, a document provided by NMFS entitled, "Careful Release Protocols for Release with Minimal Injury" and must post inside the wheelhouse the sea turtle handling and release guidelines provided by NMFS.

* * * * *

(c) * * *

(5) * * *

(i) *Possession and use of required mitigation gear.* Required sea turtle bycatch mitigation gear, which NMFS has approved under paragraph 635.21(c)(5)(iv) of this section as meeting the minimum design standards specified in paragraphs (c)(5)(i)(A) through (c)(5)(i)(L) of this section, must be carried on board, and must be used to disengage any hooked or entangled sea turtles in accordance with the handling requirements specified in paragraph (c)(5)(ii) of this section.

(A) *Long-handled line clipper or cutter.* Line cutters are intended to cut high test monofilament line as close as possible to the hook, and assist in removing line from entangled sea turtles to minimize any remaining gear upon release. NMFS has established minimum design standards for the line cutters. The LaForce line cutter and the Arceneaux line clipper are models that meet these minimum design standards, and may be purchased or fabricated from readily available and low-cost materials. One long-handled line clipper or cutter and a set of replacement blades are required to be onboard. The minimum design standards for line cutters are as follows:

(*1*) *A protected and secured cutting blade.* The cutting blade(s) must be capable of cutting 2.0–2.1 mm (0.078 in. - 0.083 in.) monofilament line (400–lb test) or polypropylene multistrand material, known as braided or tarred mainline, and should be maintained in working order. The cutting blade must be curved, recessed, contained in a holder, or otherwise designed to facilitate its safe use so that direct contact between the cutting surface and the sea turtle or the user is prevented. The cutting instrument must be securely attached to an extended reach handle and easily replaced. One extra set of replacement blades meeting these standards must also be carried on board to replace all cutting surfaces on the line cutter or clipper.

(*2*) *An extended reach handle.* The line cutter blade must be securely fastened to an extended reach handle or pole with a minimum length equal to, or greater than, 150 percent of the freeboard, or a minimum of 6 feet (1.83 m), whichever is greater. Freeboard is defined as the working distance between the top rail of the gunwale to the water's surface, and will vary based on the vessel design. It is recommended, but not required, that the handle break down into sections. There is no restriction on the type of material used to construct this handle as long as it is sturdy and facilitates the secure attachment of the cutting blade.

(B) *Long-handled dehooker for ingested hooks.* A long-handled dehooking device is intended to remove ingested hooks from sea turtles that cannot be boated. It should also be used to engage a loose hook when a turtle is entangled but not hooked, and line is being removed. The design must shield the barb of the hook and prevent it from re-engaging during the removal process. One long-handled device to remove ingested hooks is required onboard. The minimum design standards are as follows:

(*1*) *Hook removal device.* The hook removal device must be constructed of 5/16–inch (7.94 mm) 316 L stainless steel and have a dehooking end no larger than 1 7/8–inches (4.76 cm) outside diameter. The device must securely engage and control the leader while shielding the barb to prevent the hook from re-engaging during removal. It may not have any unprotected terminal points (including blunt ones), as these could cause injury to the esophagus during hook removal. The device must be of a size appropriate to secure the range of hook sizes and styles observed to date in the pelagic longline fishery targeting swordfish and tuna, or those having some possibility for use in the future (7/0–11/0 J hooks and 14/0–22/0 circle hooks).

(*2*) *Extended reach handle.* The dehooking end must be securely fastened to an extended reach handle or pole with a minimum length equal or greater than 150 percent of the freeboard, or a minimum of 6 ft (1.83 m), whichever is greater. Freeboard is defined as the working distance between the top rail of the gunwale to the water's surface, and will vary based on the vessel design. It is recommended, but not required, that the handle break down into sections. The handle must be sturdy and strong enough to facilitate the secure attachment of the hook removal device.

(*C*) *Long-handled dehooker for external hooks.* A long-handled dehooker is required for use on externally-hooked sea turtles that cannot be boated. The long-handled dehooker for ingested hooks described in paragraph (c)(5)(i)(B) of this section would meet this requirement. The minimum design standards are as follows:

(*1*) *Construction.* A long-handled dehooker must be constructed of 5/16–inch (7.94 mm) 316 L stainless steel rod. A 5–inch (12.7–cm) tube T-handle of 1–inch (2.54 cm) outside diameter is recommended, but not required. The design should be such that a fish hook can be rotated out, without pulling it out at an angle. The dehooking end must be blunt with all edges rounded. The device must be of a size appropriate to secure the range of hook sizes and styles observed to date in the pelagic longline fishery targeting swordfish and tuna, or those having some possibility for use in the future (7/0–11/0 J hooks and 14/0–22/0 circle hooks).

(*2*) *Handle length.* The handle must be a minimum length equal to the freeboard of the vessel or 3 ft (0.914 m), whichever is greater. Freeboard is defined as the working distance between the top rail of the gunwale to the water's surface, and will vary based on the vessel design.

(D) *Long-handled device to pull an "inverted V".* This tool is used to pull a "V" in the fishing line when implementing the "inverted V" dehooking technique, as described in the "Careful Release Protocols" document required under paragraph (a)(3) of this section, for disentangling and dehooking entangled sea turtles. One long-handled device to pull an "inverted V" is required onboard. If a 6–ft (1.83 m) J-style dehooker is used to comply with paragraph (C)(5)(i)(C) of this section, it will also satisfy this requirement. Minimum design standards are as follows:

(*1*) *Hook end.* This device, such as a standard boat hook or gaff, must be constructed of stainless steel or aluminum. A sharp point, such as on a gaff hook, is to be used only for holding the monofilament fishing line and should never contact the sea turtle.

(*2*) *Handle length.* The handle must have a minimum length equal to, or greater than, 150 percent of the freeboard, or a minimum of 6 ft (1.83 m), whichever is greater. Freeboard is defined as the working distance between the top rail of the gunwale to the water's surface, and will vary based on the vessel design. The handle must

be sturdy and strong enough to facilitate the secure attachment of the gaff hook.

(E) *Dipnet.* One dipnet is required onboard. Dipnets are to be used to facilitate safe handling of sea turtles by allowing them to be brought onboard for fishing gear removal, without causing further injury to the animal. Turtles should never be brought onboard without a dipnet. The minimum design standards for dipnets are as follows:

(*1*) *Size of dipnet.* The dipnet must have a sturdy net hoop of at least 31 inches (78.74 cm) inside diameter and a bag depth of at least 38 inches (96.52 cm) to accommodate turtles below 3 ft (0.914 m)carapace length. The bag mesh openings may not exceed 3 inches (7.62 cm) x 3 inches (7.62 cm). There must be no sharp edges or burrs on the hoop, or where it is attached to the handle.

(*2*) *Extended reach handle.* The dipnet hoop must be securely fastened to an extended reach handle or pole with a minimum length equal to, or greater than, 150 percent of the freeboard, or at least 6 ft (1.83 m), whichever is greater. Freeboard is defined as the working distance between the top rail of the gunwale to the water's surface, and will vary based on the vessel design. The handle must made of a rigid material strong enough to facilitate the sturdy attachment of the net hoop and able to support a minimum of 100 lbs (34.1 kg) without breaking or significant bending or distortion. It is recommended, but not required, that the extended reach handle break down into sections.

(F) *Tire.* A minimum of one tire is required for supporting a turtle in an upright orientation while it is onboard, although an assortment of sizes is recommended to accommodate a range of turtle sizes. The required tire must be a standard passenger vehicle tire, and must be free of exposed steel belts.

(G) *Short-handled dehooker for ingested hooks.* One short-handled device for removing ingested hooks is required onboard. This dehooker is designed to remove ingested hooks from boated sea turtles. It can also be used on external hooks or hooks in the front of the mouth. Minimum design standards are as follows:

(*1*) *Hook removal device.* The hook removal device must be constructed of 1/4–inch (6.35 mm) 316 L stainless steel, and must allow the hook to be secured and the barb shielded without re-engaging during the removal process. It must be no larger than 1 5/16 inch (3.33 cm) outside diameter. It may not have any unprotected terminal points (including blunt ones), as this could cause injury to the esophagus during hook removal. A sliding PVC bite block must be used to protect the beak and facilitate hook removal if the turtle bites down on the dehooking device. The bite block should be constructed of a 3/4 inch (1.91 cm) inside diameter high impact plastic cylinder (e.g., Schedule 80 PVC) that is 10 inches (25.4 cm) long to allow for 5 inches (12.7 cm) of slide along the shaft. The device must be of a size appropriate to secure the range of hook sizes and styles observed to date in the pelagic longline fishery targeting swordfish and tuna, or those having some possibility for use in the future (7/0–11/0 J hooks and 14/0–22/0 circle hooks).

(*2*) *Handle length.* The handle should be approximately 16 - 24 inches (40.64 cm - 60.69 cm) in length, with approximately a 5–inch (12.7 cm) long tube T-handle of approximately 1 inch (2.54 cm) in diameter.

(H) *Short-handled dehooker for external hooks.* One short-handled dehooker for external hooks is required onboard. The short-handled dehooker for ingested hooks required to comply with paragraph (c)(5)(i)(G) of this section will also satisfy this requirement. Minimum design standards are as follows:

(*1*) *Hook removal device.* The dehooker must be constructed of 5/16–inch (7.94 cm) 316 L stainless steel, and the design must be such that a hook can be rotated out without pulling it out at an angle. The dehooking end must be blunt, and all edges rounded. The device must be of a size appropriate to secure the range of hook sizes and styles observed to date in the pelagic longline fishery targeting swordfish and tuna, or those having some possibility for use in the future (7/0–11/0 J hooks and 14/0–22/0 circle hooks).

(*2*) *Handle length.* The handle should be approximately 16 - 24 inches (40.64 cm - 60.69 cm) long with approximately a 5–inch (12.7 cm) long tube T-handle of approximately 1 inch (2.54 cm) in diameter.

(I) *Long-nose or needle-nose pliers.* One pair of long-nose or needle-nose pliers is required on board. Required long-nose or needle-nose pliers can be used to remove deeply embedded hooks from the turtle's flesh that must be twisted during removal. They can also hold PVC splice couplings, when used as mouth openers, in place. Minimum design standards are as follows:

(*1*) *General.* They must be approximately 12 inches (30.48 cm) in length, and should be constructed of stainless steel material.

(*2*) [Reserved]

(J) *Bolt cutters.* One pair of bolt cutters is required on board. Required bolt cutters may be used to cut hooks to facilitate their removal. They should be used to cut off the eye or barb of a hook, so that it can safely be pushed through a sea turtle without causing further injury. They should also be used to cut off as much of the hook as possible, when the remainder of the hook cannot be removed. Minimum design standards are as follows:

(*1*) *General.* They must be approximately 17 inches (43.18 cm) in total length, with 4–inch (10.16 cm) long blades that are 2 1/4 inches (5.72 cm) wide, when closed, and with 13–inch (33.02 cm) long handles. Required bolt cutters must be able to cut hard metals, such as stainless or carbon steel hooks, up to 1/4–inch (6.35 mm) diameter.

(*2*) [Reserved]

(K) *Monofilament line cutters.* One pair of monofilament line cutters is required on board. Required monofilament line cutters must be used to remove fishing line as close to the eye of the hook as possible, if the hook is swallowed or cannot be removed. Minimum design standards are as follows:

(*1*) *General.* Monofilament line cutters must be approximately 7 1/2 inches (19.05 cm) in length. The blades must be 1 3/4 in (4.45 cm) in length and 5/8 in (1.59 cm) wide, when closed, and are recommended to be coated with Teflon (a trademark owned by E.I. DuPont de Nemours and Company Corp.).

(*2*) [Reserved]

(L) *Mouth openers/mouth gags.* Required mouth openers and mouth gags are used to open sea turtle mouths, and to keep them open when removing ingested hooks from boated turtles. They must allow access to the hook or line without causing further injury to the turtle. Design standards are included in the item descriptions. At least two of the seven different types of mouth openers/gags described below are required:

(*1*) *A block of hard wood.* Placed in the corner of the jaw, a block of hard wood may be used to gag open a turtle's mouth. A smooth block of hard wood of a type that does not splinter (e.g. maple) with rounded edges should be sanded smooth, if necessary, and soaked in water to soften the wood. The dimensions should be approximately 11 inches (27.94 cm) 1 inch (2.54 cm) 1 inch (2.54 cm). A long-handled, wire shoe brush with a wooden handle, and with the wires removed, is an inexpensive, effective and practical mouth-opening device that meets these requirements.

(*2*) *A set of three canine mouth gags.* Canine mouth gags are highly recommended to hold a turtle's mouth

open, because the gag locks into an open position to allow for hands-free operation after it is in place. A set of canine mouth gags must include one of each of the following sizes: small (5 inches) (12.7 cm), medium (6 inches) (15.24 cm), and large (7 inches) (17.78 cm). They must be constructed of stainless steel. A 1 3/4 inch (4.45 cm) piece of vinyl tubing (3/4–inch (1.91 cm) outside diameter and 5/8–inch (1.59 cm) inside diameter) must be placed over the ends to protect the turtle's beak.

(*3*) *A set of two sturdy dog chew bones.* Placed in the corner of a turtle's jaw, canine chew bones are used to gag open a sea turtle's mouth. Required canine chews must be constructed of durable nylon, zylene resin, or thermoplastic polymer, and strong enough to withstand biting without splintering. To accommodate a variety of turtle beak sizes, a set must include one large (5 1/2 - 8 inches (13.97 cm - 20.32 cm) in length), and one small (3 1/2 - 4 1/2 inches (8.89 cm - 11.43 cm) in length) canine chew bones.

(*4*) *A set of two rope loops covered with hose.* A set of two rope loops covered with a piece of hose can be used as a mouth opener, and to keep a turtle's mouth open during hook and/or line removal. A required set consists of two 3–foot (0.91 m) lengths of poly braid rope (3/8–inch (9.52 mm) diameter suggested), each covered with an 8–inch (20.32 cm) section of 1/2 inch (1.27 cm) or 3/4 inch (1.91 cm) light-duty garden hose, and each tied into a loop. The upper loop of rope covered with hose is secured on the upper beak to give control with one hand, and the second piece of rope covered with hose is secured on the lower beak to give control with the user's foot.

(*5*) *A hank of rope.* Placed in the corner of a turtle's jaw, a hank of rope can be used to gag open a sea turtle's mouth. A 6–foot (1.83 m) lanyard of approximately 3/16–inch (4.76 mm) braided nylon rope may be folded to create a hank, or looped bundle, of rope. Any size soft-braided nylon rope is allowed is allowed, however it must create a hank of approximately 2 - 4 inches (5.08 cm - 10.16 cm) in thickness.

(*6*) *A set of four PVC splice couplings.* PVC splice couplings can be positioned inside a turtle's mouth to allow access to the back of the mouth for hook and line removal. They are to be held in place with the needle-nose pliers. To ensure proper fit and access, a required set must consist of the following Schedule 40 PVC splice coupling sizes: 1 inch (2.54 cm), 1 1/4 inch (3.18 cm), 1 1/2 inch (3.81 cm), and 2 inches (5.08 cm).

(*7*) *A large avian oral speculum.* A large avian oral speculum provides the ability to hold a turtle's mouth open and to control the head with one hand, while removing a hook with the other hand. The avian oral speculum must be 9–inches (22.86 cm) long, and constructed of 3/16–inch (4.76 mm) wire diameter surgical stainless steel (Type 304). It must be covered with 8 inches (20.32 cm) of clear vinyl tubing (5/16–inch (7.9 mm) outside diameter, 3/16–inch (4.76 mm) inside diameter).

(ii) *Handling requirements.* (A) Sea turtle bycatch mitigation gear, as required by paragraphs (c)(5)(i)(A) - (D) of this section, must be used to disengage any hooked or entangled sea turtles that cannot be brought on board. Sea turtle bycatch mitigation gear, as required by paragraphs (c)(5)(i)(E) - (L) of this section, must be used to facilitate access, safe handling, disentanglement, and hook removal or hook cutting of sea turtles that can be brought on board, where feasible. Sea turtles must be handled, and bycatch mitigation gear must be used, in accordance with the careful release protocols and handling/release guidelines specified in paragraph (a)(3) of this section, and in accordance with the onboard handling and resuscitation requirements specified in § 223.206(d)(1).

(B) *Boated turtles.* When practicable, active and comatose sea turtles must be brought on board, with a minimum of injury, using a dipnet as required by paragraph (c)(5)(i)(E) of this section. All turtles less than 3 ft (.91 m) carapace length should be boated, if sea conditions permit.

(*1*) For boated turtles, the animal should be placed on a standard automobile tire, or cushioned surface, in an upright orientation to immobilize it and facilitate gear removal. Then, determine if the hook can be removed without causing further injury. All externally embedded hooks should be removed, unless hook removal would result in further injury to the turtle. Do not attempt to remove a hook if it has been swallowed and the insertion point is not visible, or if it is determined that removal would result in further injury. If a hook cannot be removed, ensure that as much line as possible is removed from the turtle using monofilament cutters, and cut the hook as close as possible to the insertion point using bolt cutters before releasing it. If a hook can be removed, an effective technique may be to cut off either the barb, or the eye, of the hook using bolt cutters, and then to slide the hook out. When the hook is visible in the front of the mouth, a mouth-opener may facilitate opening the turtle's mouth and a gag may facilitate keeping the mouth open. Short-handled dehookers for ingested hooks, or long-nose or needle-nose pliers should be used to remove visible hooks from the mouth that have not been swallowed on boated turtles, as appropriate. As much gear as possible must be removed from the turtle without causing further injury prior to its release. Refer to the careful release protocols and handling/release guidelines required in paragraph (a)(3) of this section, and the handling and resuscitation requirements specified in § 223.206(d)(1), for additional information.

(*2*) [Reserved]

(C) *Non-boated turtles.* If a sea turtle is too large, or hooked in a manner that precludes safe boarding without causing further damage or injury to the turtle, sea turtle bycatch mitigation gear required by paragraphs (c)(5)(i)(A) - (D) of this section should be used to disentangle sea turtles from fishing gear and disengage any hooks, or to clip the line and remove as much line as possible from a hook that cannot be removed, prior to releasing the turtle, in accordance with the protocols specified in paragraph (a)(3) of this section.

(*1*) For non-boated turtles, bring the animal close to the boat and provide time for it to calm down. Then, determine if the hook can be removed without causing further injury. All externally embedded hooks should be removed, unless hook removal would result in further injury to the turtle. Do not attempt to remove a hook if it has been swallowed, or if it is determined that removal would result in further injury. If the hook cannot be removed and/or if the animal is entangled, ensure that as much line as possible is removed prior to release, using the line cutter required at paragraph (c)(5)(i)(A) of this section. If the hook can be removed, use a long-handled dehooker as required at paragraphs (c)(5)(i)(B) and (c)(5)(i)(C) of this section to remove the hook, as appropriate. Always remove as much gear as possible from the turtle without causing further injury prior to its release. Refer to the careful release protocols and handling/release guidelines required in paragraph (a)(3) of this section, and the handling and resuscitation requirements specified in § 223.206(d)(1), for additional information.

(*2*) [Reserved]

(iii) * * *

(C) *Hook size, type, and bait.* Vessels that have pelagic longline gear on board and that have been issued, or are required to have, a limited access

swordfish, shark, or tuna longline category permit for use in the Atlantic Ocean including the Caribbean Sea and the Gulf of Mexico are limited, at all times, to possessing on board and/or using only one of the following combinations of hooks and bait:

(*1*) 18/0 or larger circle hooks with an offset not to exceed 10° and whole Atlantic mackerel (*Scomber scombrus*) bait; or,

(*2*) 18/0 or larger non-offset circle hooks and squid bait.

(*i*) For purposes of paragraphs (c)((5)(iii)(C)(1) and (2) of this section, the outer diameter of an 18/0 circle hook at its widest point must be no smaller than 1.97 inches (50 mm), when measured with the eye of the hook on the vertical axis (y-axis) and perpendicular to the horizontal axis (x-axis). The offset in paragraph (c)(5)(iii)(C)(1) of this section is measured from the barbed end of the hook, and is relative to the parallel plane of the eyed-end, or shank, of the hook when laid on its side.

(*ii*) [Reserved]

(iv) *Approval of sea turtle bycatch mitigation gear.* NMFS will file with the Office of the **Federal Register** for publication an initial list of required sea turtle bycatch mitigation gear that NMFS has approved as meeting the minimum design standards specified under paragraph (c)(5)(i) of this section. Other devices proposed for use as line clippers or cutters or dehookers, as specified under paragraphs (c)(5)(i)(A), (B), (C), (G), (H), and (K) of this section, must be approved as meeting the minimum design standards before being used. NMFS will examine new devices, as they become available, to determine if they meet the minimum design standards, and will file with the Office of the **Federal Register** for publication notification of any new devices that are approved as meeting the standards.

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4. In § 635.71, paragraph (a)(33) is revised as follows:

§ 635.71 Prohibitions.

* * * * *

(a) * * *

(33) Deploy or fish with any fishing gear from a vessel with pelagic longline gear on board without carrying the required sea turtle bycatch mitigation gear, as specified at § 635.21(c)(5)(i).

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[FR Doc. 04–2982 Filed 2–10–04; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No 040122024–4024–01; I.D. 010904A]

RIN 0648–AR75

Fisheries of the Northeastern United States; Tilefish Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to reinstate the permit requirements for commercial tilefish vessels specified under 50 CFR 648.4(a)(12). These permit requirements were set aside in a recent Federal Court Order (Court Order) in Hadaja v. Evans (May 15, 2003) on the grounds that the limited access program contained in the Tilefish Fishery Management Plan (FMP) violated National Standard 2 of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). NMFS is proposing to reinstate these permit requirements based on additional information provided by the Mid-Atlantic Fishery Management Council (Council) that supports the limited access permit criteria contained in the FMP. This action will enable NMFS to manage the tilefish fishery in accordance with the provisions of the Magnuson-Stevens Act by helping end overfishing, and ensuring that the stock rebuilding objective of the FMP is achieved.

DATES: Comments must be received on or before March 12, 2004.

ADDRESSES: Comments on the proposed rule should be sent to Patricia A. Kurkul, Regional Administrator (RA), Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298. Mark the outside of the envelope "Comments on Tilefish Action." Comments may also be submitted via facsimile (fax) to (978) 281–9135. Comments may also be submitted via e-mail to the following address: *tilefish75@noaa.gov.*

Copies of the Regulatory Impact Review (RIR) and Initial Regulatory Flexibility Analysis (IRFA) prepared for this action are available upon request from the RA at the above address. Copies of the Final Environmental Impact Statement (FEIS) prepared for the FMP may be obtained by contacting Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115 Federal Building, 300 South New Street, Dover, DE 19904. The FEIS, which was completed in 2001, contained a complete analysis of the impacts of the permit requirements contained in the FMP. Because nothing has changed since the FEIS was completed that would affect that determination, further analysis under the National Environmental Policy Act (NEPA) is unnecessary.

FOR FURTHER INFORMATION CONTACT: Allison Ferreira, Fishery Policy Analyst, (978) 281–9103, fax (978) 281–9135, e-mail *Allison.Ferreira@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The tilefish fishery is managed by the Council under the FMP. The FMP was approved by the Secretary of Commerce (Secretary) on May 10, 2001, and became effective on November 1, 2001 (66 FR 49136; September 26, 2001). The Tilefish Management Unit is all golden tilefish under U.S. jurisdiction in the Atlantic Ocean north of the Virginia/North Carolina border. The primary objective of the FMP is to eliminate overfishing and rebuild the tilefish stock through the implementation of a stock rebuilding program. Measures in the FMP established to achieve this objective include a limited entry program: a tiered commercial quota, based on the limited entry program; permit and reporting requirements for commercial vessels, operators, and dealers; a prohibition on the use of gear other than longline gear by limited access tilefish vessels; and an annual specification and framework adjustment process.

The stock rebuilding schedule established by the FMP consists of a constant harvest strategy under which the TAL is set at 1.995 million lb (905,000 kg) each year for the entire 10–year rebuilding schedule. The objective of the tilefish rebuilding schedule is to reduce the fishing mortality rate (F) from its 1998 level of F=0.45, to F=0.29 in the first year of the FMP, and gradually down to F=0.11 in the tenth year of the FMP. These measures are designed to provide at least a 50–percent probability of achieving biomass at maximum sustainable yield (Bmsy) by October 31, 2011. The annual TAL is apportioned as follows. First, a total allowable catch (TAC) of up to 3 percent of the TAL may be set aside for the purpose of funding tilefish research. Following any reduction due to the establishment of a research TAC, the TAL is reduced by 5 percent to account

for incidental catch. Finally, the remaining TAL is divided among three limited access permit categories as follows: Full-time tier 1, 66 percent; Full-time tier 2, 15 percent; and Part-time, 19 percent.

A Federal Court Order in Hadaja v. Evans set aside the regulations pertaining to the permit requirements for commercial tilefish vessels specified under § 648.4(a)(12). In its order, the Court concluded that the tilefish limited access program violated National Standard 2 of the Magnuson-Stevens Act 16 U.S.C. 1801 *et seq.*) because it was not based on the best scientific information available. The Court held that the Secretary must adopt a plan that is based on the best scientific information available, which may be the existing plan, but only if the evidence in the administrative record (record) clearly supports it.

Because the Court held that NMFS's tilefish limited access program was inconsistent with National Standard 2, its decision to set aside the permit requirements has a substantial impact on the other regulations implementing the FMP since the trigger for many of these regulations implementing the FMP is the issuance a valid limited access or incidental tilefish permit. As a result, in addition to the vessel permit requirements, the vessel operator permit requirements under § 648.5(a), the vessel reporting requirements under § 648.7(b)(2)(ii), the observer coverage regulations under § 648.11(a), and the incidental catch limit under § 648.292 are no longer in effect. As a result, the ability of NMFS to manage the tilefish fishery in accordance with the Magnuson-Stevens Act has been impacted.

The proposed action would reinstate the vessel permitting requirements of the FMP, specified under § 648.4(a)(12), that were set aside by the Court based upon a supplemental administrative record developed in conjunction with the Council to support the limited access permit criteria established in the FMP. The purpose of this action is to help end overfishing, and ensure that the stock rebuilding objective of the FMP is achieved. Because the regulatory text for the tilefish permitting requirements was never formally removed by NMFS, this proposed rule does not contain any new regulatory language.

The Court Order also set aside the regulations prohibiting the use of all gear other than longline gear for limited access tilefish vessels specified under § 648.294. Due to a lack of information to support reinstating the ban on the use of trawl gear in the directed tilefish fishery, the Tilefish Committee (Committee), Tilefish Technical Team (Technical Team), and Tilefish Industry Advisors (Industry Advisors) recommended not to address the trawl gear issue in this action at a September 18, 2003, meeting held to discuss the development of a supplemental administrative record. Thus, this action would remove the prohibition on the use of gear other than longline gear for limited access tilefish vessels, and proposes only to reinstate the tilefish vessel permitting requirements as noted above.

The Council passed a motion at its August 5–7, 2003, meeting to move forward with developing the supplemental administrative record needed to reinstate the permitting requirements of the FMP. At the September 18, 2003, meeting held to discuss the supplemental administrative record, the Tilefish Committee, the Technical Team, and the Industry Advisors discussed how the criteria for each limited access category were developed, based upon the landings data that were available at that time. This discussion was continued at a Committee meeting held in conjunction with the October 7–9, 2003, Council meeting. Based upon the discussions that took place at these two meetings, a supplemental record has been compiled that describes in detail the steps taken by the Council and Committee in developing the limited access program alternatives contained in the FMP, and the rationale behind their selection of a preferred limited access program. A summary of the information contained in the supplemental record is provided in the following paragraphs.

Summary of the Supplemental Record for Tilefish

Management of the tilefish resource was first considered in earnest in 1993, when a notice of intent (NOI) to prepare an environmental impact statement (EIS) was published on February 24, 1993 (58 FR 11217). A control date for the fishery was then published on June 15, 1993 (58 FR 33081). At that time, Council staff proposed several considerations for a management scheme, including a new entrant moratorium, an effort reduction program, and an overall quota with potential sub-quotas. At an Industry Advisors Subcommittee meeting in February 1994, the concept of dividing the tilefish fishery into full-time and part-time vessels was raised. This concept was based largely on the management scheme for the Atlantic sea scallop fishery, which consists of Full-time, Part-time, and Occasional vessel permit categories. However, due to several more pressing fishery management issues, the Council did not revisit tilefish management until 1999. On April 5, 1999 (64 FR 16417), a new NOI was published in the **Federal Register** for the EIS prepared in conjunction with the FMP, and a public scoping meeting was held on April 27, 1999.

In considering limiting access to the tilefish fishery, the Council had to consider several factors mandated under section 303(b)(6) of the Magnuson-Stevens Act. Two primary factors to be considered were present participation in the fishery and historical fishing practices in, and dependence on the fishery. The only data available to the Council with which to develop a limited entry scheme were vessel permit and landings data. This information was used to generate tables reflecting annual individual vessel landings. The information enabled the Council to exercise an element of judgement in identifying those natural breaks in the landings data, and the overall time frame that should be used as the qualifying criteria for the individual categories to reflect their differing levels of participation in the tilefish fishery.

Upon reviewing landings data provided by the NMFS Northeast Fisheries Science Center (Center), the Committee, along with the Industry Advisors, began to formulate qualifying criteria for a directed and indirect tilefish fishery at the April 1, 1999, Committee meeting. Based upon the landings data, the Industry Advisors suggested that a minimum of 250,000 lb (113,398 kg) be used as the basis for qualifying a permit for the directed fishery, and a minimum of 10,000 lb (4,536 kg) be used as the basis for qualifying for the incidental permit. Furthermore, it became apparent that there was a considerable disparity between vessels that landed 250,000 lb (113,398 kg) of tilefish a year, and those that did not. As a result, a Committee member recommended that there be a Full-time and Part-time category; the same concept that was raised at the February 1994 Committee meeting. The concept of subjecting the Incidental category to a trip limit was also raised at this meeting. After some discussion, the Committee elected to recommend that the Council move forward with three permit categories: Full-time, Part-time, and Incidental. However, the Committee requested that the Center conduct further analysis of tilefish landings data.

At the May 6, 1999, Committee meeting, the concept of a two-tier Full-time permit category was adopted by the

Committee. At this meeting, the Committee developed limited entry criteria for each of the proposed permit categories, based upon landings information provided by the Center. These data indicated that four vessels landed at least 250,000 lb (113,398 kg) of tilefish annually, for several of the last 6 years for which there were complete landings data. Based upon this information, the Committee developed the following criteria for the Full-time, tier 1 category: 250,000 lb (113,398 kg) per year for 3 years from 1993–1998, with at least 1 lb (0.5 kg) of tilefish landed prior to the June 15, 1993, control date. For the Full-time, tier 2 category, the Committee suggested qualifying criteria of 30,000 lb (13,608 kg) per year for 3 years from 1993–1998, with at least 1 lb (0.5 kg) of tilefish landed prior to the control date of June 15, 1993. For the Part-time category, the Committee suggested qualifying criteria of 10,000 lb (4,536 kg) per year for any 1 year from 1988–1993, and 10,000 lb (4,536 kg) per year in any 1 year from 1994–1998. The limited entry criteria for each alternative reflected elements of present and historical participation, as well as dependence on the fishery as required under section 303(b)(6) of the Magnuson-Stevens Act. The qualifying period ended with 1998, since this was the last year for which complete annual landings data were available. This alternative ultimately became limited entry Option 2 in the FMP.

The Council then considered the Committee's recommendation at its May 25, 1999, meeting. At this meeting, industry members voiced concern over the selection of 1988 as the cut-off year for historical participation, since a number of them had been in the fishery since the late 1970s to early to mid–1980s, but had left the fishery for a variety of reasons. The industry group representing these individuals was the Historical Tilefish Coalition. The 1988 cut-off year was originally selected simply because the Center had only analyzed data back this far, due to limitations in data prior to 1988. However, the data analyzed were not considered to be complete, because there was no requirement for vessel owners to report their tilefish landings data until the mid–1990s. Even then, vessels only had to report these landings if they held a Federal fisheries permit. After some debate, the Council adopted a new alternative for the public hearing document that extended the qualification time-period for the Full-time and Part-time categories back to 1977. Under this alternative, which is Option 5 in the FMP, a vessel could qualify for the Full-time category if it landed 50,000 lb (22,680 kg) in any one year between 1977 and June 15, 1993, or for the Part-time category if it landed 10,000 lb (4,536 kg) of tilefish in any one year between 1977 and June 15, 1993. The year 1977 was selected because the Center had been able to estimate landings back to 1977, but was unable to provide landings information for individual vessels. Some Council members expressed concern about the number of vessels that this alternative would let into the fishery, given the reduced quota needed to rebuild the fishery within 10 years.

The public hearing document for the FMP ultimately contained five options for limited entry criteria. These are represented as Options 1 through 5 in the final FMP document (*see* Table 1). The public hearing document also explained that there would be a sub-quota for each permit category, which would be based on the percentage of the overall tilefish landings from 1988 through 1998 by the vessels that qualified for each permit category. Following public hearings on the FMP, which took place in August 1999, the Council convened on October 14, 1999, to inform its members of points of contention regarding the alternatives in the FMP, and to answer any questions. Final decision on the FMP was delayed until November 23, 1999, when a special Council meeting was to be held to address the FMP. The location for this meeting was selected to be more accessible to tilefish fishermen.

TABLE 1. LIMITED ACCESS PROGRAM ALTERNATIVES IN THE TILEFISH FMP

Option	Limited Access Program Tilefish Landings Criteria
Option 1	
Full-time	At least 50,000 lb (22,680 kg) in 1 year from 1988–1993, and at least 25,000 lb (11,340 kg) per year for 2 years from 1994–1998.
Part-time	At least 10,000 lb (4,536 kg) in 1 year from 1988–1993, and at least 10,000 lb (4,536 kg) in 1 year between 1994–1998.
Option 2 (Preferred alternative in FMP)	
Full-time: tier 1.	At least 250,000 lb (113,398 kg) per year for 3 years between 1993–1998, and at least 1 lb (0.5 kg) landed prior to June 15, 1993.
Full-time: tier 2.	At least 30,000 lb (13,608 kg) per year for 3 years between 1993–1998, and at least 1 lb (0.5 kg) landed prior to June 15, 1993.
Part-time	Same as Option 1.
Option 3	
Full-time	Same as Option 1.
Part-time	At least 10,000 lb (4,536 kg) in 1 year between 1988 and June 15, 1993.
Option 4	
Full-time	At least 50,000 lb (22,680 kg) in 1 year between 1988 and June 15, 1993.
Part-time	Same as Option 3.
Option 5	
Full-time	At least 50,000 lb (22,680 kg) in 1 year from 1977 to June 15, 1993.
Part-time	At least 10,000 lb (4,536 kg) in 1 year from 1977 to June 15, 1993.
Option 6	
Full-time: tier 1.	Same as Option 2.
Full-time: tier 2.	Same as Option 2.
Part-time	Same as Option 1, or at least 28,000 lb (12,701 kg) in 1 year between 1984–1993.

Virtually every active tilefish fisherman was present at the November 1999 Council meeting. In addition, the historical participants from New Jersey were represented by the Historical Tilefish Coalition. In debating the appropriate qualifying criteria to be adopted for the Full-time category, the Council concluded that the Full-time category should be split into tier 1 and tier 2 levels. This decision was supported by the fact that four vessels landed considerably more tilefish than any other vessel active in the tilefish fishery. As a result, the Council adopted the following qualifying criteria for the Full-time, tier 1 category: 250,000 lb (113,358 kg) per year for 3 years between 1993–1998. However, the Council deliberated over the criteria to be adopted for the Full-time, tier 2 category. There was some sentiment among Council members to adopt qualifying criteria more in line with those proposed under Options 1 and 4, which were 50,000 lb (22,680 kg) in 1 year between 1988–1993, and at least 25,000 lb (11,340 kg) per year for 2 years during 1994–1998. This was because the Council was concerned about the number of vessels that would qualify for

the limited access fishery, given the reduced annual quota that would apply to the fishery. This became less of a concern once the Council decided to apply sub-quotas to each of the permit categories. These sub-quotas were to be a percentage of the overall quota that would reflect the percentage of the overall tilefish landings from 1988 through 1998 by vessels qualifying for each permit category. Therefore, as more vessels qualified for a particular permit category, the larger the percentage of the overall quota would be allocated to that permit category. The Council ultimately adopted a landings requirement of 30,000 lb (13,608 kg) for the Full-time, tier 2 category, based on the 1988 through 1998 landings data. This level of landings was set high enough above the landing requirement being considered for the Part-time category (10,000 lb (4,536kg)) to represent a level of participation in the fishery that could be considered full-time. Thus, the qualifying criteria adopted by the Council for the Full-time, tier 2 category was as follows: 30,000 lb (13,608 kg) of tilefish for any 3 years between 1993 and 1998, with at least 1 lb (0.5 kg) landed prior to June 15, 1993.

The Council considered a number of alternative qualifying criteria for the Part-time category, bearing in mind their need to address the historical participants in the fishery. Recognizing that the landing requirement was 30,000 lb (13,608 kg) for the Full-time, tier 2 category, the Council looked at a lower annual poundage level to reflect the part-time nature of the fishery. The Council was concerned that the level be set high enough to limit the number of vessels that would qualify for this category. Ultimately, the Council settled on a qualifying poundage of 10,000 lb (4,536 kg) for the Part-time category, since it was significantly below the poundage requirement for the Full-time, tier 2 category, yet above the level of landings for those vessels that truly landed only an incidental catch of tilefish. However, the difficult decision facing the Council was how far back to set the qualifying window. According to the information provided in the public hearing document, the inclusion of vessels landing tilefish back to 1977 (Option 5) would allow as many as 119 vessels into the fishery. Thus, extending the qualifying period back to 1977 raised issues of equity and conservation, but beginning the qualifying window in 1988 failed to capture the time period for the historical fishery. Furthermore, there was a lack of vessel-specific information prior to 1988. At the Council's suggestion, members of the tilefish industry brought forward their landings data at the November 23, 1999, Council meeting. At this meeting, industry proposed that the Council consider a modification to Option 2 by allowing an alternative basis for qualifying for the Part-time category. Under this modified Option 2, vessels could qualify for the Part-time category if they could prove tilefish landings of 28,000 lb (12,701 kg) in any year between 1984 and 1993. Utilizing the landings data brought forward by the tilefish industry and new data provided by the Center, the Council was able to ascertain that this modified Option 2 would allow 42 vessels to qualify for the Part-time category. While this new alternative allowed 32 more vessels to qualify for the Part-time category than under Option 1, it allowed 7 fewer vessels to qualify than under Option 3, which was the Council's preferred alternative in the public hearing document. This revised Option 2, which became Option 6 in the final FMP, was attractive to members of the Council, since it limited participation in this category more than its previously preferred option, and it captured a time-frame when the historical fishery was still going strong. After much deliberation, the Council adopted the new Option 6. Thus, the industry proposal, referred to as "the compromise" in the FMP, was carefully considered, and the reasons for adopting this option, well thought out. Therefore, the reference of this option as a "compromise" in the FMP is inaccurate.

As stated earlier, the Court set aside the permitting requirements of the FMP on the grounds that they violated National Standard 2. National Standard 2 requires that "[c]onservation and management measures shall be based on the best scientific information available." The Guidelines for the National Standards, which are found under 50 CFR part 600, indicate that scientific information includes, but is not limited to, information of a biological, ecological, or social nature. The focus of the FMP was on the biological and ecological data pertaining to the tilefish fishery because the fishery had been determined by the Secretary to be overfished. However, neither the biological or ecological data in the FMP served as the direct basis for the tilefish permitting scheme. Since the biological data clearly showed that the tilefish resource was overfished, the conclusion was to reduce fishing effort. The management method adopted by the Council to reduce fishing effort was limitation on access to the tilefish fishery. Thus, biological data were an indirect basis for the Council's consideration of a limited access system. The ecological data available to the Council did not factor into the creation of a limited access system, since the Council concluded that there was no basis to limit the number of vessels in the fishery to protect essential fish habitat. As stated previously, the only data available to the Council upon which to develop a limited entry system were the vessel permit and Center landings data. These data were utilized by the Council to develop several options for a limited access system. In addition, these data were utilized to determine each permit category's share of the overall quota based on landings by vessels that would qualify for that permit category, and to determine the exclusionary impact on certain vessels of selecting various qualifying criteria.

Classification

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

NMFS has prepared an IRFA that describes the economic impact this proposed rule, if adopted, would have on small entities. The IRFA prepared for this action follows NMFS's "Guidelines for Economic Analysis of Fishery Management Actions" (NMFS's guidelines). A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY**. A summary of the analysis follows:

The universe of vessels impacted by this action are those vessels that qualified for a limited access permit under the requirements established in the FMP, and those vessels that hold an incidental tilefish permit. A total of 32 vessels qualified for limited access permits under the limited access criteria established in the FMP. In addition, there are currently 1,650 vessels holding an open access Incidental tilefish permit, although they are no longer required to hold any Federal permit to land tilefish. All of these vessels are considered to be small entities.

Section 4.9.3 of the FMP provides an analysis of the economic impacts resulting from the various quota alternatives and limited entry alternatives considered in the FMP. According to this analysis, the economic impact to vessels qualifying under each limited access category ranged from expected revenue losses of 50 percent or greater for 1 vessel, to an expected increase in revenues for 181 vessels. A total of 10 vessels were projected to be impacted by revenue losses of 5 percent or greater, 35 vessels were projected to

have no change in revenue, and 24 vessels were projected to incur revenue losses of less than 5 percent. By limited access category, all 4 vessels (100 percent) that qualified for the Full-time, tier 1 category were projected to incur revenue losses of greater than 5 percent, while only 1 vessel (25 percent) in the Full-time tier, 2 category, and no vessels in the Part-time category were projected to incur revenue losses of greater than 5 percent. Furthermore, this analysis projected that 5 vessels (3 percent) in the Incidental category would incur revenue loss of greater than 5 percent, with 1 vessel incurring revenue losses of 50 percent or greater.

The FMP considered six limited entry alternatives as a means of controlling effort in the tilefish fishery. Each of these alternatives consisted of at least two different limited access categories, Full-time and Part-time, having different qualifying criteria. The alternatives are summarized as follows:

Option 1: Part-time - At least 10,000 lb in 1year 1988–1993, and at least 10,000 lb in 1 year between 1994–1998; Full-time - At least 50,000 lb in 1 year 1988–1993, and at least 25,000 lb per year for 2 years during 1994–1998.

Option 2: Part-time - Same as Option 1; Full-time, Tier 1 - At least 250,000 lb per year for 3 years between 1993–1998, and at least 1lb of tilefish landed prior to the June 15, 1993, control date; Full-time, Tier 2 - At least 30,000 lb per year for 3 years 1993 and 1998, and at least 1lb of tilefish landed prior to the June 15, 1993, control date.

Option 3: Part-time - At least 10,000 lb in 1 year between 1988 and June 15, 1993; Full-time - Same as Option 1.

Option 4: Part-time - Same as Option 3; Full-time - At least 50,000 lb in 1 year between 1988 and June 15, 1993.

Option 5: Part-time - At least 10,000 lb in 1 year between 1977 and June 15, 1993; Full-time - At least 50,000 lb in 1 year between 1977 and June 15, 1993.

Option 6: Part-time - Same as Option 1, or 28,000 lb in 1 year between 1984 and 1993; Full-time, Tier 1 - Same as Option 2; Full-time, Tier 2 - Same as Option 2.

The Council's preferred alternative was Option 6, which was implemented in the final rule implementing the FMP. The proposed action would reinstate Option 6 as implemented in this final rule. This action would serve to minimize the economic impacts of the overall quota established in the FMP by dividing this quota among the vessels that qualify under each limited access category. This would enable those vessels that are dependant on the tilefish fishery (those vessels in the Full-time, tier 1 category) to continue to harvest their share of the annua quota in a manner that maximizes their total revenues. If the limited entry program is not reinstated, those vessels that are dependant on the tilefish resource would be faced with the uncertainty of when the overall quota would be harvested, forcing them to fish in a manner that does not maximize their total revenues. Furthermore, in the absence of a limited entry program, a derby fishery for tilefish could occur. A derby fishery could result in large quantities of tilefish entering the market, reducing the price received by the vessel, and reducing total revenues. A derby fishery would also increase safety concerns.

This proposed rule does not duplicate, overlap or conflict with other Federal rules, and does not contain new reporting or recordkeeping requirements.

A copy of this analysis is available from NMFS (*see* **ADDRESSES**).

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: February 4, 2004.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

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

§ 648.14 [Amended]

2. In § 648.14, paragraph (cc)(6) is removed, and reserved.

§ 648.294 [Removed and reserved]

3. Section 648.294 is removed, and reserved.

[FR Doc. 04–2869 Filed 2–10–04; 8:45 am]
BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 69, No. 28
Wednesday, February 11, 2004

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

Glenn/Colusa County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn/Colusa County Resources Advisory Committee (RAC) will meet in Willows, California. Agenda items to be covered include: (1) Introductions, (2) approval of minutes, (3) public comment, (4) ski high project/possible action, (5) update on all projects, (6) how to monitor projects, (7) general discussion, (8) next agenda.

DATES: The meeting will be held on February 23, 2004, from 1:30 p.m. and end at approximately 4:30 p.m.

ADDRESSES: The meeting will be held at the Mendocino National Forest Supervisor's Office, 825 N. Humboldt Ave., Willows, CA 95988. Individuals wishing to speak or propose agenda items must send their names and proposals to Jim Giachino, DFO, 825 N. Humboldt Ave., Willows, CA 95988.

FOR FURTHER INFORMATION CONTACT: Bobbin Gaddini, Committee Coordinator, USDA, Mendocino National Forest, Grindstone Ranger District, P.O. Box 164, Elk Creek, CA 95939. (530) 968–5329; e-mail *ggaddini@fs.fed.us*.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service staff and Committee members. However, persons who wish to bring matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by February 20, 2004, will have the opportunity to address the committee at those sessions.

Dated: February 5, 2004.

James F. Giachino,

Designated Federal Official.

[FR Doc. 04–2937 Filed 2–10–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

[Docket No.: 040203037–4037–01]

Privacy Act System of Records

AGENCY: Department of Commerce.

ACTION: Notice; Commerce/ITA–7: Export.gov Community Registration.

SUMMARY: The Department of Commerce (Commerce) publishes this notice to announce the effective date of a Privacy Act System of Records notice entitled Commerce/ITA System 7: Export.gov Community Registration.

DATES: The system of records becomes effective on February 11, 2004.

ADDRESSES: For a copy of the system of records please mail requests to Gordon Keller, U.S. Department of Commerce, International Trade Administration, Room 1850, 1401 Constitution Avenue, NW., Washington, DC 20230, 202–482–3801.

FOR FURTHER INFORMATION CONTACT: Gordon Keller, U.S. Department of Commerce, International Trade Administration, Room 1850, 1401Constitution Ave., NW., Washington, DC 20230, 202–482–3801.

SUPPLEMENTARY INFORMATION: On December 17, 2003, the Commerce published and requested comments on a proposed Privacy Act System of Records notice entitled Commerce/ITA System 7: Export.gov Community Registration (68 FR 70224, December 17, 2003). No comments were received in response to the request for comments. By this notice, the Department is adopting the proposed system as final without changes effective February 11, 2004.

Dated: February 5, 2004.

Brenda Dolan,

Department of Commerce, Freedom of Information/Privacy Act Officer.

[FR Doc. 04–2897 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

Census Bureau

Boundary and Annexation Survey (BAS)

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 12, 2004.

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 forms and instructions should be directed to Nancy Goodman, Geography Division, U.S. Census Bureau, Washington, DC 20233–7400, or call (301) 763–1099.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts the BAS to collect and maintain information about the inventory of the legal boundaries for and the legal actions affecting the boundaries of: counties and equivalent entities, incorporated places, minor civil divisions, and federally recognized legal American Indian and Alaska Native areas. This information provides an accurate identification of geographic areas for the Census Bureau to use in conducting the decennial and economic censuses and ongoing surveys, preparing population estimates, and supporting other statistical programs of the Census Bureau, and the legislative programs of the Federal government.

Through the BAS, the Census Bureau asks each government to review materials for its jurisdiction to verify the

correctness of the information portrayed. Each government is asked to update the boundaries, supply information documenting each legal boundary change, and provide changes in the inventory of governments.

The BAS universe and mailing materials vary depending upon the needs of the Census Bureau in fulfilling its censuses and household surveys. Counties or equivalent entities, federally recognized American Indian reservations, off-reservation trust lands, and tribal subdivisions are included in every survey.

In the years ending in 8, 9, and 0, the BAS includes all governmentally active counties and equivalent entities, incorporated places, and legally defined minor civil divisions, and legally defined federally recognized American Indian and Alaska Native areas (including the Alaska Native Regional Corporations). Each governmental entity surveyed will receive materials covering its jurisdiction and one or more forms. These three years coincide with the Census Bureau's preparation for the decennial census.

In the years ending with 2 and 7, the BAS includes all legally defined federally recognized American Indian and Alaska Native areas, all governmental counties and equivalent entities, minor civil divisions in the six New England States and those with a population of 10,000 or greater in the States of Michigan, Minnesota, New Jersey, New York, Pennsylvania and Wisconsin, and those incorporated places that have a population of 2,500 or greater in all States.

The remaining years of the decade years ending in 1, 3, 4, 5, and 6 the BAS includes all legally defined federally recognized American Indian and Alaska Native areas, all governmental counties and equivalent entities, minor civil divisions in the six New England States, and incorporated places that have a population of 5,000 or greater in all States.

In the years ending in 1 through 7 the Census Bureau may enter into agreements with individual States to modify the universe of minor civil divisions and/or incorporated places to include additional entities that are known by that State to have had boundary changes, without regard to population size. In addition, the Census Bureau will include in the BAS each newly incorporated place in the year following notification of its incorporation. The BAS also will include each year a single respondent request for municipio, barrio, barrio-pueblo, and subbarrio boundary and status information in Puerto Rico and Hawaiian homeland boundary and status information in Hawaii.

No other Federal agency collects these data nor is there a standard collection of this information at the State level. The Census Bureau's BAS is a unique survey providing a standard result for use by Federal, State, local, and tribal governments and by commercial, private, and public organizations.

II. Method of Collection

The Census Bureau has developed an electronic response option. During the next 3 years, the Census Bureau will be developing additional electronic response options.

The first electronic response option was implemented during the 2003 survey. The respondents were issued a user name and password and given the opportunity to update the BAS forms via the Internet.

A second electronic response option, Web BAS is still in development. During the 2003 survey we tested an application in a pilot program that allowed the respondent to update both their forms and maps using the Internet. The feasibility of and methodology for this option is under development.

The third electronic response option is the Digital BAS. This option will provide a way for governments to submit digital files that represent the spatial location of their boundaries and associated information. Upon receipt and verification of these files, the Census Bureau will integrate the information into our database. The digital submission option is under development.

A BAS package that includes the following items is provided to each respondent:

1. An introductory letter from the Director of the Census Bureau.
2. The appropriate BAS Survey Form(s) that contains entity-specific identification information:

BAS–1—Incorporated Places;
BAS–2—Counties, Parishes, Boroughs, City and Boroughs, Census Areas;
BAS–3—Minor Civil Divisions; .
BAS–4—Newly Incorporated Places or Newly Activated Places;
BAS–5—American Indian and Alaska Native Areas.

3. A unique user name and password for each entity so the respondents can respond electronically via the Internet.
4. A BAS Users Guide for Annotating the Maps.
5. A set of maps or other media showing the current boundaries of the entity.
6. A return envelope and postcards for respondents.

An official in each government is asked to verify the legal boundaries and provide boundary changes. The official is then asked to sign the materials and verify the forms and return the information to the Census Bureau.

The Census Bureau inserts the boundary and feature changes into the TIGER system, the Census Bureau's geographic database and associated data files.

III. Data

Office of Management and Budget (OMB) Number: 0607–0151.

Form Numbers: BAS–1, BAS–2, BAS–3, BAS–4, and BAS–5.

Type of Review: Regular submission.

Affected Public: State, local and tribal governments.

Estimated Number of Respondents:
2005 BAS—12,000 respondents per year;
2006 BAS—13,500 respondents per year;
2007 BAS—14,000 respondents per year.

Estimated Time Per Response: 3 hours.

Estimated Total Annual Burden Hours:
2005 BAS—36,000 burden hours;
2006 BAS—40,500 burden hours;
2007 BAS—42,000 burden hours.

Estimated Total Annual Cost: The estimated total annual cost is $5,347,019 for 2005, $6,014,780 for 2006 and $6,247,072 for 2007.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, U.S.C. section 6.

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 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: February 6, 2004.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 04–2980 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-588–046]

Notice of Rescission of Antidumping Duty Administrative Review: Polychloroprene Rubber from Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Rescission of Antidumping Duty Administrative Review.

SUMMARY: On January 22, 2004, pursuant to a request made by Showa Denko Elastomers, K.K. and Showa Denko K.K. (SDEL/SDK), the Department of Commerce (the Department) initiated an administrative review of the antidumping duty finding on polychloroprene rubber (PR) from Japan. On January 30, 2004, SDEL/SDK withdrew its request for an administrative review of PR from Japan. The Department is now rescinding the administrative review of the antidumping duty finding on PR from Japan.

EFFECTIVE DATE: February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Zev Primor or Maisha Cryor, AD/CVD Enforcement, Group II, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4114 or (202) 482–5831, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 6, 1973, the U.S. Treasury Department published in the **Federal Register** (38 FR 33593) the antidumping duty finding on PR from Japan. On December 17, 2003, SDEL/SDK requested an administrative review of PR from Japan; on January 22, 2004, the Department initiated an administrative review of the antidumping finding on PR from Japan. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 69 FR 3117 (January 22, 2004). On January 30, 2004, SDEL/SDK withdrew their request for review.

Scope of Review

Imports covered by this review are shipments of PR, an oil resistant synthetic rubber also known as polymerized chlorobutadiene or neoprene, currently classifiable under items 4002.41.00, 4002.49.00, 4003.00.00 of the *Harmonized Tariff Schedule of the United States* (HTSUS). HTSUS item numbers are provided for convenience and customs purposes. The written description remains dispositive.

Rescission of Review

Section 351.213(d)(1) of the Department's regulations provides that a party that requests an administrative review may withdraw the request within 90 days after the date of publication of the notice of initiation of the requested administrative review. The Department is rescinding the administrative review of the finding on PR from Japan for the period December 1, 2002, through November 30, 2003, because the requesting party has withdrawn its request for this administrative review within the 90-day time limit, and no other interested parties have requested a review of PR from Japan for this time period.

This notice is in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 251.213(d)(4).

Dated: February 5, 2004.

Holly A. Kuga,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 04–3000 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Minority Business Development Agency

[Docket No. 000724217–4040–07]

Solicitation of Applications for the Minority Business Development Center (MBDC) Program

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) is soliciting competitive applications from organizations to operate Minority Business Development Centers (MBDCs) under its Minority Business Development Center (MBDC) Program. The MBDC geographic service areas being solicited in this Notice are: North Carolina Statewide; Illinois Statewide; Michigan Statewide; El Paso, Texas; and Arizona Statewide. The prior solicitation for these geographic service areas was unsuccessful. The anticipated start date is April 1, 2004. The total award period for awards will be two years and nine months. Funding will be provided initially for a nine-month period, and provided annually thereafter. Future funding will be at the discretion of MBDA and the Department of Commerce, and will depend upon satisfactory performance by the award recipient, availability of funds, and Agency priorities.

The MBDC Program requires MBDC staff to provide standardized business assistance services to rapid growth potential minority businesses directly; to develop a network of strategic partnerships; to charge client fees; and to provide strategic business consulting. These requirements will be used to generate increased results with respect to financing and contracts awarded to minority-owned firms and thus, are a key component of this program.

DATES: The closing date for submission of applications is March 12, 2004. Completed applications must be (1) mailed (USPS Postmark) to the address below; or (2) received by MBDA no later than 5:00 p.m. Eastern Standard Time.

ADDRESSES: If the application is mailed by the applicant or its representative, they must submit one signed original plus two (2) copies of the application. Completed application packages must be mailed to: Office of Business Development, Office of Executive Secretariat, HCHB, Room 5063, Minority Business Development Agency, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

If the application is hand-delivered by the applicant or his/her representative, one signed original plus two (2) copies of the application must be delivered to Room 1874, which is located at Entrance 10, 15th Street, NW., between Pennsylvania and Constitution Avenues.

FOR FURTHER INFORMATION CONTACT: For a copy of the full Notice and/or an application package, contact the specified MBDA National Enterprise Center (NEC) for the geographic service area in which the project will be located (see Geographic Service Areas), or via MBDA's Minority Business Internet Portal at *http://www.mbda.gov.*

SUPPLEMENTARY INFORMATION: The prior solicitation for operators for MBDCs in North Carolina, Illinois, Michigan, El Paso, Texas, and Arizona published in the **Federal Register** on August 29, 2003 (68 FR 51965), as amended on September 30, 2003 (68 FR 56265), was unsuccessful. MBDA has elected to re-compete these service areas. The evaluation criteria and selection procedures contained in the August 29, 2003 notice are applicable to this solicitation. For a copy of the August 29, 2003 and the September 30, 2003

notices, please go to: *http://www.mbda.gov.*

Electronic Access: The full Notice for the MBDC program is available via Web site *http://www.mbda.gov* or by contacting the program official identified above. This announcement will also be available through Grants.gov at *http://www.Grants.gov.*

Applicants are encouraged to submit their entire proposal electronically via the Internet *and mail or hand-deliver only the pages that require original signatures* by the closing date and time stated above. Applicants may submit their applications on MBDA's Web site: *http://www.mbda.gov.* All required forms are located at this web address. *However, the following paper forms must be submitted with original signatures in conjunction with any electronic submissions by the closing date and time stated above:* (1) SF–424, Application for Federal Assistance; (2) the SF–424B, Assurances-Non-Construction Programs; (3) the SF–LLL (Rev. 7–97) (if applicable), Disclosure of Lobbying Activities; (4) Department of Commerce Form CD–346 (if applicable), Applicant for Funding Assistance; and (5) the CD–511, Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying.

Pre-Application Conference: A pre-application conference will be held for the MBDC project solicitation. Contact the specified MBDA NEC for the geographic service area in which the project will be located to receive further information (*see* Geographic Service Areas). Picture identification is required for entrance into any Federal building. Notice of the pre-application conference will be available on MBDA's Internet Portal at *http://www.mbda.gov.*

Funding Availability: Approximately $951,000 will be available in FY 2004 for Federal assistance under this program.

Financial assistance awards under this program may range from $150,479 to $259,847 in the first nine months of the award and from $240,599 to $346,463 in the second and third year of the award in Federal funding based upon minority population, the size of the market and its need for MBDA resources.

Geographic Service Areas: An operator must provide services to eligible clients within its specified geographic service area. MBDA has defined the service area for each award below. To determine its geographic service areas, MBDA uses states, counties, Metropolitan Areas (MA), which comprise metropolitan statistical areas (MSA), consolidated metropolitan statistical areas (CMSA), and primary metropolitan statistical areas (PMSA) as defined by the OMB Committee on MAs *http://www.whitehouse.gov/omb/bulletins* and other demographic boundaries as specified herein. Service to eligible clients outside of an operator's specified service area may be requested, on a case-by-case basis, through the appropriate MBDA Regional Director and granted by the Grants Officer.

The MBDC geographic service areas being solicited in this Notice are: North Carolina Statewide, Illinois Statewide; Michigan Statewide; El Paso, Texas; and Arizona Statewide.

1. *MBDC Application:* North Carolina Statewide.

Geographic Service Area: State of North Carolina.

Award Number: 04–10–04002–01.

The recipient is required to maintain its MBDC in Raleigh/Durham, North Carolina.

Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $212,293. The total Federal amount is $180,449. The application must include a minimum cost share of 15% or $31,844 in non-Federal contributions. Contingent upon the availability of Federal funds, the cost of performance for each of the two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $283,058. The total Federal amount is $240,599. The application must include a minimum cost share of 15% or $42,459 in non-Federal contributions.

Pre-Application Conference: For the exact date, time and place, contact the Atlanta National Enterprise Center at (404) 730–3300 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact Robert Henderson, Regional Director at the phone number listed above.

2. *MBDC Application:* Illinois Statewide.

Geographic Service Area: State of Illinois.

Award Number: 05–10–04001–01.

The recipient is required to maintain its MBDC in downtown Chicago, Illinois.

Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $212,293. The total Federal amount is $180,449. The application must include a minimum cost share of 15% or $31,844 in non-Federal contributions. Contingent upon the availability of Federal funds, the cost of performance for each of two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $283,058. The total Federal amount is $240,599. The application must include a minimum cost share of 15% or $42,459 in non-Federal contributions.

Pre-Application Conference: For the exact date, time and place, contact the Chicago National Enterprise Center at (312) 353–0182 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact Eric Dobyne, Regional Director at the phone number listed above.

3. *MBDC Application:* Michigan Statewide.

Geographic Service Area: State of Michigan.

Award Number: 05–10–04003–01.

The recipient is required to maintain its MBDC in Detroit, Michigan.

Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $212,293. The total Federal amount is $180,449. The application must include a minimum cost share of 15% or $31,844 in non-Federal contributions. Contingent upon the availability of Federal funds, the cost of performance for each of two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $283,058. The total Federal amount is $240,599. The application must include a minimum cost share of 15% or $42,459 in non-Federal contributions.

Pre-Application Conference: For the exact date, time and place, contact the Chicago National Enterprise Center at (312) 353–0182 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact Eric Dobyne, Regional Director at the phone number listed above.

4. *MBDC Application:* El Paso.

Geographic Service Area: El Paso, Texas MA.

Award Number: 06–10–04002–01.

The recipient is required to maintain its MBDC in El Paso, Texas.

Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $177,034. The total Federal amount is $150,479. The application must include a minimum cost share of 15% or $26,555 in non-Federal contributions. Contingent upon the availability of Federal funds, the cost of

performance for each of two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $236,046. The total Federal amount is $200,639. The application must include a minimum cost share of 15% or $35,407 in non-Federal contributions.

Pre-Application Conference: For the exact date, time and place, contact the Dallas National Enterprise Center at (214) 767–8001 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact John Iglehart, Regional Director at the phone number listed above.

5. *MBDC Application:* Arizona Statewide.

Geographic Service Area: State of Arizona.

Award Number: 09–10–04002–01.

The recipient is required to maintain its MBDC in Phoenix, Arizona.

Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $305,703. The total Federal amount if $259,847. The application must include a minimum cost share of 15% or $45,856 in non-Federal contributions. Contingent upon the availability of Federal funds, the cost of performance for each of two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $407,604. The total Federal amount is $346,463. The application must include a minimum cost share of 15% or $61,141 in non-Federal contributions.

Pre-Application Conference: For the exact date, time and place, contact the San Francisco National Enterprise Center at (415) 744–3001 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact Linda Marmolejo, Regional Director at the phone number listed above.

Authority: Executive Order 11625 and 15 U.S.C. 1512.

Catalog of Federal Domestic Assistance (CFDA): 11.800 Minority Business Development Center (MBDC) Program.

Eligibility Criteria: For-profit entities (including sole-proprietorships, partnerships, and corporations), and non-profit organizations, state and local government entities, American Indian Tribes, and educational institutions are eligible to operate MBDCs.

Matching Requirements: Cost sharing of at least 15% is required for all geographic service areas.

Intergovernmental Review

Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Limitation of Liability

In no event will MBDA or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige MBDA or the Department of Commerce to award any specific project or to obligate any available funds.

Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of October 1, 2001 (66 FR 49917), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109), are applicable to this solicitation.

Executive Order 12866

This notice has been determined to be not significant for purposes of E.O. 12866.

Administrative Procedure Act/ Regulatory Flexibility Act

Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Paperwork Reduction Act

This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, CD 346, and SF–LLL have been approved by OMB under the respective control numbers 0348–0043, 0348–0044, 0348–0040, 0605–0001, and 0348–0046. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act unless that collection displays a currently valid OMB Control Number.

Ronald N. Langston,

National Director, Minority Business Development Agency.

[FR Doc. 04–2983 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

Minority Business Development Agency

[Docket No. 000724218–4041–08]

Solicitation of Applications for the Native American Business Development Center (NABDC) Program

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) is soliciting competitive applications from organizations to operate a Native American Business Development Centers (NABDC) under its Native American Business Development Center (NABDC) Program. The NABDC geographic service area being solicited in this Notice: The States of Minnesota/ Iowa. The prior solicitation for this geographic service area was unsuccessful. The anticipated start date is April 1, 2004. The total award period for awards will be two years and nine months. Funding will be provided initially for a nine-month period, and provided annually thereafter. Future funding will be at the discretion of MBDA and the Department of Commerce, and will depend upon satisfactory performance by the award recipient, availability of funds, and Agency priorities.

The NABDC Program requires project operators to deploy standardized business assistance services to the Native American business public directly, to develop a network of strategic partnerships and to provide strategic business consulting within the geographic service area. These requirements will be used to generate increased results with respect to financing and contracts awarded to Native American and minority-owned firms and thus, are a key component of this program.

DATES: The closing date for submission of applications is March 12, 2004. Completed applications must be (1) mailed (USPS Postmark) to the address below; or (2) received by MBDA no later than 5 p.m. eastern standard time.

ADDRESSES: If the application is mailed by the applicant or its representative, they must submit one signed original plus two (2) copies of the application. Completed application packages must be mailed to: Office of Business Development, Office of Executive Secretariat, HCHB, Room 5063, Minority Business Development Agency, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

If the application is hand-delivered by the applicant or his/her representative, one signed original plus two (2) copies of the application must be delivered to Room 1874, which is located at Entrance 10, 15th Street, NW., between Pennsylvania and Constitution Avenues.

FOR FURTHER INFORMATION CONTACT: For a copy of the full Notice and/or an application package, contact the specified MBDA National Enterprise Center (NEC) for the geographic service area in which the project will be located (*see* Geographic Service Areas), or via MBDA's Minority Business Internet Portal at *http://www.mbda.gov.*

SUPPLEMENTARY INFORMATION: The prior solicitation for operators for the NABDC in the State of Minnesota published in the **Federal Register** on August 29, 2003 (68 FR 51965), as amended on September 30, 2003 (68 FR 56267), was unsuccessful. MBDA has elected to re-compete this service area, expanding the service area to include the State of Iowa. The evaluation criteria and selection procedures contained in the August 29, 2003 notice are applicable to this solicitation. For a copy of the August 29, 2003 notice, please go to *http://www.mbda.gov.*

Electronic Access: The full Notice for the NABDC program is available via Web site *http://www.mbda.gov* or by contacting the program official identified above. This announcement will also be available through Grants.gov at *http://www.Grants.gov.*

Applicants are encouraged to submit their entire proposal electronically via the Internet *and mail or hand-deliver only the pages that require original signatures* by the closing date and time stated above. Applicants may submit their applications on MBDA's Web site: *http://www.mbda.gov.* All required forms are located at this Web address. *However, the following paper forms must be submitted with original signatures in conjunction with any electronic submissions by the closing date and time stated above:* (1) SF–424, Application for Federal Assistance; (2) the SF–424B, Assurances-Non-Construction Programs; (3) the SF–LLL (Rev. 7–97) (if applicable), Disclosure of Lobbying Activities; (4) Department of Commerce Form CD–346 (if applicable), Applicant for Funding Assistance; and (5) the CD–511, Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying.

Pre-Application Conference: A pre-application conference will be held for the NABDC project solicitation. Contact the specified MBDA NEC for the geographic service area in which the project will be located to receive further information, (*see* Geographic Service Areas). Picture identification is required for entrance into any Federal building. Notice of the pre-application conference will be available on MBDA's Internet Portal at *http://www.mbda.gov.*

Funding Availability: Approximately $120,000 will be available in FY 2004 for Federal assistance under this program.

The Financial assistance award under this program is $120,000 for the first nine months of the award and $300,000 in the second and third year of the award in Federal funding based upon Native American and minority population, the size of the market and its need for MBDA resources.

Geographic Service Areas: An operator is required to serve the Native American and minority business community throughout the states of Minnesota and Iowa. MBDA has defined the service area for this award below. To determine its geographic service areas, MBDA uses states, counties, Metropolitan Areas (MA), which comprise metropolitan statistical areas (MSA), consolidated metropolitan statistical areas (CMSA), and primary metropolitan statistical areas (PMSA) as defined by the OMB Committee on MAs *http://www.whitehouse.gov/omb/bulletins* and other demographic boundaries as specified herein. Service to eligible clients outside of an operator's specified service area may be requested, on a case-by-case basis, through the appropriate MBDA Regional Director and granted by the Grants Officer.

The NABDC geographic service area being solicited in this Notice is: The States of Minnesota/Iowa.

1. *MBDC Application:* Minnesota/Iowa NABDC.

Geographic Service Area: States of Minnesota/Iowa.

Award Number: 05–10–04004–01.

The recipient is required to have the NABDC physically located in only one of these states; however, if the operator does not have physical presence in both states, it must specify in detail how it plans to service the geographic service area. Contingent upon the availability of Federal funds, the cost of performance for the first funding period from April 1, 2004 to December 31, 2004 is estimated at $120,000. The total Federal amount is $120,000. The minimum cost share of 15% is not required.

Contingent upon the availability of Federal funds, the cost of performance for each of two (2) remaining 12-month funding periods from January 1, 2005 to December 31, 2006, is estimated at $300,000. The total Federal amount is $300,000. The minimum cost share of 15% is not required.

Pre-Application Conference: For the exact date, time and place, contact the Chicago National Enterprise Center at (312) 353–0182 or visit MBDA's Web site at *http://www.mbda.gov.*

For Further Information and a copy of the application kit, contact Eric Dobyne, Regional Director at the number listed above.

Authority: Executive Order 11625 and 15 U.S.C. 1512.

Catalog of Federal Domestic Assistance (CFDA): 11.801 Native Business Development Center (NABDC) Program.

Eligibility Criteria: For-profit entities (including sole-proprietorships, partnerships, and corporations), and non-profit organizations, state and local government entities, American Indian Tribes, and educational institutions are eligible to operate NABDCs.

Matching Requirements: None.

Intergovernmental Review: Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Limitation of Liability: In no event will MBDA or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige MBDA or the Department of Commerce to award any specific project or to obligate any available funds.

Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of October 1, 2001 (66 FR 49917), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109), are applicable to this solicitation.

Executive Order 12866: This notice has been determined to be not significant for purposes of E.O. 12866.

Administrative Procedure Act/ Regulatory Flexibility Act: Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Paperwork Reduction Act: This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, CD 346, and SF–LLL have been approved by OMB under the respective control numbers 0348–0043, 0348–0044, 0348–0040, 0605–0001, and 0348–0046. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act unless that collection displays a currently valid OMB Control Number.

Ronald N. Langston,

National Director, Minority Business Development Agency.

[FR Doc. 04–2984 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 020504C]

New England Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Advisory Panel and its Joint Herring Oversight Committee and Advisory Panel in February and March, 2004 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from these groups will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meetings will be held on February 25, 2004, and March 1–2, 2004. *See* **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held in Portsmouth, NH and Portland, ME. *See* **SUPPLEMENTARY INFORMATION** for specific locations.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Meeting Dates and Agendas

Wednesday, February 25, 2004, at 9:30 a.m. B Groundfish Advisory Panel Meeting.

Location: Holiday Inn, 300 Woodbury Ave., Portsmouth, NH 03801; telephone: (603) 431–8000.

The Groundfish Advisory Panel will meet to discuss Framework Adjustment 40 to the Northeast Multispecies Fishery Management Plan (FMP). They will develop recommended requirements for the use of Category B days-at-sea (DAS). They will consider identifying opportunities for using Category B (regular) DAS that are based on seasons, areas, and gear types, and may consider additional Special Access Programs (SAPs). The panels' recommendations will be forwarded to the Groundfish Oversight Committee for consideration at a future meeting. The Advisory Panel will also discuss the steaming time issue and will discuss other business.

Monday, March 1, 2004, at 9:30 a.m. and Tuesday, March 2, 2004, at 8:30 a.m. B Joint Herring Oversight Committee and Advisory Panel Meeting.

Location: Holiday Inn by the Bay, 88 Spring Street, Portland, ME 04101; telephone: (207) 775–2311.

The Committee will review progress on development of alternatives and analyses for Amendment 1 to the Herring FMP. They will review Herring Plan Development Team recommendations regarding the range of alternatives in Amendment 1 and possible elimination of some alternatives. Also on the agenda is the review of recommendations from the Enforcement Committee, Habitat Technical Team, and other groups regarding the range of alternatives under consideration in Amendment 1. These groups will develop Herring Committee recommendations regarding the range of alternatives in Amendment 1, including possible elimination of some alternatives.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (*see* **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: February 5, 2004.

Tracey Thompson,

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

[FR Doc. E4–251 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 020504D]

New England 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 New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Oversight Committee in March, 2004. Recommendations from the committee will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meeting will held on Tuesday, March 2, 2004 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn by the Bay, 88 Spring Street, Portland, ME 04101; telephone: (207) 775–2311.

Council address: New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Groundfish Oversight Committee will meet to develop alternatives for Framework 40 (FW 40) to the Northeast

Multispecies Fishery Management Plan (FMP). FW 40 will identify opportunities to use regular and reserve Category B Days-At-Sea (DAS). In addition, it will consider changing 10 Category C DAS to 10 Category B (reserve) DAS for those vessels that will not receive Category A or Category B DAS under Amendment 13. FW 40 will also consider changes to the conservation tax applied in the DAS leasing and DAS transfer programs. The Committee will receive the report of the Groundfish Advisory Panel and will develop specific details of proposed measures that, subject to Council approval, will be included in FW 40. The Committee will also discuss other business, including receiving the report of the Advisory Panel on steaming time issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (*see* **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: February 6, 2004.

Tracey Thompson,

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

[FR Doc. E4–252 Filed 2–11–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 020504B]

Pacific Fishery Management Council, Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The groundfish subcommittee of the Pacific Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will meet via telephone conference call to review revised stock assessment information for cabezon and lingcod. The stock assessments are to be used for developing management recommendations for 2005–2006 groundfish fisheries. The work session is open to the public.

DATES: The SSC groundfish subcommittee will review the cabezon assessment from 8 a.m. until 12 p.m. on Wednesday, February 25, 2004. Also on Wednesday, February 25, 2004, the subcommittee will review the lingcod assessment from 1 p.m. until business for the day is completed.

ADDRESSES: Four public listening stations will be established for the public to participate in the telephone conference call. *See* **SUPPLEMENTARY INFORMATION** for the locations of the listening stations.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Waldeck, Staff Officer; 503–820–2280.

SUPPLEMENTARY INFORMATION: The listening station locations are:

1. NMFS, Alaska Fisheries Science Center, Room 2143, 7600 Sand Point Way NE, Building 4, Seattle, WA 98115, telephone: 206–526–6548;
2. Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384; telephone: 503–820–2280;
3. NMFS Southwest Fisheries Science Center, Room 219, 110 Schaffer Road, Santa Cruz, CA 95060; telephone: 831–420–3949;
4. NMFS, Southwest Fisheries Science Center, Room C–115, 8604 La Jolla Shores Drive, La Jolla, CA 92037; telephone: 858–546–7052.

At the November 2003 Council meeting, the SSC noted apparent deficiencies in the cabezon and lingcod stock assessments. The stock assessments had been developed to inform management decision making for the 2005–20 fishing years. However, because the SSC could not endorse the cabezon and lingcod stock assessments, the Council deferred full incorporation of these assessments until the SSC could review revised assessments prior to the March 2004 Council meeting. Since the November 2003 Council meeting, Stock Assessment Teams have prepared revised assessments for cabezon and lingcod. This new information will be reviewed and discussed by the groundfish subcommittee during the telephone conference call. Public comment will be accommodated during the conference call. The initial recommendations of the groundfish subcommittee will be finalized by the SSC and presented to the Council at the March 2004 Council meeting in Tacoma, WA (March 7–12, 2004).

Entry to NMFS facilities requires identification with a photograph (such as a student ID, state drivers license, etc.) A security guard will review the identification and issue a Visitor's Badge valid for the date of the meeting.

Although non-emergency issues not contained in this notice may come before the SSC groundfish subcommittee for discussion, those issues may not be the subject of formal action during this meeting. SSC groundfish subcommittee action will be restricted to those issues specifically listed in this notice, and any issues arising after publication of this notice 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 subcommittee's intent to take final action to address the emergency.

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. Carolyn Porter at 503–820–2280 at least 5 days prior to the meeting date.

Dated: February 5, 2004.

Tracey Thompson,

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

[FR Doc. E4–250 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 000410097–4033–09]

Public Telecommunications Facilities Program: Closing Date

AGENCY: National Telecommunications and Information Administration (NTIA), Commerce.

ACTION: Notice availability of funds.

SUMMARY: Pursuant to the Consolidated Appropriations Act, 2004, the National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce, announces the solicitation of applications for planning and construction grants for public telecommunications facilities under the Public Telecommunications Facilities Program (PTFP). The PTFP

assists, through matching grants, in the planning and construction of public telecommunications facilities in order to: (1) Extend delivery of services to as many citizens as possible by the most cost-effective means, including use of broadcast and non-broadcast technologies; (2) increase public telecommunications services and facilities available to, operated by, and controlled by minorities and women; (3) strengthen the capability of existing public television and radio stations to provide public telecommunications services to the public.

DATES: Applications must be received prior to 6 p.m. eastern standard time, Wednesday, March 31, 2004. Applications submitted by facsimile or electronic means are not acceptable. If an application is received after the Closing Date due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the Closing Date and Time, (2) significant weather delays or natural disasters, or (3) delays due to national security issues, NTIA will, upon receipt of proper documentation, consider the application as having been received by the deadline. NTIA will not accept applications posted on the Closing Date or later and received after the deadline.

ADDRESSES: To obtain a printed application package, submit completed applications, or send any other correspondence, write to: NTIA/PTFP, Room H–4625, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230. Application materials may be obtained electronically via the Internet (*http://www.ntia.doc.gov/ptfp*).

FOR FURTHER INFORMATION CONTACT: William Cooperman, Director, Public Broadcasting Division, telephone: (202) 482–5802; fax: (202) 482–2156. Information about the PTFP can also be obtained electronically via the Internet (*http://www.ntia.doc.gov/ptfp*).

SUPPLEMENTARY INFORMATION:

Electronic Access

The full funding opportunity announcement for the PTFP FY 2004 grant cycle is available on the NTIA Web site: *http://www.ntia.doc.gov/ptfp*, or by contacting the PTFP office at the address noted above. The full announcement is also available through *http://www.Grants.gov*.

Funding Availability

The Congress has appropriated $19.75 million for FY 2004 PTFP awards. For FY 2003, NTIA awarded $40.3 million in funds to 169 projects, including 68 radio awards, 90 television awards and 11 nonbroadcast awards. The radio awards ranged from $7,979 to $244,442. The television awards ranged from $42,344 to $1,790,935. The nonbroadcast awards ranged from $42,000 to $304,872.

Statutory and Regulatory Authority

The Public Telecommunications Facilities Program is authorized by the Communications Act of 1934, as amended, 47 U.S.C. 390–393, 397–399(b). The PTFP operates pursuant to Rules which were published on November 8, 1996 (61 FR 57966). Copies of the 1996 Rules (15 CFR part 2301) are posted on the NTIA Internet site at *http://www.ntia.doc.gov/Rules/currentrules.htm* and NTIA will make printed copies available to applicants upon request.

The following supplemental policies will also be in effect:

(A) Applicants may file emergency applications at any time.

(B) Applicants may file requests for FCC authorizations with the FCC after the PTFP Closing Date. Grant applicants for Ku-band satellite uplinks may submit FCC applications after a PTFP award is made. NTIA may accept FCC authorizations that are in the name of an organization other than the PTFP applicant.

(C) PTFP applicants are not required to submit copies of their PTFP applications to the FCC, nor are they required to submit copies of the FCC transmittal cover letters as part of their PTFP applications. PTFP applicants for distance learning projects must notify the state telecommunications agencies in the states in which they are located but are not required to notify every state telecommunications agency in a potential service area.

(D) NTIA will fund all television projects, other than for new service expansion, with a presumption of 40% Federal share. For digital television conversion projects, NTIA has created two new Subpriorities in the Broadcast Other category, will permit purchase of eligible equipment with local match funds after July 1, 1999, and will add three points to applications which request no more than a 25% Federal share.

(E) For digital radio conversion projects, NTIA has created a new Subpriority in the Broadcast Other category.

Catalog of Domestic Federal Assistance: 11.550, Public Telecommunications Facilities Program.

Eligibility

Eligible applicants must be: (a) A public or noncommercial educational broadcast station; (b) a noncommercial telecommunications entity; (c) a system of public telecommunications entities; (d) a non-profit foundation, corporation, institution, or association organized primarily for educational or cultural purposes; or (e) a state, local, or Indian tribal government (or agency thereof), or a political or special purpose subdivision of a state.

Evaluation and Selection Process

See 15 CFR 2301.16 for a description of the Technical Evaluation and 15 CFR 2301.18 for the Selection Process.

Evaluation Criteria

See 15 CFR 2301.17 for a full description of the Evaluation Criteria. The six evaluation criteria are (1) Applicant Qualifications, (2) Financial Qualifications, (3) Project Objectives, (4) Urgency, (5) Technical Qualifications (construction applicants only) or Planning Qualifications (planning applicants only), and (6) Special Consideration.

Funding Priorities and Selection Factors

See 15 CFR 2301.4 and the supplemental policies above for a description of the PTFP Priorities and 15 CFR 2301.18 for the Selection Factors.

Cost Sharing Requirements

PTFP requires cost sharing. By statute, PTFP cannot fund a Construction project for more than 75% of the eligible project costs. NTIA has established a policy of funding most new public broadcasting station activation projects at a 75% federal share, most other radio and nonbroadcast projects at a 50% federal share, and most other television projects at a 40% federal share. NTIA can fund Planning applications up to 100% of the eligible project costs, but has established a policy of funding Planning applications at a 75% share. Any applicant can request federal funding up to the statutory maximum and provide justification for the request.

Intergovernmental Review

PTFP applications are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs," if the state in which the applicant organization is located participates in the process. Usually submission to the State Single Point of Contact (SPOC) needs to be only the first two pages of the Application Form, but applicants should contact their own SPOC offices to find out about and comply with its requirements. The names and addresses of the SPOC offices are listed on the PTFP Web site and at the Office of Management and Budget's home page at *http://www.whitehouse.gov/omb/grants/spoc.html*.

Universal Identifier

All applicants (nonprofit, state, local government, universities, and tribal organizations) will be required to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number during the application process. *See* the October 30, 2002 (67 FR 66177) and April 8, 2003 (68 FR 17000) **Federal Register** notices for additional information. Organizations can

receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line 1–866–705–5711 or via the Internet (*http://www.dunandbradstreet.com*).

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements

The Department of Commerce Pre-Award Notification of Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of October 1, 2001 (66 FR 49917), as amended by the Federal Register notice published on October 30, 2002 (67 FR 66109), are applicable to this solicitation.

Limitation of Liability

In no event will the Department of Commerce be responsible for proposal preparation costs if this program fail to receive funding or is cancelled because of other agency priorities. Publication of this announcement does not oblige the agency to award any specific project or to obligate any available funds.

Paperwork Reduction Act

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection displays a currently valid Office of Management and Budget (OMB) control number. The PTFP application form has been cleared under OMB control no. 0660–0003.

Executive Order 12866

It has been determined that this notice is a "not significant" rule under Executive Order 12866.

Executive Order 13132

It has been determined that this notice does not contain policies with Federalism implications as that term is defined in E.O. 13132.

Administrative Procedure Act/ Regulatory Flexibility Act

Prior notice and opportunity for public comment are not required by the Administrative Procedure Act or any other law for this notice concerning grants, benefits, and contracts (5 U.S.C. 553(a)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Bernadette McGuire-Rivera,

Associate Administrator, Office of Telecommunications and Information Applications.

[FR Doc. 04–2947 Filed 2–10–04; 8:45 am]

BILLING CODE 3510–60–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the "Corporation") has submitted a public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995, Pub. L. 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Mr. Mark Abbott, at (202) 606–5000, extension 120, (*mabbott@cns.gov*); (TTY/TDD) at (202) 606–5256 between the hours of 9 a.m. and 4 p.m. Eastern Standard Time, Monday through Friday.

Comments may be submitted, identified by the title of the information collection activity, by any of the the following two methods within 30 days from the date of publication in this **Federal Register:**

(1) By fax to: (202) 395–6974, Attention: Ms. Fumie Yokota, OMB Desk Officer for the Corporation for National and Community Service; and

(2) Electronically by e-mail to: *Fumie_Yokota@omb.eop.gov.*

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the Corporation's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility and clarity of the information to be collected; and
- Propose ways 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 submissions of responses.

Description: The Corporation for National and Community Service (the Corporation) awards federal grants to states, institutions of higher education, non-profit organizations, Indian tribes and U.S. territories to operate national service programs. The Corporation is obligated by statute to monitor grantee compliance with the appropriate Federal Statues, Regulations and OBM circulars. The information requested in this biannual report will be the primary means for collecting data on both grantee fiscal/programmatic compliance and progress towards meeting the performance measures specified in the grant awards. For statutory authority, please see the National and Community Service Act of 1990, as amended.

Information provided in the Performance Reports will be used by Learn and Serve America to ensure grantees are making adequate progress towards meeting performance measures, and that activities are appropriate under the terms and conditions of the grant award. This information will also be used to help determine eligibility for second and third year Continuation Grants, which are available to Learn and Serve America grantees subject to funding availability and adequate progress towards meeting performance measures.

This report will also track the grantees' sub-grants, allowing the Corporation the ability in the future to collect important performance data at the subgrantee level (a request to collect subgrantee information is forthcoming in a separate OMB Paperwork Reduction Act submission). Systematic review and a risk-based assessment of each Performance Report will be conducted by the appropriate Learn and Serve America Program officer within 30 days of receipt of the reports.

Currently, the Corporation is soliciting comments concerning Learn and Serve Aamerica Grantee Performance Report.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: Learn and Serve America Grantee Performance Report.

OMB Number: None.

Agency Number: None.

Affected Public: Current LSA Grantees.

Total Respondents: 133.

Frequency: Twice per year.

Average Time Per Response: 2 hours.

Estimated Total Burden Hours: 532 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: February 4, 2004.

Amy B. Cohen,

Director, Learn and Serve America.

[FR Doc. 04–2963 Filed 2–10–04; 8:45 am]

BILLING CODE 6050–$$–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the "Corporation") has submitted a public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995, Pub. L. 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Ms. Amy Cohen, at (202) 606–5000, extension 209, (*acohen@cns.gov*); (TTY/TDD) at (202) 606–5256 between the hours of 9 a.m. and 4 p.m. Eastern Standard Time, Monday through Friday.

Comments may be submitted, identified by the title of the information collection activity, by any of the following two methods within 30 days from the date of publication in this **Federal Register:**

(1) By fax to: (202) 395–6974, Attention: Ms. Fumie Yokota, OMB Officer for the Corporation for National and Community Service; and

(2) Electronically by e-mail to: *Fumie_Yokota@omb.eop.gov.*

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the Corporation's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility and clarity of the information to be collected; and
- Propose ways 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 submissions of responses.

Description

The Presidential Freedom Scholarship program recognizes high school juniors and seniors for outstanding leadership in service. Each high school in the United States may award up to two recipients with a $1,000 scholarship for college: Five hundred dollars ($500) is funded from the Corporation's National Service Trust, and the remaining $500 is secured locally from civic groups, local business, and other community based organizations.

While the selection of the recipients is made by the high school, the principal must complete an application in order for the Corporation to release the funds in the form of a check made out to the student and the college that he/she is planning to attend. The application may be completed either in paper or online form.

The Corporation is seeking public comment for approval of the Presidential Freedom Scholarship Application which will be used by high school principals to nominate high school juniors and seniors for this scholarship.

Type of Review: New information collection.

Agency: Corporation for National and Community Service.

Title: Presidential Freedom Scholarship Application.

OMB Number: None.

Agency Number: None.

Affected Public: High School Principals and/or guidance counselors.

Total Respondents: 7,000.

Frequency: Annually.

Average Time Per Response: 30 minutes.

Estimated Total Burden Hours: 3,500 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: January 30, 2004.

Amy Cohen,

Director, Learn and Serve America.

[FR Doc. 04–2964 Filed 2–10–04; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability for Donation of the Amphibious Assault Ship ex-NEW ORLEANS (LPH 11) and the Aircraft Carrier ex-RANGER (CV 61); Correction

AGENCY: Department of the Navy, DOD.

ACTION: Notice; Correction.

SUMMARY: The Naval Sea Systems Command published a document in the **Federal Register** of January 15, 2004, concerning a Notice of Availability for Donation of the Amphibious Assault Ship ex-NEW ORLEANS (LPH 11) and the Aircraft Carrier ex-RANGER (CV 61). The document erroneously listed the ex-RANGER (CV 61) as available for donation.

FOR FURTHER INFORMATION CONTACT: Ms. Gloria Carvalho, (202) 781–0485.

Correction

In the **Federal Register** of January 15, 2004, in FR Doc. 04–872, on page 2337, in the second column, omit all references to ex-RANGER (CV 61), and correct the "Summary" caption to read:

SUMMARY: The Department of the Navy hereby gives notice of the availability for donation, under the authority of 10 U.S.C. section 7306, of the amphibious assault ship ex-NEW ORLEANS (LPH 11) located at the MARAD National Defense Reserve Fleet, Suisun Bay, Benecia, CA. Eligible recipients include: (1) Any State, Commonwealth, or possession of the United States or any municipal corporation or political subdivision thereof; (2) the District of Columbia; or (3) any organization incorporated as a non-profit entity under section 501 of the Internal Revenue Code. The transfer of a ship for donation under 10 U.S.C section 7306 shall be made at no cost to the United States government. The donee will be required to maintain the ship as a static museum/memorial in a condition that is satisfactory to the Secretary of the Navy. Prospective donees must submit a comprehensive application that addresses the significant financial, technical, environmental and curatorial responsibilities associated with donated Navy ships. Further application information can be found on the Navy Ship Donation Program Web site: *http://www.navsea.navy.mil/ndp.* All vessels currently in a donation hold status, including the ex-NEW ORLEANS (LPH 11), will be reviewed by the Chief of Naval Operations during the annual Ship Disposition Review (SDR) process, at which time a determination will be

made whether or not to extend the donation hold status. This notice of availability will expire in 6 months from the date of issue.

Dated: February 2, 2004.

J.T. Baltimore,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 04–2946 Filed 2–10–04; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before March 12, 2004.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Melanie Kadlic, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the Internet address *Melanie_Kadlic@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.*, new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: February 5, 2004.

Angela C. Arrington,

Leader, Regulatory Information Management Group, Office of the Chief Information Officer.

Office of Vocational and Adult Education

Type of Review: Revision.

Title: Vocational Technical Education Annual Performance and Financial Reports.

Frequency: Annually.

Affected Public: State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 54.

Burden Hours: 5,400.

Abstract: The information contained in the Consolidated Annual Performance Report for Vocational Technical Education is needed to monitor State performance of the activities and services funded under the Carl D. Perkins Vocational and Technical Education Act of 1998. The respondents include eligible agencies in 54 states and insular areas. This revision clarifies instructions and definitions and eliminates the collection of some data elements.

Requests for copies of the submission for OMB review; comment request may be accessed from *http://edicsweb.ed.gov*, by selecting the "Browse Pending Collections" link and by clicking on link number 2420. When you access the information collection, click on "Download Attachments "to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651 or to the e-mail address *vivan.reese@ed.gov*. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to (202) 708–9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Shelia Carey at her e-mail address *Shelia.Carey@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 04–2902 Filed 2–10–04; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah, Annual Planning Retreat. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: March 5–6, 2004.

ADDRESSES: Lake Barkeley State Resort Park, 3500 State Park Road, Cadiz, KY 42211.

FOR FURTHER INFORMATION CONTACT: William E. Murphie, Deputy Designated Federal Officer, Department of Energy Portsmouth/Paducah Project Office, 1017 Majestic Drive, Suite 200, Lexington, Kentucky 40513, (859) 219–4001.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration and waste management activities.

Tentative Agenda

Friday, March 5

7:30 p.m.—Review of the Proposed Retreat Agenda: Steve Kay
7:40 p.m.—CAB Self-Evaluation Survey Summary Discussion
9 p.m.—Adjourn

Saturday, March 6

8:30 a.m.—Welcome: Bill Tanner
8:40 a.m.—Roundtable Discussion—CAB Goals and Operations
9:30 a.m.—Break
10 a.m.—Annual Workplan
12 noon—Lunch
1 p.m.—CAB Budget and Support Staff Contract Issues
2 p.m.—Task Force/Subcommittee Discussion (realignment and reassignments)
2:30 p.m.—Summary/Wrap Up
3 p.m.—Adjourn

Copies of the final agenda will be available at the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact David Dollins at the address listed below or by telephone at (270) 441–6819. Requests must be received five days prior to the meeting and

reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comments will be provided a maximum of five minutes to present their comments as the first item of the meeting agenda.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information Center and Reading Room at 115 Memorial Drive, Barkley Centre, Paducah, Kentucky between 8 a.m. and 5 p.m. on Monday thru Friday or by writing to David Dollins, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001 or by calling him at (270) 441–6819.

Issued at Washington, DC on February 5, 2004.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 04–2960 Filed 2–10–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 04–01–NG; et al.]

Office of Fossil Energy; Irving Oil Terminals Inc., et al.; Orders Granting and Amending Authority To Import and Export Natural Gas, Including Liquefied Natural Gas

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during January 2003, it issued Orders granting and amending authority to import and export natural gas, including liquefied natural gas. These Orders are summarized in the attached appendix and may be found on the FE Web site at *http://www.fe.doe.gov* (select gas regulation). They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import & Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on February 5, 2004.

Sally Kornfeld,

Manager, Natural Gas Regulation, Office of Natural Gas & Petroleum Import & Export Activities, Office of Fossil Energy.

APPENDIX.—ORDERS GRANTING AND VACATING IMPORT/EXPORT AUTHORIZATIONS

[DOE/FE Authority]

Order No.	Date issued	Importer/exporter FE docket No.	Import volume	Export volume	Comments
1933	1–7–04	Irving Oil Terminals Inc., 04–01–NG	13.77 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on January 1, 2004, and extending through December 31, 2005.
1829–A	1–7–04	Engage Energy, LLC (Formerly Engage Energy America LLC), 02–81–LNG.	.....	.....	Name change on blanket import and export authority.
1934	1–13–04	NYSEG Solutions, Inc., 04–02–NG	15 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on January 1, 2004, and extending through December 31, 2005.
1935	1–13–04	Panhandle Eastern Pipe Line Company, 03–87–NG.	5 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on January 13, 2004, and extending through January 12, 2006.

[FR Doc. 04–2968 Filed 2–10–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 03–82–NG, et al.]

Office of Fossil Energy; Puget Sound Energy, Inc., et al.; Orders Granting and Vacating Authority To Import and Export Natural Gas

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during December 2003, it issued Orders granting and vacating authority to import and export natural gas, including liquefied natural gas. These Orders are summarized in the attached appendix and may be found on the FE Web site at *http://www.fe.doe.gov* (select gas regulation). They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import & Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on January 30, 2004.

Sally Kornfeld,

Manager, Natural Gas Regulation, Office of Natural Gas & Petroleum Import & Export Activities, Office of Fossil Energy.

APPENDIX.—ORDERS GRANTING AND VACATING IMPORT/EXPORT AUTHORIZATIONS

[DOE/FE Authority]

Order No.	Date issued	Importer/exporter FE docket No.	Import volume	Export volume	Comments
1924	12–4–03	Puget Sound Energy, Inc., 03–82–NG	[1] 75 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on December 6, 2003, and extending through December 5, 2005.
1925	12–4–03	Peoples Energy Wholesale Marketing LLC, 03–80–NG.	10 Bcf	10 Bcf	Import and export natural gas from and to Canada, beginning on December 6, 2003, and extending through December 5, 2005.
1927	12–8–03	Direct Energy Marketing Inc., 03–81–NG ...	[1] 500 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on December 8, 2003, and extending through December 7, 2005.
1928	12–8–03	Direct Energy Marketing Limited 03–83–NG	[1] 500 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on December 1, 2003, and extending through November 30, 2005.
1928	12–8–03	Direct Energy Marketing Limited 03–83–NG	.....	.....	Vacate blanket import and export authority granted in Docket No. Order No. 1742.
1929	12–11–03	Enbridge Gas Distribution Inc. 03–84–NG ..	[1] 300 Bcf		Import and export a combined total of natural gas from and to Canada, beginning on January 1, 2004, and extending through December 31, 2005.
1930	12–17–03	Williams Power Company, Inc. (Formerly, Williams Energy Marketing & Trading Company) 03–85–NG.	200 Bcf	.....	Import natural gas from Canada, beginning on December 17, 2003, and extending through December 16, 2005.
1931	12–23–03	Suncor Energy Inc. and Suncor Energy Marketing Inc. 03–86–NG.	128 Bcf	.....	Import natural gas from Canada, beginning on January 1, 2004, and extending through December 31, 2005.

[FR Doc. 04–2969 Filed 2–10–04; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Biomass Research and Development Technical Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Biomass Research and Development Technical Advisory Committee under the Biomass Research and Development Act of 2000. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that agencies publish these notices in the **Federal Register** to allow for public participation. This notice announces the meeting of the Biomass Research and Development Technical Advisory Committee.

DATES: March 11, 2004.

TIME: 8:30 a.m.

ADDRESSES: Hilton Crystal City Hotel at National Airport, Crystal Room, 2399 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: John Ferrell, Designated Federal Officer for the Committee, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–7766.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance that promotes research and development leading to the production of biobased industrial products.

Tentative Agenda: Agenda will include discussions on the following:

- The Biomass R&D Technical Advisory Committee will meet to obtain on overview of progress and the history of research efforts in major biomass technology areas. The Committee also will receive updates on the status of the USDA—DOE joint solicitation for biomass R&D, activities to promote Federal procurement of biobased products, and method for tracking progress of research awards under the joint solicitation.

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the Biomass Research and Development Technical Advisory Committee. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, you should contact John Ferrell at 202–586–7766 or *Bioenergy@ee.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chair of the Committee will make every effort to hear the views of all interested parties. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. The Chair will conduct the meeting to facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days at the Freedom of Information Public Reading Room; Room 1E–190; Forrestal Building; 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on February 6, 2004.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 04–2967 Filed 2–10–04; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Notice

February 4, 2004.

The following notice of meeting is published pursuant to section 3(A) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: February 11, 2004, 10 a.m.

PLACE: Room 2C, 888 First Street, NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*** Note.**—Items listed on the agenda may be deleted without further notice.

FOR FURTHER INFORMATION CONTACT: Magalie R. Salas, Secretary, telephone (202) 502–8400, for a recording listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Reference and Information Center.

850th—Meeting, February 11, 2004, Regular Meeting, 10 a.m.

Administrative Agenda

A–1.
Docket# AD02–1, 000, Agency Administrative Matters

A–2.
Docket# AD02–7, 000, Customer Matters, Reliability, Security and Market Operations

Markets, Tariffs and Rates—Electric

E–1.
Omitted

E–2.
Docket# ER03–1102, 000, California Independent System Operator Corporation

E–3.
Docket# ER03–1272, 000, Entergy Services, Inc
Other#S ER03–1272, 001, Entergy Services, Inc

E–4.
Omitted

E–5.
Docket# ER04–308, 000, Cabrillo Power I LLC and Cabrillo Power II LLC

E–6.
Docket# ER04–295, 000, Pacific Gas and Electric Company

E–7.
Docket# ER03–1354, 000, Black Hills Power, Inc.
Other#S ER03–1354, 001, Basin Electric Power Cooperative
ER03–1354, 002, Powder River Energy Corporation

E–8.
Omitted

E–9.
Docket# ER04–341, 000, Vermont Electric Cooperative, Inc.

E–10.
Omitted

E–11.
Docket# ER04–361, 000, PJM Interconnection L.L.C.

E–12.
Omitted

E–13.
Omitted

E–14.
Docket# ER03–142, 000, Southern California Edison Company

E–15.
Docket# ER03–599, 000, Entergy Services, Inc
Other#S ER03–599, 001, Entergy Services, Inc
ER03–599, 002, Entergy Services, Inc
ER03–599, 003, Entergy Services, Inc

E–16.
Docket# ER04–139, 000, Michigan Electric Transmission Company, LLC
Other#s ER04–139, 001, Michigan Electric Transmission Company, LLC
ER04–315, 000, Michigan Electric Transmission Company, LLC

E–17.
Docket# ER03–600, 000, Cross-Sound Cable Company, LLC
Other#s ER03–600, 001, Cross-Sound Cable Company, LLC

E–18.
Docket# ER04–230, 000, New York Independent System Operator, Inc.
Other#s ER04–230, 001, New York Independent System Operator, Inc.

E–19.
Docket# NJ03–3, 001, United States Department of Energy Bonneville Power Administration

E–20.
Omitted

E–21.
Docket# ER02–851, 013, Southern Company Services, Inc.

E–22.
Docket# ER03–93, 000, El Paso Electric Company

E–23. Docket# TX03–1, 000, Mirant Las Vegas, LLC, Duke Energy, Moapa, LLC, GenWest, LLC, Las Vegas, Cogeneration II, LLC, Reliant Energy, Bighorn, LLC
Other#s ER02–1741, 000, Nevada Power Company
ER02–1741, 001, Nevada Power Company
ER02–1741, 002, Nevada Power Company
ER02–1742, 000, Nevada Power Company
ER02–1742, 001, Nevada Power Company
ER02–1742, 002, Nevada Power Company
TX03–1, 001, Mirant Las Vegas, LLC, Duke Energy Moapa, LLC, GenWest, LLC, Las Vegas Cogeneration II, LLC, Reliant Energy Bighorn, LLC
TX03–1, 002, Mirant Las Vegas, LLC, Duke Energy Moapa, LLC, GenWest, LLC, Las Vegas, Cogeneration II, LLC, Reliant Energy Bighorn, LLC

E–24.
Docket# TX96–2, 001, City of College Station, Texas
Other#s TX96–2, 004, City of College Station, Texas
TX96–2, 005, City of College Station, Texas
TX96–2, 006, City of College Station, Texas
TX96–2, 007, City of College Station, Texas
TX96–2, 008, City of College Station, Texas

E–25.
Docket# ER97–2355, 005, Southern California Edison Company
Other#s ER98–1261, 002, Southern California Edison Company
ER98–1685, 001, Southern California Edison Company

E–26.
Docket# ER01–890, 004, Boston Edison Company
Other#s ER01–890, 005, Boston Edison Company
ER02–1465, 001, Boston Edison Company
ER02–1465, 002, Boston Edison Company

E–27.
Docket# EL03–14, 001, City of Azusa, California
Other#s EL00–105, 007, City of Vernon, California
ER00–2019, 007, California Independent System Operator Corporation
EL03–15, 001, City of Anaheim, California
EL03–20, 001, City of Riverside, California
EL03–21, 001, City of Banning, California

E–28.
Docket# ER03–540, 007, Carolina Power & Light Company and Florida Power Corporation

E–29.
Omitted

E–30.
Docket# EL01–93, 007, *Mirant Americas Energy Marketing, LP, Mirant New England, LLC, Mirant Kendall, LLC, and Mirant, LLC* v. *ISO New England Inc.*

E–31.
Omitted

E–32.
Docket# ER03–1140, 001, Entergy Services, Inc.
Other#s ER03–1140, 002, Entergy Services, Inc.

E–33.
Omitted

E–34.
Omitted

E–35.
Docket# ER99–2326, 005, Pacific Gas and Electric Company
Other#s EL99–68, 005, Pacific Gas and Electric Company

E–36.
Docket# ER99–28, 005, Sierra Pacific Power Company
Other#s EL99–38, 004, Sierra Pacific Power Company
ER99–945, 004, Sierra Pacific Power Company

E–37.
Docket# EG04–24, 000, Duke Energy Vermillion, LLC

E–38.
Docket# EG04–25, 000, POSDEF Power Company, L.P.

E–39.
Docket# EG04–29, 000, Jubail Energy Company

E–40.
Docket# EG04–27, 000, Shuweihat CMS International Power Company

Other#s EG04–28, 000, Shuweihat O&M Limited Partnership
E–41.
Docket# EL04–13, 000, Golden Spread Electric Cooperative, Inc.
E–42.
Docket# EL04–24, 000, California Independent System Operator Corporation
E–43.
OMITTED
E–44.
OMITTED
E–45.
OMITTED
E–46.
OMITTED
E–47.
OMITTED
E–48.
OMITTED
E–49.
OMITTED
E–50.
Omitted
E–51.
Docket# TX96–4, 001, Suffolk County Electrical Agency
E–52.
Docket# EL00–66, 000, *Louisiana Public Service Commission and the Council of the City of New Orleans* v. *Entergy Corporation*
Other#s EL95–33, 002, *Louisiana Public Service Commission* v. *Entergy Services, Inc.*
ER00–2854, 000, Entergy Services, Inc.
E–53.
Docket# EL04–30, 000, Black Hills Ontario, L.L.C.
Other#s QF84–122, 004, Black Hills Ontario, L.L.C.
E–54.
Docket# ER03–684, 000, Wisconsin Power & Light Company

Miscellaneous Agenda

M–1.
Docket# RM03–8, 000, Quarterly Financial Reporting and Revisions to the Annual Reports
M–2.
Docket# RM02–4, 002, Critical Energy Infrastructure Information
Other#s PL02–1, 002, Critical Energy Infrastructure Information
RM03–6, 001, Amendments to Conform Regulations with Order No. 630 (Critical Energy Infrastructure Information Final Rule)

Markets, Tariffs and Rates—Gas

G–1.
Docket# RM04–4, 000, Creditworthiness Standards for Interstate Natural Gas Pipelines
G–2.
Docket# OR96–2, 000, *ARCO Products Co. a Division of Atlantic Richfield Company, Texaco Refining and Marketing Inc., and Mobil Oil Corporation* v. *SFPP*
Other#s OR92–2, 002, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
OR96–2, 002, SFPP, L.P.
OR96–10, 000, *ARCO Products Co. a Division of Atlantic Richfield Company, Texaco Refining and Marketing Inc., and Mobil Oil Corporation* v. *SFPP*
OR96–10, 002, SFPP, L.P.
OR96–15, 000, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
OR96–17, 000, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
OR96–17, 002, SFPP, L.P.
OR97–2, 000, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
OR98–1, 000, *ARCO Products Co. a Division of Atlantic Richfield Company, Texaco Refining and Marketing Inc., and Mobil Oil Corporation* v. *SFPP*
OR98–1, 000, *Tosco Corporation* v. *SFPP*
OR98–2, 000, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
IS98–1, 000, SFPP, L.P.
OR98–13, 000, *Tosco Corporation* v. *SFPP*
OR00–4, 000, *ARCO Products Co. a Division of Atlantic Richfield Company, Texaco Refining and Marketing Inc., and Mobil Oil Corporation* v. *SFPP*
OR00–7, 000, *Navaho Refining Corporation* v. *SFPP*
OR00–9, 000, *Ultramar Diamond Shamrock Corporation and Ultramar, Inc.* v. *SFPP*
OR00–9, 000, *Tosco Corporation* v. *SFPP*
OR00–10, 000, *Refinery Holding Company* v. *SFPP*
G–3.
Docket# RP04–138, 000, Tennessee Gas Pipeline Company
G–4.
Docket# PR01–16, 000, Bridgeline Holdings, L.P.
Other#s PR01–16, 001, Bridgeline Holdings, L.P.
G–5.
Docket# PR04–1, 000, Kinder Morgan Border Pipeline, L.P.
Other#s PR04–1, 001, Kinder Morgan Border Pipeline, L.P.
G–6.
Docket# CP00–6, 009, Gulfstream Natural Gas System, L.L.C.
Other#s RP03–173, 001, Gulfstream Natural Gas System, L.L.C.
G–7.
Docket# RP98–40, 000, Panhandle Eastern Pipe Line Company
Other#s GP98–27, 000, ONEOK Exploration Co.
SA99–7, 000, Charlotte Hill Gas Co.
SA98–100, 000, Partnership Properties Co., a/k/a IMC Global, Inc.
G–8.
Docket# RP03–222, 000, Columbia Gas Transmission Corporation
G–9.
Docket# RP03–281, 000, Columbia Gas Transmission Corporation
RP03–281, 001, Columbia Gas Transmission Corporation
RP03–281, 002, Columbia Gas Transmission Corporation
G–10.
Docket# RP03–123, 000, Southern Natural Gas Company
Other#s RP02–86, 001, Southern Natural Gas Company
RP03–123, 001, Southern Natural Gas Company
RP04–79, 000, Southern Natural Gas Company
G–11.
Docket# PR03–18, 000, Katy Storage and Transportation, L.P.
G–12.
Docket# RP03–582, 002, Florida Gas Transmission Company
RP03–582, 001, Florida Gas Transmission Company
G–13.
Omitted
G–14.
Docket# PR00–9, 002, GulfTerra Texas Pipeline, L.P.
G–15.
Docket# RP03–484, 001, *Toca Producers* v. *Southern Natural Gas Company*
Other#s RP01–208, 001, Amoco Production Company, BP Exploration & Oil Inc., Chevron U.S.A. Inc., Exxon/Mobil Gas Marketing Company, and Shell Offshore, Inc.
G–16.
Omitted
G–17.
Docket# RP00–387, 003, Florida Gas Transmission Company
Other#S RP00–387, 004, Florida Gas Transmission Company
G–18.
Docket# RP00–469, 004, East Tennessee Natural Gas Company
Other#S RP00–469, 005, East Tennessee Natural Gas Company
RP00–469, 006, East Tennessee Natural Gas Company
RP01–22, 006, East Tennessee Natural Gas Company
RP01–22, 007, East Tennessee Natural Gas Company
RP01–22, 008, East Tennessee Natural Gas Company
RP03–177, 001, East Tennessee Natural Gas Company
RP03–177, 002, East Tennessee Natural Gas Company
RP03–177, 003, East Tennessee Natural Gas Company
G–19.
Docket# RP02–23, 000, *El Paso Natural Gas Company* v. *Phelps Dodge Corporation*
G–20.
Docket# RP98–39, 034, Northern Natural Gas Company
Other#s GP98–5, 000, ExxonMobil Oil Corporation
GP98–12, 000, BP America Production Company
GP98–14, 000, Anadarko Petroleum Corporation
G–21.
Docket# OR01–2, 000, *Big West Oil Company* v. *Frontier Pipeline Company and Express Pipeline Partnership*
Other#s OR01–4, 000, *Chevron Products Company* v. *Frontier Pipeline Company and Express Pipeline Partnership*
G–22.
Docket# RP03–7, 002, Natural Gas Pipeline Company of America
Other#s RP03–7, 003, Natural Gas Pipeline Company of America

Energy Projects—Hydro

H–1.
Docket# P–2161, 008, Rhinelander Paper Company
H–2.
Omitted
H–3.
Docket# P–2305, 018, Sabine River Authority of Texas and Sabine River Authority of Louisiana
H–4.
Docket# P–1971, 081, Idaho Power Company
Other#s P–1971, 082, Idaho Power Company
H–5.
Docket# P–2149, 106, Public Utility District No. 1 of Douglas County, Washington
Other#s P–943, 083, Public Utility District No. 1 of Chelan County, Washington
P–2145, 057, Public Utility District No. 1 of Chelan County, Washington

Energy Projects—Certificates

C–1.
Docket# CP02–430, 004, Saltville Gas Storage Company, LLC
C–2.
Docket# CP01–49, 002, Northwest Pipeline Corporation
CP01–49, 003, Northwest Pipeline Corporation
C–3.
Docket# CP03–352, 000, Southern Star Central Gas Pipeline, Inc.
C–4.
Docket# CP01–415, 017, East Tennessee Natural Gas Company
C–5.
Docket# CP02–396, 006, Greenbrier Pipeline Company, LLC
Other#s CP02–397, 006, Greenbrier Pipeline Company, LLC
CP02–398, 006, Greenbrier Pipeline Company, LLC
C–6.
Docket# CP03–11, 003, Jupiter Energy Corporation
C–7.
Docket# CP01–418, 001, B–R Pipeline Company
C–8.
Interagency Agreement for the Safety and Security Review of Liquefied Natural Gas Facilities

The Capitol Connection offers the opportunity for remote listening and viewing of the meeting. It is available for a fee, live over the Internet, via C–Band Satellite. Persons interested in receiving the broadcast, or who need information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.gmu.edu* and click on "FERC".

Magalie R. Salas,

Secretary.

[FR Doc. 04–3061 Filed 2–9–04; 10:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Meeting, Notice of Vote, Explanation of Action Closing Meeting and List of Persons To Attend

February 4, 2004.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552b:

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

DATE AND TIME: February 11, 2004, (Within a relatively short time after the regular Commission Meeting).

PLACE: 888 First Street, NE., Washington, DC 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Non-Public Investigations and Inquiries, Enforcement Related Matters, and Security of Regulated Facilities.

FOR FURTHER INFORMATION CONTACT: Magalie R. Salas, Secretary, Telephone (202) 502–8400.

Chairman Wood and Commissioners Brownell, Kelliher, and Kelly voted to hold a closed meeting on February 11, 2004. The certification of the General Counsel explaining the action closing the meeting is available for public inspection in the Commission's Public reference room at 888 First Street, NW., Washington, DC 20426.

The Chairman and the Commissioners, their assistants, the Commission's Secretary and her assistant, the General Counsel and members of her staff, and a stenographer are expected to attend the meeting. Other staff members from the Commission's program offices who will advise the Commissioners in the matters discussed will also be present. Staff from the U.S. Coast Guard (USCG), and the U.S. Department of Transportation (DOT) are expected to attend the meeting also. FERC Commissioners, and USCG and DOT staff will discuss matters of concern shared among all three governmental entities.

Magalie R. Salas,

Secretary.

[FR Doc. 04–3062 Filed 2–9–04; 10:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0398; FRL–7342–9]

Tribal Pesticide and Special Projects; Request for Proposals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Office of Pesticide Programs (OPP), in coordination with the EPA regional offices, is soliciting pesticide and special project proposals from eligible tribes, Alaska native villages, and intertribal consortia for fiscal year (FY) 2004 funding. Under this program, cooperative agreement awards will provide financial assistance to eligible tribal governments, Alaska native village governments, or intertribal consortia to carry out projects that assess or reduce risks to human health and the environment from pesticide exposure. The total amount of funding available for award in FY 2004 is expected to be approximately $445,000, with a maximum funding level of $50,000 per project.

DATES: Proposals must be received by your EPA regional office on or before 5 p.m. March 29, 2004.

ADDRESSES: Proposals may be submitted to your EPA regional office by mail, fax, or electronically. Please follow the detailed instructions provided in Unit IV.H. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Karen Rudek, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6005; fax number: (703) 308–1850; e-mail address: *rudek.karen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview Information

The following listing provides certain key information concerning the proposal opportunity.

- *Federal agency name*: Environmental Protection Agency (EPA).
- *Funding opportunity title*: Tribal Pesticide and Special Projects; Request for Proposals.
- *Announcement type*: The initial announcement of a funding opportunity.
- *Catalog of Federal Domestic Assistance (CFDA) number*: 66.500.
- *Dates*: Applications must be received by EPA on or before March 29, 2004.

II. General Information

A. Does this Action Apply to Me?

Potentially affected entities include federally recognized tribal governments, federally recognized Alaska native village governments, or qualified intertribal consortia. For this solicitation, the word "tribe" refers to federally recognized tribes as well as to federally recognized Alaska native villages. An "intertribal consortium" is defined as a partnership of two or more federally recognized tribes that is authorized by its membership to apply for, and receive, assistance under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Only one project proposal from each tribal government or intertribal consortium will be considered for funding. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0398. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Room 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/.* An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1, above. Once in the system, select "search," then key in the appropriate docket ID number.

III. Introduction

In 1997, EPA published its first solicitation for project proposals that supported pesticide management and water quality protection in Indian country. (For the purposes of this solicitation, the term "Indian country" means: (1) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running throughout the reservation; (2) all dependent Indian communities within the borders of the United States, whether within the original or subsequently acquired territory thereof, and whether within or without the limits of the State; and (3) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

Each year since 1997, EPA's Office of Pesticide Programs, in coordination with the EPA regional offices, has published similar solicitations, awarding approximately $445,000 annually to eligible tribes and intertribal consortia for projects supporting pesticide management and water quality goals. This **Federal Register** notice provides qualification and application requirements to parties who may be interested in submitting proposals for fiscal year 2004 monies. The total amount available for award during this funding cycle is expected to be approximately $445,000. Maximum award amount per proposal is set at $50,000, and only one proposal per applicant will be accepted for consideration. Indirect cost rates will not increase the $50,000 maximum funding amount.

IV. Program Description

A. Purpose and Scope

Cooperative agreements awarded under this program are intended to provide financial assistance to eligible tribal governments or intertribal consortia for projects that assess and/or reduce the risks of pesticide exposure to human health and the environment. Funds may be used to support new activities that fit the requirements of this solicitation, or to further existing eligible projects or programs. Projects may be targeted to any pesticide related concern or need facing a tribe or intertribal consortium. Although the proposal may request funding for activities that will further long-term objectives, this program provides one time funding, and the maximum period of performance for funded activities is expected to be approximately 12 months.

This program is included in the Catalog of Federal Domestic Assistance at *http://www.cfda.gov/public/whole.pdf.*

B. Goals and Objectives

EPA intends that recipients will use funding provided under this Tribal Pesticide and Special Project Program to help address the specific, pesticide related concerns of their communities. The Agency will consider funding a broad range of projects that assess or reduce pesticide exposure risks to human health and the environment in Indian country. For a partial listing of eligible types of projects, see Unit IV.E.

C. Eligibility

1. *Applicants.* Any federally recognized tribal government or intertribal consortium (as defined in Unit I.A.) that is eligible to receive federal funds may submit a project proposal. Only federally recognized tribes and intertribal consortia are eligible for funding under this program, and only one project proposal may be submitted per applicant.

To be eligible for consideration, applicants must meet all of the following criteria. Failure to meet the following criteria will result in the automatic disqualification of the proposal for consideration for funding:

- The applicant must be eligible to receive funding under this announcement. (If you are applying as a consortium, you must provide verification of your eligibility according to the requirements of Unit I.A.)
- The proposal must meet all format and content requirements contained in this notice.
- The proposal must comply with the directions for submittal contained in this notice.

If the applicant has received project funding in prior years through the Office of Pesticide Programs tribal grant program, does this proposal package include evidence that outcomes of prior projects were beneficial, sustainable, and/or transferable. (If the applicant has never received an award under this grant program, that should be clearly noted. If unexpected barriers were encountered during implementation of a prior project, those should be noted and briefly discussed as well.)

2. *Qualifications.* Qualified applicants are limited to all federally recognized tribes and Alaska native villages, and intertribal consortia as defined in Unit I.A of this notice. Additional application requirements are listed under Unit IV.G.

3. *Incomplete or late proposals.* Incomplete or late proposals will be disqualified for funding consideration. Contact the appropriate regional staff person if you need assistance or have questions regarding the creation or submission of a project proposal. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP 2003–0398 in the subject line on the first page of your proposal.

D. Authority

EPA expects to enter into grants and cooperative agreements under the authority provided in FIFRA, section 20 which authorizes the Agency to issue grants or cooperative agreements for research, public education, training, monitoring, demonstration and studies; and in FIFRA section 23(a)(1) which authorizes EPA to enter into cooperative agreements with states and Indian tribes to implement pesticide enforcement programs. Pursuant to the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act for FY 1999, pesticide program implementation grants under section 23(a)(1) of FIFRA are available for "pesticide program development and implementation, including enforcement and compliance activities."

The award and administration of these grants will be governed by the Uniform Administrative Requirements for Grants and Cooperative Agreements to states, tribes, and local governments set forth at 40 CFR part 31. Grants awarded pursuant to this solicitation are program grants subject to the regulations for "Environmental Program Grants for Tribes" set forth at 40 CFR part 35, subpart B. In addition, the provisions in 40 CFR part 32, governing government wide debarment and suspension, and the provisions in 40 CFR part 40, regarding restrictions on lobbying, apply.

All costs incurred under this program must be allowable under the applicable OMB Cost Circular A-87. Copies of this circular can be found at *http://www.whitehouse.gov/omb/circulars/*. In accordance with EPA policy and the OMB circular, any recipient of funding must agree not to use assistance funds for fund-raising, or political activities such as lobbying members of Congress or lobbying for other federal grants, cooperative agreements, or contracts. See 40 CFR part 40.

E. Activities that May Be Funded

Projects may be targeted to any pesticide concern or need facing a tribe or intertribal consortium, including, but not limited to:

- Water quality.
- Development/support of exposure and risk assessment capacity.
- Traditional tribal lifeways/subsistence. Effects of pesticides on cultural activities.
- Assessment of the need for and/or development of a pesticide management policy or plan.
- Consideration of integrated pest management, reduced pesticide use, or alternatives to pesticides.
- Sampling.
- Concerns associated with the return of culturally and spiritually significant items that may have been exposed to pesticides as part of historical preservation efforts by museums or other collectors.
- Noxious weed education materials and/or control alternatives.
- Public outreach/education materials relating to pest management and/or pesticide safety.

In addition, eligible proposals may be focused on the monitoring of surface water or ground water (e.g., assessing dietary exposure to pesticides via drinking water, determining those water bodies that may be impaired by pesticides, predicting potential exposure to endangered or threatened aquatic species, or establishing a baseline of contamination from which to measure progress toward future improvement in the environment).

Water quality projects may involve information gathering and baseline development including vulnerability assessment, identifying pesticides (from either on or off reservation sources) that are most likely to impact water quality, providing information to pesticide users on ways they can assist in protecting the quality of water sources, and developing other measures that protect water from pesticides. Water quality work may also focus on the development or implementation of programs aimed at preventing contamination of water sources, mitigating contaminated water sources or implementing best management practices.

Other projects, not necessarily linked to water quality issues, may include the establishment of tribal pesticide codes, creating and implementing a system for the proper disposal of pesticides, and/or educational outreach to the community. Sampling projects may include soil sampling, residue sampling on culturally significant/medicinal plants, or sampling to determine the effects of pesticides on cultural activities, such as subsistence hunting and fishing.

Water quality and non-water quality pesticide related projects are equally eligible for funding under this grant program. Reviewers will give additional consideration to proposals that recognize and build upon existing, publicly available, technical and educational information. There are no cost share requirements for this project; however, leveraging of these funds by matching funds and/or in-kind contributions is encouraged.

F. Award and Distribution of Funds

1. *Available funding.* Funding for each award recipient will be in the form of a cooperative agreement for $50,000 or less, under FIFRA sections 20 and 23(a)(1). Total funding available for award is expected to be approximately $445,000.

Should additional funding become available for award, the Agency may make additional monies available, based on this solicitation and in accordance with the final selection process, without further notice of competition. The Agency also reserves the right to decrease available funding for this program, or to make no awards based on this solicitation. All costs charged to these awards must be allowable under the applicable OMB Cost Circular, A–87 which may be found at *http://www.whitehouse.gov/omb/circulars/*.

2. *Evaluation process and criteria.* Proposals will be reviewed and approved for validity and completeness by EPA regional office personnel. If the region determines that an application is incomplete, the proposal will not be considered further. The region will forward all complete proposal packages, along with regional comments, to an EPA review panel convened by the Office of Pesticide Programs. If necessary, the panel will consult with regional staff regarding proposal content and regional comments. If money remains after the award selection process is completed, the review team will determine the allocation of the remaining money. Final selections will be made by close of business 60 days after the closing date for receipt of proposals.

Applicants must submit information, as specified in this solicitation, to address award criteria. Applicants must also provide information specified in this solicitation that will assist EPA in assessing the tribe's capacity to do the work outlined in the project proposal. The proposed work plan and budget should reflect activities that can realistically be completed during the period of performance of the cooperative agreement. Criteria that will be used to review, rank and award funding are found below.

a. *General background information requirement.* Pesticide related projects

that address a wide variety of issues of concern to Indian country are eligible for funding under this grant program. If the applicant tribe or consortium has previously received project funding from the Office of Pesticide Programs Tribal Grant Program, specific information about those funded projects should be included with this proposal, for example:

- What was the project?
- When was the award made, and for what dollar amount?
- What successes or barriers were encountered as the project moved forward?
- What outputs from previously funded OPP projects continue to provide benefits to the tribe (e.g., retention of trained personnel, continued use of purchased equipment, accretion of baseline, sampling and analysis data)?
- Information on projects previously funded by this OPP tribal grant program may be provided in several ways: You may include descriptive language either in the narrative of the current proposal or as an appendix to the current proposal, or you may include a copy of the previous project's final report as an appendix to this proposal. The name of the EPA Project Officer for any projects previously funded under this grant program should also be included. If the applicant has never received funding under this grant program, that should be clearly noted in the proposal.

Failure to address this information request may render your proposal non responsive to this solicitation. If you have questions about this requirement, please contact your EPA region, or the person listed under **FOR FURTHER INFORMATION CONTACT.**

b. *Selection criteria - Total possible points: 100*

Technical Qualifications, Overall Management Plan, Past Awards and Performance (30 Points)

Does the person(s) designated to lead the project have the technical expertise he or she will need to successfully complete it? Does the project leader have experience in grant and project management?

Proposals should provide complete information on the education, skills, training and relevant experience of the project leader. As appropriate, please cite technical qualifications and specific examples of prior, relevant experience. If this project will develop new tribal capacity, describe how the project leader and/or staff will gain necessary training and expertise.

To whom does the project leader report? What systems of accountability and management oversight are in place to ensure that this project stays on track?

If previously performed work directly impacts this project, briefly describe the connection. If a directly relevant project is currently ongoing, what progress has been made? If this new project builds upon earlier efforts, how will the tribe use the knowledge, data, and experience derived from previous projects to shape this new proposed activity?

If appropriate, reviewers will give additional consideration to proposals that recognize and build upon existing, publicly available, technical and educational information.

Justification for Need of the Project, Soundness of Technical Approach (35 Points)

To provide reviewers with context for your proposed project, and to assist them in gaining the clearest possible sense of the positive impact of this project on your tribe and the environment, please briefly provide some information about your reservation:

1. Specify the size, geography, and general climate of the reservation.
2. About how many residents are tribal members and how many are not tribal members?
3. How much of the reservation is under cultivation?
4. Does the reservation include wetlands or other preserves?
5. If there is relevance to your project, briefly describe the tribal and non-tribal populations of surrounding counties/states, and surrounding land use.
6. How many people (tribal/non-tribal) are employed by the tribal government (e.g., in government services, including health care, police and fire protection)?
7. How many are employed on the reservation in other areas that use pesticides or may be impacted by their use (e.g., agriculture, animal husbandry, fisheries/fishing, forestry, construction, casinos/resorts/golf course maintenance, etc.)?
8. If you are concerned about pesticide pollution that may originate within reservation boundaries, what are the potential sources and what chemicals might be involved?
9. If you are concerned with pollution migration from off-reservation sources, what are those potential sources, and what chemicals are of specific concern?
10. Is the tribe concerned about water quality issues? If so, please describe the nature of these concerns.
11. Does the tribe currently have any pesticide policy or pesticide management program in place?
12. Why is this project important to the tribe or the tribal consortium? What environmental issues(s) will it address and how serious and/or pervasive are these issues? What is the expected outcome of the project? What benefits will this project bring to the tribe in terms of human and environmental health?
13. Has the tribe identified a need to coordinate or consult with other parties (tribal and/or non-tribal) to ensure the success of this project? If so, who are they and what is your plan to involve them? How will they be affected by the outcome of the project?
14. What are the key outputs of this project? How do you propose to quantify and measure progress? Have interim milestones for this project been established? If so, what are they? How will you evaluate the success of the project in terms of measurable environmental results?
15. Does your budget request accurately reflect the work you propose? Please provide a clear correlation between expenses and project objectives. Will EPA funding for this project be supplemented with funding from other source(s)? If so, please identify them.
16. Please describe the steps you will take to ensure successful completion of the project. Provide a time line and description of interim and final results and deliverables.

Benefits, Sustainability, Transferable Results (35 Points)

Will the results from this project continue to provide benefits to the tribe or other tribes after the period of performance has expired and this funding is no longer available? How are the benefits of this effort expected to be sustained over time? Can the project results be incorporated into existing and/or future pesticide-related tribal environmental activities? Are any of the deliverables, experiences, products, or outcomes resulting from the project transferable to other communities? Might this project readily be implemented by another tribe?

What ecological or human health benefits does this project provide? What quality of life issues does the project address? Does the project have limited or broad application to address risks related to pesticides?

Does the applicant recognize a need for coordination between tribal agencies and outside communities, and/or federal, state or local agencies? Will the project help build tribal infrastructure and capacity? How?

c. *Selection official.* The final funding decision will be made from the group of top rated proposals by the Chief of the Government and International Services

Branch, Field and External Affairs Division, Office of Pesticide Programs.

d. *Dispute resolution process.* The procedures for dispute resolution at 40 CFR 30.63 and 40 CFR 31.70 apply.

G. Application Requirements

1. *Content requirements.* Proposals must be typewritten, double spaced, in 12 point or larger print, on 8.5 x 11 inch paper with minimum 1 inch horizontal and vertical margins. Pages must be numbered, in order, starting with the cover page and continuing through the appendices. One original and one electronic copy (e-mail or disk) is required.

In order to be considered for funding, proposals must be submitted to the regional tribal pesticide staff contact indicated in Unit IV.H. of this solicitation.

Your application package must include the following:

- *Cover page.* Including descriptive project title.
- *Executive summary.* The executive summary shall be a stand alone, overview document, of one page or less. It should quickly explain the high points of the proposed project and why it is important for the protection of human health and the environment in your part of Indian country. What do you intend to do with these grant funds and what do you expect these activities to accomplish?
- *Table of contents.* List the different sections of your proposal and the page number on which each section begins.
- Tribal project manager contact information, including qualifications.
- *Proposal narrative.* Includes sections I–IV as identified below. The narrative should not exceed 10 pages.
- *Part I--Project title.* Descriptive project title.
- *Part II--Project description and objectives.* In this section describe the project, its goals, and address relevant evaluation criteria.
- *Part III--Approach and methods.* In this section describe approach and methods and address appropriate evaluation criteria.
- *Part IV--Impact assessment.* In this section describe impacts your project will have on human health and the environment and address appropriate evaluation criteria.

2. *Draft work plan (1–2 pages).* The submitted draft work plan should outline:

- Description/list of deliverables.
- The separate phases of the project.
- The tasks associated with each phase of the project.
- The time frames for completion of each phase or task.
- The name, title of the person(s) who will conduct each phase or task.
- The dates when progress reports will be provided to EPA, clearly showing deliverables, accomplishments, delays and/or obstacles. (Project costs cannot be incurred until a final work plan has been approved by the appropriate EPA regional office.)

3. *Estimated budget.* The estimated budget should outline costs for personnel, fringe benefits, travel, equipment, supplies, contractual, indirect cost rate, and any other costs associated with the proposed project.

4. *Letter or resolution from the tribal leadership showing support for, and commitment to, the project.* (If it is not possible to obtain a letter/resolution from your tribal leader to submit with your project proposal, an interim letter of explanation must be included with the proposal. An original letter/resolution from your tribal leadership will be required prior to project award.) If the applicant is a consortium of federally recognized tribes (as defined in Unit I.A.), a letter from the consortium leadership, on consortium letterhead, affirming consortium status and member tribes' support for the project, must accompany the proposal.

5. *Letter of confirmation of availability for any other funds needed to complete the project.* If your proposal requires the use of additional funds for leveraging, please include a letter from the funding source, confirming that these monies are available for the project. If the budget includes a tribal in-kind contribution, a letter of confirmation is not needed.

6. *Confidential business information.* Applicants must clearly mark information considered confidential business information. EPA will make a final confidentiality determination for information the applicant claims as confidential business information, in accordance with Agency regulations at 40 CFR part 2, subpart B.

7. *Additional information.* Additional information, including maps, data tables, excerpts from studies, photographs, news media reports, or other documents may be included in appendices to the main project proposal, when they add significant supporting detail to the main proposal. Appendix titles, and their starting page numbers, should be included in the Table of Contents, just after the proposal cover page.

H. Application Procedures

1. *Submission instructions.* The applicant must submit the project proposal to the appropriate EPA regional contact, as listed below. One original, signed package must be sent by mail. An electronic copy of the proposal is also required and may either accompany the mailed package or be sent separately via e-mail to the regional contact. The proposal must be received by your EPA region no later than close of business March 29, 2004. Incomplete or late proposals will be disqualified for funding consideration. Contact the appropriate regional staff person if you need assistance or have questions regarding the creation or submission of a project proposal. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP 2003–0398 in the subject line on the first page of your proposal.

EPA regional tribal pesticide contacts are as follows:

EPA Region I (Connecticut, Maine, New Hampshire, Rhode Island, Vermont). Rob Koethe, EPA Region I, One Congress St., Suite 1100, (CPT), Boston, MA 02114–2023, telephone: (617) 918–1535, fax: (617) 918–1505, e-mail: *koethe.robert@epa.gov.*

EPA Region II (New Jersey, New York, Puerto Rico, Virgin Islands). Tracy Truesdale, EPA Region II, U.S. EPA Facilities, Raritan Depot (MS50), 2890 Woodbridge Ave., Edison, NJ 08837–3679, telephone: (732) 906–6894, fax: (732) 321–6771, e-mail: *truesdale.tracy@epa.gov.*

EPA Region III (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia). Fatima El Abdaoui, EPA Region III, Chestnut Building (3AT11), Philadelphia, PA 19107, telephone: (215) 814–2129, fax: (215) 814–3114, e-mail: *el-abdaoui.fatima@epa.gov.*

EPA Region IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee). Randy Dominy, EPA Region IV, 61 Forsyth St., SW., Atlanta, GA 30303, telephone: (404) 562–8996, fax: (404) 562–8973, e-mail: *domini.randy@epa.gov.*

EPA Region V (Illinois, Indiana, Michigan, Minnesota, Wisconsin). Meonii Crenshaw, EPA Region V, 77 West Jackson Boulevard (DRT8J), Chicago, IL 60604–3507, telephone: (312) 353–4716, fax: (312) 353–4788, e-mail: *crenshaw.meonii@epa.gov.*

EPA Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas). Jerry Collins, EPA Region VI, 1445 Ross Avenue, Dallas, TX 75202–2733, telephone: (214) 665–7562, fax: (214) 665–7263, e-mail: *collins.jerry@epa.gov.*

EPA Region VII (Iowa, Kansas, Missouri, Nebraska). John Tice, EPA Region VII, 100 Centennial Mall N., Room 289, Lincoln, NE 68508,

telephone: (402) 437–5080, fax: (402) 323–9079, e-mail: *tice.john@epa.gov.*

EPA Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming). Margaret Collins, EPA Region VIII, 999 18th St., (8P P3T), Denver, CO 80202–2466, telephone: (303) 312–6023, fax: (303) 312–6116, e-mail: *collins.margaret@epa.gov.*

EPA Region IX (Arizona, California, Hawaii, Nevada, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam). Marcy Katzin, EPA Region IX, 75 Hawthorne St., (CMD 5), San Francisco, CA 94105, telephone: (415) 947–4215, fax: (415) 947–3583, *katzin.marcy@epa.gov.*

EPA Region X (Alaska, Idaho, Oregon, Washington). Theresa Pimentel, EPA Region X, 1200 Sixth Avenue, (ECO-084), Seattle, WA 98101, telephone: (206) 553–0257, fax: (206) 553–1775, e-mail: *pimentel.theresa@epa.gov.*

2. *Notification process.* Regions will notify their respective applicants of the selections. Those applicants not awarded funds may request an explanation for the lack of award from EPA regional staff.

V. Post Selection Activity

Selected applicants must formally apply for funds through the appropriate EPA regional office. In addition, selected applicants must negotiate a final work plan, including reporting requirements, with the designated EPA regional project officer. For more general information on post award requirements and the evaluation of grantee performance, see 40 CFR part 31.

VI. Submission to Congress and the Comptroller General

Grant solicitations such as this are considered rules for the purpose of the Congressional Review Act (CRA). The CRA, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 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).

List of Subjects

Environmental protection, Pesticides, Tribes.

Dated: February 5, 2004.

William H. Sanders,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 04–2955 Filed 2–6–04; 2:07 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0021; FRL–7343–7]

Tribal Pesticide Program Council; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Tribal Pesticide Program Council (TPPC) will hold a 3–day meeting, beginning on March 10, 2004, and ending on March 12, 2004, including a closed session from 1:15 p.m. to 2:15 p.m. on Wednesday and Thursday. This notice announces the location and times for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on Wednesday, March 10, 2004, and Thursday, March 11, 2004, from 9 a.m. to 5 p.m., and Friday, March 12, 2004, from 9 a.m. to noon.

ADDRESSES: The meeting will be held at the Doubletree Hotel-Crystal City, 300 Army-Navy Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Georgia A. McDuffie, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0195; fax number: (703) 308–1850; e-mail address: *mcduffie.georgia@epa.gov* or

Lillian Wilmore, TPPC Facilitator, P.O. Box 470829, Brookline Village, MA 02447–0829; telephone number: (617) 232–5742; fax: (617) 277–1656; e-mail address: *naecology@aol.com.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are interested in TPPC's information exchange relationship with EPA regarding important issues related to human health, environmental exposure to pesticides, and insight into EPA's decision-making process. All parties are invited and encouraged to attend the meetings and participate as appropriate. Potentially affected entities may include, but are not limited to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult either person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0021. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments. access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Tentative Agenda

This unit provides the tentative agenda for the meeting.

1. TPPC state of the Council Report.
2. Presentation and questions and answers by EPA's Office of Pesticide Programs Field and External Affairs Division.
3. Reports from working groups and TPPC participation in other meetings:Forum on State and Tribal Toxic Actions (FOSTTA); Pesticide Program Dialogue Committee; Western Region; Tribal Operations Committee, Tribal Customary & Traditional Lifeways; 7th National Forum on Contaminants in Fish; and other reports or presentations.
4. Tribal caucus (2).
5. EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) tribal strategy update.
6. Dialogue and discussion on development of a tribal pesticide program.
7. Discussion on TPPC's participation on the Worker Protection Working Group.
8. National issues on noxious weeds for tribes.
9. Homeland Security--tribal and other farms and pesticide storage issues.
10. Discussion on the involvement of tribes in the Strategic Ag Initiative.
11. Update on the Federal Inspector Credentials Criteria and opportunity for discussion.
12. Tribal West Nile Virus concerns and to include a discussion on National Pollutant Discharge Elimination System (NPDES) issues.
13. Update on Lifeline.
14. Endangered species issues.
15. Half-day training session.

List of Subjects

Environmental protection.

Dated: February 2, 2004.

Jay Ellenberger,

Acting Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 04–2815 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7620–1]

Guidelines on Awarding Section 319 Grants to Indian Tribes in FY 2004; Request for Grant Proposals for Watershed Projects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA has developed guidelines for awarding Clean Water Act section 319 nonpoint source grants to Indian Tribes in FY 2004. As has been the case for the past four fiscal years, EPA anticipates Congress will authorized EPA to award nonpoint source pollution control grants to Indian Tribes under section 319 of the Clean Water Act in FY2004 in an amount that exceeds the statutory cap (in section 518(f) of the Clean Water Act) of ⅓ of 1% of the total 319 appropriation. These guidelines are intended to assist all Tribes that have approved nonpoint source assessments and management programs and also have "treatment-as-a-state" status to receive section 319 funding to help implement those programs. The guidelines describe the process for awarding base funding to Tribes in FY 2004, including submissions of proposed work plans. The guidelines also describe the process and schedule to award, through a grants competition, additional funds for selected watershed implementation projects for FY 2004 funding, including the schedule for submissions of watershed project summaries and the selection criteria for funding watershed projects.

DATES: The guidelines are effective February 11, 2004.

ADDRESSES: Persons requesting additional information or a complete copy of the document should contact Ed Drabkowski at (202) 566–1198; e-mail at *drabkowski.ed@epa.gov;* or by mail at U.S. Environmental Protection Agency (4503T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Persons requesting additional information or complete copy of the document should contact Ed Drabkowski at (202) 566–1198; or by e-mail at *drabkowski.ed@epa.gov;* or by mail at U.S. Environmental Protection Agency (4503T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The full text of the *Guidelines on Awarding Section 319 Grants to Indian Tribes in FY 2004* is also available on the Nonpoint Source Control Branch homepage at *http://www.epa.gov/owow/nps.*

Dated: January 30, 2004.

Diane C. Regas,

Director, Office of Wetlands, Oceans, and Watersheds.

Memorandum

Subject: Guidelines on Awarding Section 319 Grants to Indian Tribes in FY 2004; Request for Grant Proposals for Watershed Projects

From: Diane C. Regas, Director, Office of Wetlands, Oceans and Watersheds.

To: EPA Regional Water Division Directors, Regional Tribal Coordinators/Program Managers, Tribal Caucus, EPA Tribal Operations Committee.

EPA anticipates that Congress will, for the fifth year in a row, authorize EPA to award nonpoint source pollution control grants to Indian Tribes under Section 319 of the Clean Water Act ("CWA") in FY 2004 in an amount that exceeds the statutory cap (in Section 518(f) of the CWA) of ⅓ of 1% of the total 319 appropriation. This will enable all of the Tribes that have approved nonpoint source assessments and management programs and "treatment-as-a-State" ("TAS") status (hereinafter referred to as "approved Tribes") by January 7, 2004, to be eligible to receive Section 319 funding to help implement those programs.

The repeated allowance of increased funding for Tribal nonpoint source ("NPS") programs in FY 2004 reflects Congress' continuing recognition that Indian Tribes need and deserve increased financial support to implement nonpoint source programs that address critical water quality concerns on tribal lands. EPA shares this view and will continue to work closely with the Tribes to assist them in developing and implementing effective Tribal nonpoint source pollution programs. To date, EPA has already approved eighty-four (84) Tribal nonpoint source management programs, covering more than 40 million acres of land (representing approximately 74% of all Indian country), and we expect to approve additional programs in FY 2004.

As was the case last year, the new authorization to exceed ⅓ of 1% applies only to the current year (FY 2004). As in the past, EPA will work with the Tribes to continue to demonstrate that increased 319 funds for Tribes can be used effectively to achieve water quality improvement. We were pleased by the high quality of the Tribes' work plans that formed the basis of the grants awarded to Tribes in FY 2003, which included base grants awarded to seventy-one (71) Tribes as well as grants for specific watershed projects awarded to twenty-seven (27) Tribes through a competitive process. We believe that the Tribes and EPA succeeded in directing the FY 2003 grants towards high-priority activities that will produce on-the-ground results that provide improved water quality. We believe that this success warrants continued substantial investment of 319 grant dollars in FY 2004 to address the extensive NPS control needs throughout Indian country, as discussed below. In recognition of this fact, we are awarding a total of $7,000,000 to Tribes for FY 2004.

Summary of Process for FY 2004 Grants to Tribes

In FY 2004, we will set aside $7,000,000 for Tribal nonpoint source grants. This amount is based on the same three factors as were used last year:

1. We will continue to support all eligible Tribes with base grants.
2. We will award base funding to eligible Tribes as follows:

a. $30,000 in base funding will be awarded to eligible Tribes whose land area is less than 1,000 square miles (640,000 acres).

b. $50,000 in base funding will be awarded to eligible Tribes whose land area is greater than 1,000 square miles (640,000 acres).

3. We will award the remaining funds to eligible Tribes through a competitive process to support the implementation of priority watershed projects.

Detailed Discussion of Process for FY 2004 Grants to Tribes

1. Base Funding

Each Tribe that has an approved nonpoint source assessment and management program (and TAS status) as of January 7, 2004, will receive base funding based on the following land area scale:

Square miles (acres)	Base amount
Less than 1,000 sq. mi. (less than 640,000 acres)	$30,000
Over 1,000 sq. mi. (over 640,000 acres)	50,000

The land area scale is the same as used last year. EPA is continuing to rely upon land area as the deciding factor for a cutoff because nonpoint source pollution is strongly related to land use; thus land area is a reasonable criterion that generally is highly relevant to identifying Tribes with the greatest needs (recognizing that many Tribes have needs that significantly exceed available resources).

The base funding as outlined above may be used for a range of activities that implement the Tribe's approved NPS management program, including hiring a program coordinator; conducting nonpoint source education programs; providing training; developing and implementing, alone or in conjunction with other agencies or other funding sources, watershed-based plans and on-the-ground watershed projects. In general, this base funding should not be used for general assessment activities.

Each Tribe that requests base funding must submit to the appropriate EPA Regional office a proposed work plan that conforms to applicable legal requirements (*see* 40 CFR Sections 35.505 and 35.507) and is consistent with the Tribe's approved nonpoint source management program. This proposed work plan should clearly describe each significant category of activity to be funded; the roles of any federal, local, or other partners in completing each activity; the schedule and budget for implementing funded activities; and the outputs to be produced by performance of the activity. Outputs of activities should be quantified; results of projects should be measurable and indicators to do so clearly stated. Tribes should submit their proposed work plan to the appropriate Regional office by February 18, 2004. Regions should review the proposed work plan and, where appropriate, recommend improvements to the plan. If a Tribe has not submitted an approvable work plan February 25, 2004, its allocated amount will be added to the competitive pool, discussed immediately below, which will be used to fund tribal NPS program and watershed project priorities.

Regions should work with the Tribes to expeditiously award the base grants. However, if the Tribe will be awarded additional funds to implement a watershed project, as discussed below, the tribe or the Region may prefer combining the formal process for submission of the final application for both the base and competitive funds. Regions should confer with their Tribes and endeavor to proceed in a manner and on a schedule that is most compatible with the Tribes' and Regions' needs and preferences.

2. Competitive Funding: Request for Proposals to Select Watershed Projects for FY 2004 Funding (Process and Schedule)

The remaining funds will be awarded to Tribes that have approved nonpoint source management programs as of January 7, 2004, on a competitive basis to provide funding for on-the-ground nonpoint source watershed projects that are designed to achieve additional water quality improvement. Each selected project will be eligible to receive up to $150,000, depending on the demonstrated need. The funds will be awarded using the process described below.

a. Watershed Project Review Committee

As we did for the FY 2003 grants, EPA will establish a Watershed Project Review Committee comprised of nine EPA staff, including three EPA Regional Nonpoint Source Coordinators, three EPA Regional Tribal Coordinators, two staff members of the Nonpoint Source Control Branch, and one staff member of the American Indian Environmental Office. The committee will then make funding decisions in accordance with the process described below.

b. Watershed Project Summaries

Tribes that have approved nonpoint source assessments and management programs as well as TAS status as of January 7, 2004, are invited to apply for watershed project funding by submitting watershed project summaries for proposed projects up to a maximum budget of $150,000. (This funding is in addition to the base funding that each approved tribe will receive, as described above.) Tribes that apply for funding for watershed projects should submit a brief (*e.g.*, 5 pages) summary of a watershed project implementation plan by February 18, 2004, to the appropriate EPA Regional office for initial screening. (Complete grant applications should not be submitted until after projects are selected, pursuant to review by the Watershed Project Review Committee, as described below.) The Regional office will, by February 27, 2004, forward the proposals that meet the required criteria to EPA Headquarters for distribution to the Watershed Project Review Committee. (e-mail-versions would be appreciated where possible because they can be shared among the reviewers most rapidly and easily.)

The watershed project summary should outline the nonpoint source pollution problem and the on-the-ground improvement to be addressed; the project's goals and objectives and the expected water quality benefit to the receiving waterbody; the lead implementing agency (either the tribe or another organization authorized by the tribe to be the project leader) and other agencies that will be authorized to expend project funds; the types of best management practices or measures that will be implemented; the projected implementation schedule; the project's budget items including construction costs; and the environmental performance measures that will be used to evaluate the success of the project. Each watershed plan summary should be clearly written with enough detail to show why the proposed project should be selected for competitive funding. This is critical to help ensure that the best projects are funded.

c. Selection Criteria for Funding Watershed Projects

In ranking the projects, each reviewer on EPA's Watershed Project Review Committee will consider the extent to which the following factors are present in each project.

1. The proposed project is listed as a priority implementation project or is located in a priority watershed identified in the Tribal NPS management program.

2. The watershed plan summary includes a clear and specific identification of the on-the-ground improvement project to be constructed or installed and the water quality problem to be addressed, including the pollutants of concern and their sources (including critical areas to be treated, if known).

3. The watershed plan summary includes a clear and objective statement of the project's goals and objectives in terms of controlling nonpoint sources and/or of improving/protecting water quality.

4. The summary identifies the best management practices or measures to be implemented and the location where these measures and practices will be implemented.

5. Where relevant, the watershed project is designed to implement measures and practices that consists of implementation actions or load calculations that are intended to help restore an impaired waterbody for which an approved nonpoint source total maximum daily load (NPS TMDL) has been developed or the NPS components of mixed-source TMDL's. [**Note:** EPA recognizes that most Tribes have not yet developed NPS TMDLs. However, Section 319 funding may be used to develop and implement approved NPS TMDLs for any 303(d) listed waterbody. Where a Tribe has developed a relevant water quality standard and NPS TMDL and seeks Section 319 funding to assist in the implementation of the NPS TMDL, that should be considered by reviewers to be a relevant factor supporting the funding request.]

6. The proposed project is designed to include cooperation and/or combination of resources with other programs, parties, and agencies to provide additional technical and/or financial assistance to the project (*e.g.* leveraging CWA Section 106 funding for water quality monitoring; utilizing Farm Bill Environmental Quality Incentives Program funds).

7. The summary outlines the construction cost of the project and the amount of Section 319 grant dollars that are requested, not to

exceed $150,000. Please note that a 40% non-federal match is also required. However, pursuant to Section 35.635(b), EPA's Regional Administrator may increase the maximum Federal share if the Tribe or intertribal consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of the intertribal consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship. In no case will the federal share be greater than 90 percent.

8. The summary includes an implementation schedule with appropriate milestones.

9. The summary includes a statement of how the project will be evaluated to determine its success and to derive lessons that will assist the Tribe (and other Tribes) in future projects. This evaluation will be developed into an annual report to the Region and a final report on completion of the project.

d. Award of Grants for Tribal Watershed Projects

(i) Award Decisions

The Watershed Project Review Committee will hold a conference call by March 12, 2004, to ensure that all Committee members fully understand and agree on how to objectively apply the criteria discussed above. Rankings will be developed by considering all of the factors as a whole, in accordance with a weighting system to be decided upon by the Committee.

By April 7, 2004, the Committee will compile the ranking of proposed watershed projects based on the selection criteria and then forward their rankings to the Nonpoint Source Control Branch at EPA Headquarters. Headquarters will tally the Committee's rankings and then hold a conference call to provide a final opportunity for members of the Review Committee to discuss the rankings among themselves. By April 14, 2004, EPA will select the highest ranked proposals and announce to the Regions which Tribes' watershed projects have been selected for funding. These Tribes will be notified immediately by phone or e-mail, with a written letter to follow.

(ii) Final Work Plans/Full Grant Applications

Once a Region and Tribe have been notified of the amount that will be awarded to the Tribe, they will negotiate a final work plan consistent with 40 CFR 35.507. After making appropriate changes, the Tribe must submit a final work plan to the Region by May 7, 2004. If a Tribe fails to or is unable to submit an approvable work plan by May 7, 2004, the 319(h) grant will instead be awarded to the next highest ranking unfunded application. Regions should endeavor to finalize the grant awards no later than 60 days after receipt of a complete grant application with an approvable work plan.

(iii) Match Requirements

The match requirement for Section 319 competitive grants is 40 percent of the approved work plan costs. The match requirement for Section 319 base grants is also 40 percent unless included as part of an approved Performance Partnership Grant which sets the match requirement at 5 percent of the allowable cost of the work plan budget for base funding only. Both the base funding and competitive funding components are discussed above. In general, consistent with 40 CFR 31.24, the match requirement may be satisfied by allowable costs borne by non-federal grants, by cash donations from non-federal third parties, or by the value of third party in-kind contributions.

EPA's regulations also provide that EPA may decrease the match requirement to as low as 10% if the Tribe can demonstrate in writing to the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of the intertribal consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship. (*See* 40 CFR 35.535.)

In making grant awards to Tribes that provide for a reduced match requirement, Regions should include a brief finding that the Tribe has demonstrated that it does not have adequate funds to meet the required match.

Intertribal Consortia

Some Tribes have formed intertribal consortia to promote cooperative work. An intertribal consortium is a partnership between two or more Tribes that is authorized by the governing bodies of those Tribes to apply for and receive assistance under this program. (*See* 40 CFR 35.502.) The intertribal consortium is eligible only if the consortium demonstrates that all its members meet the eligibility requirements for the Section 319 program and authorize the consortium to apply for and receive assistance in accordance with 40 CFR 35.504. An intertribal consortium must submit to EPA adequate documentation of the existence of the partnership and the authorization of the consortium by its members to apply for and receive the grant. (*See* 40 CFR 35.504.)

Technical Assistance to Tribes

In addition to providing nonpoint source funding to Tribes, EPA remains committed to providing continued technical assistance to Tribes in their efforts to control nonpoint source pollution. During the past several years, EPA has presented many workshops to Tribes throughout the United States to assist them in developing: (1) Nonpoint source assessments to further their understanding of nonpoint source pollution and its impact on water quality; (2) nonpoint source management programs to apply solutions to address their nonpoint source problems; and (3) specific projects to effect on-the-ground solutions. The workshops also have provided information on related EPA and other programs that can help Tribes address nonpoint source pollution, including the provision of technical and funding assistance. Other areas of technical assistance include watershed-based planning, water quality monitoring, Section 305(b) reports on water quality, and Section 303(d) lists of impaired waters. EPA intends to continue providing nonpoint source workshops to interested Tribes around the United States in FY 2004 and to provide other appropriate technical assistance as needed.

Non-Tribal Lands

The following discussion explains the extent to which Section 319(h) grants may be awarded to Tribes for use outside the reservation. We discuss two types of off-reservation activities: (1) Activities that are related to waters within a reservation, such as those relating to sources upstream of a waterway entering the reservation, and (2) activities that are unrelated to waters of a reservation. As discussed below, the first type of these activities may be eligible; the second is not.

1. Activities That Are Related to Waters Within a Reservation

Section 518(e) of the CWA provides that EPA may treat an Indian Tribe as a State for purposes of Section 319 of the CWA if, among other things, "the functions to be exercised by the Indian Tribe pertain to the management and protection of water resources which are * * * within the borders of an Indian reservation." 33 U.S.C. 1377 (e)(2). EPA already awards grants to Tribes under Section 106 of the CWA for activities performed outside of a reservation (on condition that the Tribe obtains any necessary access agreements and coordinates with the State, as appropriate) that pertain to reservation waters, such as evaluating impacts of upstream waters on water resources within a reservation. Similarly, EPA has awarded Section 106 grants to States to conduct monitoring outside of State borders. EPA has concluded that grants awarded to an Indian Tribe pursuant to Section 319(h) may similarly be used to perform eligible Section 319(h) activities outside of a reservation if: (1) The activity pertains to the management and protection of waters within the reservation, and (2) just as for on-reservation activities, the Tribe meets all other applicable requirements.

2. Activities That Are Unrelated to Waters of a Reservation

As discussed above, EPA is authorized to award Section 319(h) grants to Tribes to perform eligible Section 319(h) activities if the activities pertain to the management and protection of waters within a reservation and the Tribe meets all other applicable requirements. In contrast, EPA is not authorized to award Section 319(h) grants for activities that do not pertain to waters of a reservation. For off-reservation areas, including "usual and accustomed" hunting, fishing, and gathering places, EPA must determine whether the activities pertain to waters of a reservation prior to awarding a grant.

Milestones Summary

Date for Tribes to be Eligible for 319 Grants.	January 7, 2004
Tribes Submit Base Grant Work Plans to Region.	February 18, 2004
Tribes Submit Competitive Grant Proposals to Region.	February 18, 2004
Region Comments on Tribe's Base Grant Work Plan.	February 25, 2004

Region Forwards Competitive Proposals to Headquarters.	February 27, 2004
Review Committee Discusses Proposals.	March 12, 2004
Review Committee Forwards Ranking Scores to HQ.	April 7, 2004
Headquarters Notifies Regions/Tribes of Selections.	April 14, 2004
Tribes Submit Final Grant Application to Region.	May 7, 2004

Statutory and Regulatory Requirements

All Section 319(h) grants will be awarded and administered consistent with the statutory requirements in Section 319(h) and 518(e) of the Clean Water Act and applicable regulations in 40 CFR Parts 31 and 35.

Conclusion

By once again lifting the ⅓ of 1% statutory cap in FY 2004, Congress continues to provide the Tribes and EPA with an excellent opportunity to further Tribal efforts to reduce nonpoint pollution and enhance water quality on Tribal lands. EPA looks forward to working closely with the Tribes to assist them in implementing effective nonpoint source programs in FY 2004 and creating a sound basis to assure that adequate funds will continue to be provided in the future.

If you have any questions, please do not hesitate to call me or have your staff contact Ed Drabkowski at (202) 566–1198 (or e-mail at *drabkowski.ed@epa.gov).*

cc: Carol Jorgensen, Director, American Indian Environmental Office, EPA; Jeff Besougloff, AIEO; Jerry Pardilla, National Tribal Environmental Council; Billy Frank, Northwest Indian Fisheries Council; Don Sampson, Columbia River Intertribal Fish Commission; James Schlender, Great Lakes Indian Fish and Wildlife Commission; All Tribes that have an approved Nonpoint Source Management Program; Regional Water Quality Branch Chiefs; Regional Nonpoint Source Coordinators.

[FR Doc. 04–2958 Filed 2–10–04; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Renewal of an Information Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the proposed renewal of an information collection, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled "Occasional Qualitative Surveys."

DATES: Comments must be submitted on or before April 12, 2004.

ADDRESSES: Interested parties are invited to submit written comments to Steve Hanft, Paperwork Clearance Officer, Legal Division, Room MB–3064, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to "Occasional Qualitative Surveys." Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m. Comments may also be submitted to the OMB desk officer for the FDIC: Joseph F. Lackey, Jr., Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Steve Hanft, (202) 898–3907, or at the address above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

Title: Occasional Qualitative Surveys.

OMB Number: 3064–0127.

Frequency of Response: On occasion.

Affected Public: Financial institutions, their customers, and members of the public generally.

Estimated Number of Respondents: 5,000.

Estimated time per response: 1 hour.

Estimated Total Annual Burden: 5,000 hours.

General Description of Collection: This collection involves the occasional use of qualitative surveys to gather anecdotal information about regulatory burden, bank customer satisfaction, problems or successes in the bank supervisory process (both safety-and-soundness and consumer related), and similar concerns. In general, these surveys would not involve more than 500 respondents, would not require more than one hour per respondent, and would be completely voluntary. It is not contemplated that more than ten such surveys would be completed in any given year.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (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.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, DC, this 5th day of February, 2004.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 04–2940 Filed 2–10–04; 8:45 am]

BILLING CODE 6714–01–U

FEDERAL DEPOSIT INSURANCE CORPORATION

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Agency Information Collection Activities: Submission to OMB for Review; Comment Request

AGENCIES: Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision (OTS), Treasury.

ACTION: Joint notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act of 1995.

SUMMARY: As part of their continuing effort to reduce paperwork burden in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FDIC and OTS (collectively, the Agencies) hereby give notice that they plan to submit to the Office of Management and Budget (OMB) a request for OMB review and approval of revisions to the information collection described below. The Agencies may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

Titles:

FDIC: Beneficial Ownership Reports.

OTS: '34 Act Disclosures

OMB Control Numbers:

FDIC: 3064–0030.

OTS: 1550–0019.

Form Numbers:

FDIC: SEC 3, 4, and 5.

OTS: SEC Schedules 13D, 13G, 14A, 14C, 14D–1, and TO; SEC Forms 3, 4, 5, 10, 10–SB, 10–K, 10–KSB, 8–K, 8–A, 12b–25, 10–Q, 10–QSB, 15, and annual report.

Expiration of current OMB clearance:
FDIC: August 31, 2006.
OTS: March 31, 2004.

Affected Public:
FDIC: Directors, officers and principal shareholders of insured financial institutions (insiders).
OTS: Directors, officers and principal shareholders of insured financial institutions (insiders); savings associations.

DATES: Comments should be submitted by March 12, 2004.

ADDRESSES: Comments should be directed to the Agencies and the OMB Desk Officer for the Agencies as follows:

FDIC: Steven F. Hanft, Paperwork Clearance Officer, Legal Division, Room MB–3064, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429. All comments should refer to "beneficial ownership reports." Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m. Commenters are encouraged to submit comments by fax or electronic mail (FAX number: (202) 898–3838; e-mail: *comments@fdic.gov*).

OTS: Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention: 1550–0019, FAX number (202) 906–6518, or e-mail to *infocollection.comments@ots.treas.gov*. OTS will post comments and the related index on the OTS Internet Site at *www.ots.treas.gov*. In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *publicinfo@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755.

OMB Desk Officer for the Agencies: Joseph F. Lackey, Jr., Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, or e-mail to *jlackeyj@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: You may request additional information from:

FDIC: Steven F. Hanft, Paperwork Clearance Officer, (202) 898–3907, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

OTS: Marilyn K. Burton, OTS Clearance Officer, (202) 906–6467, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: The change to this collection requested by the Agencies concerns the filing method for reports of beneficial ownership by insiders whose equity securities are registered with the Agencies. In the past, the Agencies have required paper filings. The Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Sarbanes-Oxley Act of 2002, changed this requirement to electronic filing. Currently, the Agencies are authorizing voluntary electronic filing through an electronic system, which has been available since July 30. Electronic filing will be made mandatory by a separate, later action by the Agencies. The new electronic system is an important step in the Agencies' ongoing efforts to streamline the filing and retrieval of reports filed with the Agencies under the Securities Exchange Act of 1934. It will also reduce burden on insiders who must file these reports within two business days of completing a transaction in equity securities of the institution.

Additionally, OTS collects other periodic disclosure documents required to be filed by savings associations pursuant to the Exchange Act on forms promulgated by the U.S. Securities and Exchange Commission for its registrants. OTS seeks public comment on its proposed renewal of this collection, in addition to the planned change in filing method for reports of beneficial ownership.

The Agencies' burden estimates follow.

Burden Estimates:
Estimated Number of Respondents:
FDIC: 1,333.
OTS: 16.
Estimated Number of Responses:
FDIC: 1,800.
OTS: 401.
Estimated Annual Burden Hours:
FDIC: 1,100 hours.
OTS: 66,567 hours.
Frequency of Response:
FDIC: On occasion.
OTS: On occasion; quarterly; annually.

Comments: All comments submitted in response to this notice will become a matter of public record. Comments are invited on:

(a) Whether the collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated at Washington, DC, this 5th day of February, 2004.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: February 5, 2004.

By the Office of Thrift Supervision.

Richard M. Riccobono,

Deputy Director.

[FR Doc. 04–2944 Filed 2–10–04; 8:45 am]

BILLING CODE 6714–01–P; 6720–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission. Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 010051–033.

Title: Mediterranean Space Charter Agreement.

Parties: Evergreen Marine Corp. (Taiwan) Ltd.; Farrell Lines, Inc.; Hapag-Lloyd Container Linie GmbH; Italia di Navigazione, LLC; Lykes Lines Limited, LLC; A.P. Moller-Maersk A/S; Mediterranean Shipping Company S.A.; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; and Zim Israel Navigation Co., Ltd.

Synopsis: The amendment updates the corporate names of A.P. Moller-Maersk and Italia di Navigazione.

Agreement No.: 011233–016.

Title: USA Southern and Eastern Africa Discussion Agreement.

Parties: A.P. Moller-Maersk Sealand, Mediterranean Shipping Company, and Safmarine Line, Ltd., as members of the U.S./Southern Africa Conference, and Gulf Africa Line and Lykes Lines Limited, LLC.

Synopsis: The amendment removes P&O Nedlloyd Limited as a party to the

agreement and changes the address of the agreement's offices.

Agreement No.: 011290–032.

Title: International Vessel Operators Hazardous Material Association Agreement.

Parties: Aliança Navegacao e Logistica Ltda.; APL Co. PTE Ltd.; Atlantic Container Line AB; Australia-New Zealand Direct Line; Bermuda Container Line; Canada Maritime Agencies Ltd.; China Shipping Container Lines Co., Ltd.; CMA CGM, S.A.; Compania Latino Americana de Navegacion SA; Contship Containerlines; Crowley Maritime Corporation; Evergreen Marine Corp. (Taiwan) Ltd.; Hamburg-Südamerikanische Dampfschifffahrts-gesellschaft KG; Hanjin Shipping Co., Ltd.; Hapag-Lloyd Container Linie GmbH; Horizon Lines, LLC; Hyundai Merchant Marine Co., Ltd.; Independent Container Line Ltd.; Italia di Navigazione, LLC; Kawasaki Kisen Kaisha Ltd.; Lykes Lines Limited, LLC; Marine Transport Lines, Inc.; Maruba SCA; Mediterranean Shipping Co. S.A.; Mitsui O.S.K. Lines, Ltd.; A.P. Moller-Maersk A/S; National Shipping Co. of Saudi Arabia; Nippon Yusen Kaisha Line; Orient Overseas Container Line Limited; P&O Nedlloyd B.V.; P&O Nedlloyd Limited; Safmarine Container Lines; Seaboard Marine Ltd.; Senator Lines GmbH; TMM Lines Limited; Tropical Shipping & Construction Co., Ltd.; United Arab Shipping Co. S.A.G.; Yang Ming Marine Transport Corp.; and Zim Israel Navigation Company, Ltd.

Synopsis: The amendment adds United Arab Shipping Co. as a party to the agreement, updates the corporate names of Italia di Navigazione and Horizon Lines, and clarifies Senator Lines' status as an associate agreement party.

Agreement No.: 011642–007.

Title: East Coast United States/East Coast of South America Vessel Sharing Agreement.

Parties: A.P. Moller-Maersk A/S; Safmarine Container Lines N.V.; P&O Nedlloyd Limited; P&O Nedlloyd B.V.; Mercosul Line Navegacao e Logistica Ltda.; Compania Sud Americana de Vapores, S.A.; Companhia Libra de Navegacao; Alianca Navegacao e Logistica Ltda.; and Hamburg-Sud.

Synopsis: The modification updates the corporate names of A.P. Moller-Maersk and Mercosul Line, removes references to Hamburg-Sud's former trade names, and deletes obsolete references to a discontinued vessel string.

Agreement No.: 011689–006.

Title: Zim/CSCL Space Charter Agreement.

Parties: China Shipping Container Lines Co. Ltd. and Zim Israel Navigation Company, Ltd.

Synopsis: The modification removes certain limitations on China Shipping regarding its utilization of space on Zim's vessels and adds Pusan as a port of call under the agreement. The parties request expedited review.

Agreement No.: 011869.

Title: Haiti Shipping Lines/Frontier Liner Services Space Charter and Sailing Agreement.

Parties: Frontier Liner Services, Inc. Haiti Shipping Lines, Inc.

Synopsis: The agreement would authorize Frontier to make slots available to Haiti Shipping Lines in the trade between Port Everglades, Florida, and Cap Haitien, Haiti. The parties request expedited review.

Dated: February 6, 2004.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 04–3002 Filed 2–10–04; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicants

Jet Freight International Co., Ltd., 1915 S. San Pedro St., Los Angeles, CA 90011. Officers: Chia Yu Pan, C.E.O. (Qualifying Individual), Liling Tseng Pan, Secretary.

Wings Logistics USA Corp., 153–04 Rockaway Blvd., Jamaica, NY 11434. Officer: Oscar Marc Schlossberg, President (Qualifying Individual).

H & T Logistics Corporation, 244 Fifth Avenue, 2nd Floor, #2259, New York, NY 10001–7604. Officers: Jesse R. Waugh, President (Qualifying Individual), Richard Rivera, Managing Director.

Besco Shippers Inc., 1543 Hook Road, Bld. A, Folcroft, PA 19032. Officer: Ludlow A. Harding, President (Qualifying Individual).

Elite Shipping, Inc., 8455 NW., 74th Street, Miami, FL 33166. Officers: Ivan Israel Chavarria, Vice President (Qualifying Individual), David Cardoao, President.

Aliana Express, Inc., 11440 Yearling Circle, Cerritos, CA 90703. Officer: James Sungpyo Kim, C.E.O./C.F.O. (Qualifying Individual).

Canaan Int'l Freight, Inc., 179–02 150th Avenue, Jamaica, NY 11434. Officer: Sara Kwon, President (Qualifying Individual).

Trans Gate International, LLC., 155–06 S. Conduit Avenue, Suite #202, Jamaica, NY 11434. Officers: Ji Hoon Cho, Managing Member (Qualifying Individual), So-Young Lee, Managing Member.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

Met Logistics, Inc., 333 Pierce Road, Suite 150, Itasca, IL 60143. Officers: Timothy Campbell, President (Qualifying Individual), Taichuan Chen, Director.

JDB International Inc., Gava International Freight Consolidators (USA), Inc., 2110 Estes Avenue, Elk Grove Village, IL 60007. Officers: Dale Jordan, Director-Operations (Qualifying Individual), Roberto Baldi, Director-Sales.

EFI Logistics, Inc., 333 Market Street, Suite 250, San Francisco, CA 94105. Officers: David V. Enberg, Secretary/Treasurer (Qualifying Individual), James T. Fitzgerald, President.

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants

Sembcorp Logistics (USA) Inc., 815–817 West Arbor Vitae Street, Inglewood, CA 90301. Officers: Philip KK Chan, Sen. Vice President (Qualifying Individual), Fiona Chan Sioh Noi, President.

Air Cargo Transport Services, Inc., dba Priority Worldwide Services, 504 McCormick Drive, Suite H, Glen Burnie, MD 21061. Officers: Jinna Peters, Secretary (Qualifying Individual), Marc Tohir, Vice President.

I.C.A.T. Logistics, Inc., 514 Progressive Drive, Suite G, Linthicum, MD 21090. Officers: Joanne Keita Johnson, Director (Qualifying Individual), Richard L. Campbell, Jr., President.

Dated: February 6, 2004.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 04–3001 Filed 2–10–04; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Chronic Disease Prevention and Health Promotion

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Interagency Committee on Smoking and Health: Meeting.

Time and Date: 9 a.m.–4 p.m., March 9, 2004.

Place: Howard University, Armour J. Blackburn University Center, West Ballroom 6th and Howard Place, NW., Washington, DC 20059. Telephone: (202) 806–6100.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpretator, or have other special needs, please notify the contact person by 4:30 p.m., no later than March 5, 2004.

Purpose: The Interagency Committee on Smoking and Health advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other Federal, State, local and private agencies and (b) establishment and maintenance of liaisons with appropriate private entities, Federal agencies, and State and local public health agencies with respect to smoking and health activities.

Matters to be Discussed: The agenda will focus on Addressing Tobacco-related Disparities Among Population Groups/Youth with a focus on Communities of Color.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the internet at *http//www.cdc.gov/tobacco* in mid-April or from Ms. Monica L. Swann, Program Specialist, Office on Smoking and Health, 200 Independence Avenue, SW., Suite 317B, Washington, DC 20201, telephone: (202) 205–8500.

Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 5, 2004.

Alvin Hall,

Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. 04–2971 Filed 2–10–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0456]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2004.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prevention of Medical Gas Mixups at Health Care Facilities

FDA has received four reports of medical gas mixups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups, to determine if further steps are warranted to ensure the safety of patients.

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
210/211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of October 10, 2003 (68 FR 58692), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received two comments. One comment had specific questions regarding the requirements to register firms exporting foods from Korea. The responder of the second comment feels the agency is gathering facts with the intent of developing and implementing future guidance that would be enforced on manufacturers, fillers, and transfillers of medical gases. This comment also requests the agency

meet with the medical gases industry before issuing any guidance.

The intent of this survey is stated above and is not applicable to the medical gases industry.

The agency does however, agree with the statement addressed in the second comment regarding the initial contact FDA makes with the 285 facilities would be more effective and save valuable resources if made by telephone. This call could determine whether the health care facility is one of those covered by this assignment and our April 6, 2001, FDA public health advisory entitled "Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities."

Dated: February 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–2998 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provided revised susceptibility information for food-animal pathogens listed in the clinical microbiology section of labeling for ceftiofur sodium sterile powder for injection.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplement to NADA 140–338 which provides for the veterinary prescription use of NAXCEL (ceftiofur sodium) Sterile Powder for Injection. The supplemental NADA provided updated susceptibility data for food-animal pathogens listed in the clinical microbiology section of labeling. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that this supplemental NADA is approved as of December 31, 2003. The basis of approval is discussed in the freedom of information summary.

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

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: January 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–2892 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 224–04–8000]

Memorandum of Understanding Between the Food and Drug Administration and the National Library of Medicine, National Institutes of Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Library of Medicine, National Institutes of Health (NIH) to transfer an initial lot of records and arrange the future transfer of similar records on a continual basis.

DATES: The agreement became effective December 23, 2003.

FOR FURTHER INFORMATION CONTACT: John Swann, Office of Regional Operations (HF–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3756.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: February 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

224-04-8000

Memorandum of Understanding between the Food and Drug Administration and the National Library of Medicine

I. Purpose

The purpose of this agreement is to transfer an initial lot of records and arrange the future transfer of similar records on a continual basis from the Food and Drug Administration (FDA) to the National Library of Medicine, National Institutes of Health (NIH).

II. Background

This agreement is needed to ensure the preservation of and access to a collection of historically significant records. Judicial case files (formerly known as seizure case files) are the published and unpublished documentation of action taken by the Bureau of Chemistry (1907-1927), the Food, Drug, and Insecticide Administration (1927-1930), and the Food and Drug Administration (1930 to the present) against violations of the laws under the jurisdiction of FDA and its predecessor agencies; for the majority of actions, the laws in question are the 1906 Food and Drugs Act and the 1938 Food, Drug, and Cosmetic Act. Because of the increasing breadth of these laws, the judicial case files offer a unique insight into the span of the twentieth-century American marketplace--especially certain health related industries--and the consumer's place therein. Also, they shed light on the relationship between government and industry, particularly in the way manufacturers provided health care and nutrition to the public. Such a view would be difficult or impossible to achieve in any other single collection of records.

The National Archives has classified the judicial case files as temporary records in FDA's Records Control Schedule. Under provisions for the disposition of temporary records in 36 CFR 1228.60 and 36 CFR 1228.136, FDA has sought to identify a venue where these records can be cared for indefinitely and made available to the public. The National Library of Medicine has a well-known archive that has been used by researchers from around the world. The judicial case files fit in well with NLM's archival documentation strategy that, among other aims, captures the development of biomedical science and health care in America. As with its many other collections of records, NLM would be able to publicize the judicial case files to a wide audience of historians and other researchers.

III. Substance of Agreement and Responsibilities of Each Agency

This agreement binds FDA as a donor of certain of its records, and NLM as a recipient and repository of the same records. FDA agrees not to destroy any judicial case files, and to transfer all rights, responsibilities, and ownership of said records to NLM. FDA acknowledges that the copyright of all materials contained in the collection that have been prepared by Federal officials in the performance of their official duties are in

the public domain. NLM in turn agrees to apply to this collection all standard operating procedures of archival management, to utilize for this collection the same means used to publicize other collections in its archive, and to make the collection available to all interested parties under the policies in effect for administration of archival collections. NLM may transfer to another institution or dispose of any of the materials that it determines are not required by the Library. However, prior to such a transfer or disposal, NLM will notify FDA and arrange to return these materials, if so requested.

The transaction of records is to be initiated with a transfer, as soon as practicable, of one group of records consisting of 13 accession lots, covering the approximate period from 1907-1963. These records are identified below:

Records Series	WNRC Accession No.	Period Covered	Volume
Seizure/Prosec.	88-59B-2098	1907-1937	870 cu. ft. (1446 boxes; bx 1-1446)
Seizure Case	88-52A-89	1938-1940	121 cu. ft. (121 boxes; bx 1-121)
Seizure Case	88-52AA-214	1940-1944	37 cu. ft. (37 boxes; bx 1-37)
Seizure Case	88-52AB-214	1940-1944	135 cu. ft. (135 boxes; bx 52-186)
E&F Case	88-52B-214	1940-1944	191 cu ft. (191 boxes; bx 187-377)
F Seizure Case	88-52C-214	1940-1944	63 cu. ft. (81 boxes; bx 378-458)
Seizure/Prosec.	88-52D-214	1940-1944	14 cu. ft. (14 boxes; bx 38-51)
Seizure Case	88-56A-278	1945-1947	208 cu. ft. (208 boxes; bx 1-208)
MFG Card Index	88-56B-278	1907-1940	16 cu. ft. (16 boxes; bx 209-224)
Seizure Case	88-59A-2703	1947-1950	189 cu. ft. (189 boxes; bx 1-189)
Seizure Case	88-60A-554	1951-1954	186 cu. ft. (186 boxes; bx 1-186)

Seizure Case	88-63A-128	1954-1957	117 cu. ft. (117 boxes; bx 1-117)
Seizure Case	88-64A-314	[1958-1963]	100 cu. ft. (100 boxes; bx 1-100)

Subsequent transfers of records dated after 1963, though the volume of records in each transaction may vary, will occur at regular intervals, at times and places agreeable to both parties. However, no records less than 20 years old will be transferred. No later than 31 December 2005, all judicial case files up through 1970 will be transferred by FDA to NLM; no later than 31 December 2007, all judicial case files up through 1980 will be transferred by FDA to NLM; and no later than 31 December 2009, all judicial case files up through 1988 will be transferred by FDA to NLM. Thereafter, every five years FDA will transfer to NLM all judicial case files that are 21 years old or older.

IV. Name and Address of Participating Parties

A. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

B. National Library of Medicine
National Institute of Health
8600 Rockville Pike
Bethesda, Maryland 20894

V. Liaison Officers

A. Contacts for FDA

a) Seung Ja Sinatra, FDA Records Officer, Division of Management Systems, Office of Management Programs, Office of Managements Systems, Office of the Commissioner, HFA-250, Room 4B-41, 5600 Fishers Lane, Rockville, Maryland 20857, 301-827-4274 (ssinatra@oc.fda.gov)

b) John P. Swann, FDA Historian, FDA History Office, Office of Resource Management, Office of Regulatory Affairs, HFC-24, Room 12-69, 5600 Fishers Lane, Rockville, Maryland 20857, 301-827-3756 (jswann@ora.fda.gov)

B. Contacts for NLM

a) Paul H. Theerman, Head, Images and Archives, History of Medicine Division, Room 1 E-21, Building 38, National Library of Medicine,

National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-594-0975 (paul_theerman@nlm.nih.gov)

b) John Rees, Associate Curator of Manuscripts, History of Medicine Division, Room 1 E-21, Building 38, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-8953 (john_rees@nlm.nih.gov)

VI. Period of Agreement

The agreement becomes effective upon signature of both parties and will continue without expiration. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

APPROVED AND ACCEPTED FOR THE NATIONAL LIBRARY OF MEDICINE

By Jon G. Retzlaff

Jon G. Retzlaff
Executive Officer,
National Library of Medicine

Date 12/30/03

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By

Jeff Weber
Associate Commissioner for Management
Office of Management
Food and Drug Administration

Date 12/23/03

[FR Doc. 04–2905 Filed 2–10–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0035]

Draft Guidance for Industry on the Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on a draft guidance entitled "Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis." The guidance was issued in 1994 (1994 draft guidance). During the past decade, a significant body of data related to the diagnosis, prevention, and treatment of osteoporosis has been published. Much of this information is relevant to osteoporosis drug development and, in particular, relates to issues surrounding clinical trial design and duration. The agency is preparing to develop an updated draft guidance on the same topic and is seeking comment on the 1994 draft guidance.

DATES: Submit written or electronic comments on the 1994 draft guidance by April 12, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 1994 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 1994 draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Hedin, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6392.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, with input from an ad hoc workshop and an advisory committee, first issued guidance on osteoporosis drug development in 1979. The guidance was issued in response to the need for effective and safe drugs to prevent and treat osteoporosis. The agency revised the guidance in 1984. Most recently, FDA issued the 1994 draft guidance entitled "Guidelines for Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis."

The 1994 draft guidance recommends study designs, patient populations for study, and techniques for evaluating skeletal mass and fracture frequency that are considered central to demonstrating the efficacy and safety of drugs used to treat and prevent osteoporosis. Since issuance of the 1994 guidance, a number of drugs have been approved for the prevention and treatment of osteoporosis. In general, approval of these drugs was based on favorable bone mineral density and decreased fracture incidence from 2- and 3–year placebo-controlled trials.

Results from these trials and other published data have raised a number of issues and questions that the agency plans to address in an updated draft osteoporosis guidance. To aid in the development of the draft guidance, FDA is requesting comment on the 1994 draft guidance. The agency seeks specific comment on the following questions:

- Is it appropriate to continue to use placebo controls in fracture end-point trials?
- Do fracture end-point trials need to be 3 years in duration, or could shorter studies provide adequate evidence of a new osteoporosis drug's effectiveness and safety?

The 1994 draft guidance was issued before the 1997 publication of FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). In accordance with the GGPs, the agency will take into account any comments received on the 1994 draft guidance, develop a new draft guidance, and make it available for comment. When finalized, that guidance will represent the agency's current thinking on the preclinical and clinical evaluation of agents used in the prevention or treatment of postmenopausal osteoporosis. Agency guidance 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 1994 draft guidance. Two copies of 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. The 1994 draft guidance and received comments are available for public examination in the Division of Dockets Management 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 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–2999 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of a Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on March 10–11, 2004, in the Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, MD (301–657–1234 or 800–233–1234). The meeting begins each day at 8:30 a.m. The SACATM provides advise on the statutorily mandated duties of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

Agenda

The meeting is being held on March 10–11, 2004 from 8:30 a.m. until adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are asked to register with the NTP Executive Secretary (Dr. Kristina Thayer at the NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919–541–5021; facsimile: 919–541–0295; or E-mail: *thayer.niehs.nih.gov).*

Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting (see contact information above).

A preliminary agenda is provided below. A copy of the agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site (*http://ntp-server.niehs.nih.gov*) under "What's New" or available upon request to the NTP Executive Secretary (contact information provided above). Additional information about SACATM is available through the NICEATM/ICCVAM Web site (*http://iccvam.niehs.nih.gov*) under "Advisory Committee". Following the meeting, summary minutes will be prepared and available at this Web site and upon request to the NTP Liaison and Scientific Review Office (contact information above). Information about NICEATM and ICCVAM activities can also be found at the NICEATM/ICCVAM Web site (*http://iccvam.niehs.nih.gov*) or by contacting the Director of NICEATM, Dr. William Stokes (919–541–2384, or e-mail: *niceatm@niehs.nih.gov).*

Preliminary Agenda

Scientific Advisory Committee on Alternative Toxicological Methods—March 10–11, 2004

Hyatt Regency Hotel, 301–657–1234 or 800–233–1234, One Bethesda Metro Center, Bethesda, MD 20814.

March 10, 2004

8:30 a.m.

1. Call to Order and Introductions
2. Welcome and Remarks from NIEHS/NTP
3. Welcome and Remarks from ICCVAM Chair
4. Update on Activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
5. Update on Activities of the European Centre for the Validation of Alternative Methods (ECVAM)
6. Toxicology in the 21st Century: The Role of the National Toxicology Program

a. Public Comment

7. Update on Animal Use

12 p.m.
Lunch Break (on your own)
1 p.m.
8. ICCVAM Strategic Planning Process
a. Public Comment
9. ICCVAM Recommended Performance Standards for In Vitro Dermal Corrosivity Methods
a. Public Comment
10. Evaluation of the Predictivity of In Vivo Dermal Corrosivity Test Methods
a. Public Comment
11. Overview of ILSI/HESI Subcommittee's Activities on Identification of Biomarkers of Toxicity and Summary of First Meeting
12. Validation of Genetically Modified Mouse Models
a. Public Comment
5 p.m.
Adjourn

March 11, 2004

8:30 a.m.
1. Introductions and Call to Order
2. ICCVAM–NICEATM–ECVAM Workshop on Validation of Toxicogenomics-Based Test Systems
a. Public Comment
3. In Progress Test Method Evaluation Nomination: In Vitro Test Methods for Identifying Substances Causing Irreversible Ocular Damage
4. New Test Method Nominations: EPA Test Method Nomination for Test Methods to Identify Negative, Mild, and Moderate Ocular Irritants (*i.e.* Those With Reversible or No Effect)
a. Public Comment
11:30 p.m.
Lunch (on your own)
12:30 p.m.
New Test Method Nominations continued: In Vitro Vaccine Potency Tests for Veterinary Leptospira Vaccines
a. Public Comment
6. Report on the ECVAM Workshop on In Vitro Replacements for Acute Systemic Toxicity
a. Public Comment
2:45 p.m.
7. Other Issues
3:15 p.m.
Adjourn

Public Comment Welcome

Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the NTP Executive Secretary (contact information above) by March 1, 2004, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the NTP Executive Secretary (contact information above) by March 1, 2004, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the SACATM and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (*http://ntp-server.niehs.nih.gov*) under "What's New".

Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the NTP Executive Secretary and should be received by March 1, 2004, to enable review by the SACATM and NIEHS/NIH prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background

The SACATM was established January 9, 2002 to fulfill section 3(d) of Public Law 106–545, the ICCVAM Authorization Act of 2000 [42 U.S.C. 285l–3(d)] and is composed of scientists from the public and private sectors (**Federal Register:** March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the National Institute of Environmental Health Sciences (NIEHS), the Interagency Coordinating Committee on the Validation of Alternative Toxicological Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding statutorily mandated duties of the ICCVAM and activities of the NICEATM. The committee's charter is posted on the Web at *http://iccvam.niehs.nih.gov* under "Advisory Committee" and is available in hard copy upon request from the NTP Executive Secretary (contact information above).

Dated: February 2, 2004.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–2931 Filed 2–10–04; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Cancer Institute.

Date: March 2, 2004.

Time: 2 p.m. to 4 p.m.

Agenda: The purpose of this meeting will be to discuss the Cancer Health Disparities Progress Review Group Report.

Place: National Institutes of Health, Building 31, Room 11A03, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Cherie Nichols, Executive Secretary, National Cancer Institute, National Institute of Health, Building 31, Room 11A03, Bethesda, MD 20892, (301) 496–5515.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/joint/htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,

Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2915 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(b)(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Special Emphasis Panel for R25, and K05 Grant Applications.

Date: March 22, 2004.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 6116 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lynn M. Amende, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard Room 8105, Bethesda, MD 20892–8328, (301) 451–4759, *amendel@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2917 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National cancer Institute Special Emphasis Panel, Understanding Mechanisms of Physical Activity Behavior Change.

Date: March 17–18, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: C. Michael Kerwin, Ph.D, MPH, Scientific Review Administrator Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892–8329, (301) 496–7421, *kerwinm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2918 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute, Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Novel Technologies for in Vivo Imaging (R21/R33).

Date: March 22–23, 2004.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892, (301) 496–7576, *bielak@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2919 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institutes; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Prognosis and Prediction (PAR03–0908 & PAR03 099).

Date: March 9–10, 2004.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Lalita D. Palekar, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8105, Bethesda, MD 20892–7405, (301) 496–7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2922 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Academic Public Private Partnership Program Planning Grants.

Date: March 11–12, 2004.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Joyce C. Pegues, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892, (301) 594–1286, *peguesj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Officer of Federal Advisory Committee Policy.

[FR Doc. 04–2923 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel SBIR Topic 198, Chemical Optimization and Structure Activity Relationships.

Date: February 20, 2004.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lalita D. Palekar, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8105, Bethesda, MD 20892–7405, (301) 496–7575.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2924 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel

Date: February 20, 2004.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Claudio A. Dansky Ullmann, MD, Scientific Review Administrator, National Cancer Institute, Division of Extramural Activities, Grants Review Branch, Research Programs Review Branch, 6116 Executive Blvd., Rm 8119, MSC 8328, Bethesda, MD 208982, (301) 451–4761, *ullmannc@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Treatment Research; 93.396, Cancer biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2925 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel Research Infrastructure.

Date: February 24–25, 2004.

Time: February 24, 2004, 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Bo Hong, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1078, Bethesda, MD 20817, (301) 435–0813, *hongb@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Special Emphasis Panel Comparative Medicine.

Date: March 2, 2004.

Time: 1:30 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: One Democracy Plaza, 6701 Democracy Blvd., Room 1076, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1076, Bethesda, MD 20892–4874, (301) 435–0814, *lambert@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel Research Infrastructure.

Date: March 3–4, 2004.

Time: March 3, 2004, 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bo Hong, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1078, Bethesda, MD 20817, (301) 435–0813, *hongb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93,333, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2930 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 24–25, 2004.

Time: 8:30 a.m. to 12:30 p.m.

Agenda: The agenda will include Opening Remarks, Administrative Matters, Director's Report, NCMHD, Advisory Council Subcommittee Reports, Health Disparities Reports/Collaborations, Update on the Sullivan Commission, and other Council business.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Lisa Evans, JD, Senior Advisory for Policy, National Center for Minority Health and Health Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, 301–402–1366, *evans@ncmhd.nih.gov.*

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2927 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Review of Conference Applications (R13s).

Date: February 26, 2004.

Time: 8 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Robert B Moore, PhD, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7178, MSC 7924, Bethesda, MD 20892, (301) 435–0725.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Mentored Patient Oriented Research Career Development Awards.

Date: February 26–27, 2004.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Robert B Moore, PhD, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7178, MSC 7924, Bethesda, MD 20892, (301) 435–0725.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2928 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group, Clinical and Treatment Subcommittee AA3.

Date: February 26–27, 2004.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Elsie Taylor, MS, Scientific Review Administrator, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Blvd., Bethesda, MD 20892–7003, (301) 443–9787, *etaylor@niaaa.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group, Biomedical Research Review Subcommittee AA–1.

Date: February 27, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affairs, National Institute on Alcohol, Abuse and Alcoholism, 6000 Executive Blvd, Suite 409, Bethesda, MD 20892–7003, (301) 443–2926, *skandasa@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2914 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Suicide Prevention Materials.

Date: February 23, 2004.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, (301)–402–8152, *mbroitma@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Tools and Systems for Implementation.

Date: February 24, 2004.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisor Committee Policy.

[FR Doc. 04–2916 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sectios 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commerical property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Initial Review Group, NINR IRG Meeting (NRRC 29).

Date: February 26–27, 2004.

Time: 8:15 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jeffert M. Chernak, PhD, Scientific Review Administrator, Office of Review, National Institute of Nursing Research, 6701 Democracy Plaza, Suite 712, MSC 4870, Bethesda, MD 20817, (301) 402–6959, *chernak@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2920 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–39, Review of R13s.

Date: February 25, 2004.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372, *george__hausch@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–36, Review of K23s.

Date: March 2, 2004.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lynn M King, PhD, Scientific Review Administrator, Scientific Review Branch, 45 Center Dr., Rm 4AN–38K, National Institute of Dental & Craniofacial Research, National Institutes of Health, Betheada, MD 20892–6402, (301) 594–5006.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–40, Review of R13s.

Date: March 2, 2004.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372, *george__hausch@nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–33, Review of R01s.

Date: March 29, 2004.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rebecca Roper, MS, MPH, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr., room 4AN32E, Bethesda, MD 20892, (301) 451–5096.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–37, Review of R13s.

Date: March 31, 2004.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372, *george_hausch@nig.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2921 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Library and Informatics Review Committee.

Date: March 11–12, 2004.

Time: March 11, 2004, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Time: March 12, 2004, 8 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Hua-Chuan Sim, MD, Health Science Administrator, National Library of Medicine, Extramural Programs, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2929 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. the grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Channel SEP.

Date: February 12, 2004.

Time: 7:30 a.m. to 8:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Jurys Doyle Hotel, 1500 New Hampshire Ave., NW., Washington, DC 20036.

Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7850, Bethesda, MD 20892, (301) 435–1265, *langm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Biochemical Sciences Integrated Review Group, Physiological Chemistry Study Section.

Date: February 19–20, 2004.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Richard Panniers, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7842, Bethesda, MD 20892, (301) 435–1741.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Skeletal Biology Development and Disease Study Section.

Date: February 23–24, 2004.

Time: 7:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Wyndham, 1143 New Hampshire Avenue, Washington, DC 20037.

Contact Person: Priscilla B. Chen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787, *chenp@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Oral, Dental and Craniofacial Sciences Study Section.

Date: February 24–25, 2004.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: J. Terrell Hoffeld, DDS, PhD, Dental Officer, USPHS, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7816, Bethesda, MD 20892, (301) 435–1781, *th88q@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Parenting Children Development in Alcoholic Families.

Date: February 24, 2004.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Adolescent Motherhood.

Date: February 24, 2004.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Impact of Partner Aggression.

Date: February 24, 2004.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Adolescent Drug Use.

Date: February 24, 2004.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Children and Effects of Divorce.

Date: February 24, 2004.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Substance Use: Adolescent Stress and Hormones.

Date: February 25, 2004.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael Micklin, PhD, Chief, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@mail.nih.gov.*

Name of Committee: Genetic Sciences Integrated Review Group, Genome Study Section.

Date: February 25–27, 2004.
Time: 5 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: The Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Contact Person: Camilla E. Day, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1037, *dayc@csr.nih.gov*.

Name of Committee: Cell Development and Function Integrated Review Group, Biology and Diseases of the Posterior Eye Study Section.
Date: February 25–27, 2004.
Time: 7 p.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.
Contact Person: Michael H. Chaitin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435–0910, *chaitinm@csr.nih.gov*.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.
Date: February 26–27, 2004.
Time: 8 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.
Contact Person: Joyce C. Gibson, DSC, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435–4522, *gibsonj@csr.nih.gov*.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Atherosclerosis and Inflammation of the Cardiovascular System Study Section.
Date: February 26–27, 2004.
Time: 8 a.m. to 8 a.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.
Contact Person: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov*.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Vascular Cell and Molecular Biology Study Section.
Date: March 1–2, 2004.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.
Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 F10 21L: Fellowships: DIG and MOSS.
Date: March 1, 2004.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Court Yard by Marriott Embassy Row Hotel, 1600 Rhode Island Avenue. NW., Washington, DC 20036.
Contact Person: Mushtaq A. Khan, PhD, DVM, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, (301) 435–1778, *khanm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 DIG C 02M: Member conflicts: CIGP, GCMB and GMPB.
Date: March 1, 2004.
Time: 8 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.
Contact Person: Patricia Greenwel, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, (301) 435–1169, *greenwep@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 F10 20L: Fellowships: CVS, RES, and MOSS.
Date: March 1–2, 2004.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Court Yard by Marriott Embassy Row, 1600 Rhode Island Avenue, NW., Washington, DC 20036.
Contact Person: Peter J. Perrin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2183, MSC 7818, Bethesda, MD 20892, (301) 435–0682, *perrinp@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Myelogenous Leukemia.
Date: March 1, 2004.
Time: 3 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Chhanda L. Ganguly, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7802, Bethesda, MD 20892, (301) 435–1739, *gangulyc@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 DIG–B (04) XNDA Member Conflicts.
Date: March 1, 2004.
Time: 12 p.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, (Telephone Conference Call).
Contact Person: Najma Begum, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, (301) 435–1243, *begumn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 DIG B02: Member Conflict XNDA.
Date: March 2, 2004.
Time: 11 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Najma Begum, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, (301) 435–1243, *begumn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict for SSPS–A.
Date: March 2, 2004.
Time: 3 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Karin F. Helmers, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, (301) 435–1017, *helmersk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 DIG B03: Member Conflict HBPP.
Date: March 3, 2004.
Time: 11 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Najma Begum, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, (301) 435–1243, *begumn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Social Psychology.
Date: March 4–5, 2004.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Courtyard Washington Embassy Row, 1600 Rhode Island Avenue, NW., Washington, DC 20036.
Contact Person: Michael Micklin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7818, Bethesda, MD 20892, (301) 435–1258, *micklinm@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 4, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–2926 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Reports, Forms, and Record Keeping Requirements: Agency Information Collection Activity Under OMB Review; Aircraft Operator Security

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice.

SUMMARY: This notice announces that TSA has forwarded the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and clearance of an extension of the currently approved collection under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on November 26, 2003, 68 FR 66473.

DATES: Send your comments by March 12, 2004. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS–TSA Desk Officer, at (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Conrad Huygen, Privacy Act Officer, Transportation Security Administration, West Tower 412–S, TSA–17, 601 S. 12th Street, Arlington, VA 22202–4220; telephone (571) 227–1954; facsimile (571) 227–2912.

SUPPLEMENTARY INFORMATION:

Transportation Security Administration (TSA)

Title: Aircraft Operator Security.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0003.

Forms(s): NA.

Affected Public: Air carriers.

Abstract: TSA is seeking to renew information collection request number 1652–0003, which was originally obtained by the Federal Aviation Administration (FAA) to ensure compliance with the standards that were developed and implemented at 14 CFR part 108. The Aviation and Transportation Security Act of 2001 (ATSA), Public Law 107–71, transferred the responsibility for civil aviation security from the FAA to TSA. In February 2002, TSA implemented aircraft operator security standards at 49 CFR part 1544, while 14 CFR part 108 was repealed. This regulation requires aircraft operators to maintain and update their security programs for inspection by TSA to ensure security, safety, and regulatory compliance.

Number of Respondents: 83.

Estimated Annual Burden Hours: 43,160.

TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

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

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Issued in Arlington, Virginia, on February 6, 2004.

Susan T. Tracey,

Chief Administrative Officer.

[FR Doc. 04–2994 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Environmental Assessment Regarding Proposed Issuance of an Incidental Take Permit to the Burlington Northern and Sante Fe Railway Company on Lands in the Middle Fork Flathead River Corridor

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare an Environmental Assessment; notice of public scoping meetings.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended, the Fish and Wildlife Service (Service) intends to prepare an Environmental Assessment (EA). The EA will address the proposed issuance of a Permit to allow take of grizzly bears incidental to rail operations between Browning (milepost 1123.9) and Conkelley (milepost 1208.7), Montana.

The proposed Permit will authorize take of grizzly bear, a federally listed threatened species, in accordance with the Endangered Species Act of 1973, as amended, and other species of concern should they become listed in the future.

The Burlington Northern and Santa Fe Railway Company (BNSF) is preparing a Habitat Conservation Plan (HCP) as part of an application for the Permit. The HCP will address the effects to grizzly bears of BNSF's railroad operations on approximately 137 kilometers (85 miles) of railroad right-of-way. The Service is furnishing this Notice to advise other agencies and the public of our intentions and to announce the initiation of a 45-day scoping period during which other agencies and the public are invited to provide written comments on the scope of the issues and potential alternatives to be included in the EA.

Pursuant to the NEPA, 42 U.S.C. 4321 *et seq.*, and its implementing regulations, 40 CFR 1500.0, *et seq.*, BNSF and the Service jointly announce their intent to prepare an EA for the proposed action of reviewing and approving the proposed HCP and issuing an incidental take permit. The BNSF and the Service also jointly announce their intent to hold scoping meetings, the date, time, and place of which are provided in this notice below. This notice is provided pursuant to section 10(c) of the Endangered Species Act, 16 U.S.C. 1531 *et seq.*, and NEPA implementing regulations, 40 CFR 1506.6.

DATES: Scoping will commence as of February 11, 2004. Written comments on the scope of the proposed action, the approval of a HCP and the concomitant issuance of the Permit should be received on or before March 29, 2004. Three scoping meetings will be held, on the following dates—February 10, 11, and 12, 2004. Each meeting will run from 4 p.m. until 8 p.m. The BNSF and the Service will use an open-house format for the meetings, allowing interested members of the public to attend at any point during the meetings to gather information and/or provide comments.

ADDRESSES: Meeting locations are scheduled as follows—February 10, 2004, Montana Fish, Wildlife and Parks, 490 N. Meridian Road, Kalispell, Montana; February 11, 2004, Middlefork Quick Response Building, Highway 2, Essex, Montana; February 12, 2004, Blackfeet Tribal Complex, Government Square, Tribal Conference Room, Browning, Montana. Written comments

regarding the proposed action and the proposed EA should be addressed to Tim Bodurtha, Supervisor, U.S. Fish and Wildlife Service, 780 Creston Hatchery Road, Kalispell, Montana 59901.

FOR FURTHER INFORMATION CONTACT: Tim Bodurtha, U.S. Fish and Wildlife Service, 780 Creston Hatchery Road, Kalispell, Montana 59901, (406) 758–6882, facsimile (406) 758–6877, e-mail *FW6_BNSF_ScopingHCP@fws.gov,* or Michael Perrodin, BNSF Environmental Operations Manager, 235 Main Street, Havre, Montana 59501, (406) 265–0483, facsimile (406) 265–0356.

SUPPLEMENTARY INFORMATION: The Endangered Species Act and its implementing regulations prohibit the taking of threatened and endangered species. The term "take" is defined under the Endangered Species Act to mean to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt to engage in any such conduct. Harm is defined by the Service to include significant habitat modification or degradation where it actually kills or injures fish or wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, sheltering, spawning, rearing, and migrating.

The Service, under certain circumstances, may issue permits to take listed animal species if such taking is incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for threatened or endangered species are found at 50 CFR 17.22 and 50 CFR 17.32.

Background

The railroad, which traverses the Middle Fork Flathead River corridor, is a portion of the original Great Northern Railway that began operations in 1878. The mainline, from Minneapolis to Seattle, was completed in 1893. Through subsequent mergers, the Great Northern became part of the Burlington Northern Railroad and eventually part of the BNSF. Today, BNSF operates a modern railroad through the corridor. The track is continuous welded rail, traffic is centrally controlled, and operations are computerized. Current rail traffic through the corridor is about 30 freight trains and 2 passenger trains (operated by Amtrak) per day. Depending on market conditions, daily traffic may be as high as 50 freight trains.

The grizzly bear was listed as a threatened species, pursuant to the Endangered Species Act, in 1975. The original Grizzly Bear Recovery Plan was approved in 1982, and a revised plan was approved in 1993. The Middle Fork Flathead River corridor lies within the Northern Continental Divide Grizzly Bear Recovery Zone. Among other objectives, the Grizzly Bear Recovery Plan includes objectives to reduce accidental deaths of bears and minimize activities that result in attraction of bears to sites of conflict.

Railroad operation is one cause of accidental grizzly bear deaths in the Middle Fork Flathead River corridor. Mortalities have occurred because the railroad right-of-way crosses several natural bear movement corridors. Section 10(a)(2)(B) of the Endangered Species Act contains provisions for the issuance of incidental take permits to non-Federal landowners for the take of endangered and threatened species, provided the take is incidental to otherwise lawful activities and will not appreciably reduce the likelihood of the survival and recovery of the species in the wild. An applicant for a Permit under section 10 of the Endangered Species Act must prepare and submit to the Service for approval, a Conservation Plan (commonly known as HCP) containing a strategy for minimizing and mitigating the impacts of the take on listed species associated with the proposed activities to the maximum extent practicable. The applicant also must ensure that adequate funding for the Conservation Plan will be provided.

The BNSF initiated discussions with the Service regarding the development of a HCP and obtaining a Permit. During this process, BNSF intends to employ the Service's technical assistance and assistance of local wildlife biologists.

The BNSF proposes to develop the HCP to achieve conservation of the grizzly bear by minimizing the potential for grizzly bear-train collisions and mitigating for the consequences of unavoidable grizzly bear-train collisions.

As currently envisioned, the HCP would involve a multi-year Permit covering approximately 137 kilometers (85 miles) of railroad right-of-way through the Middle Fork Flathead River Corridor, from Conkelley east to Browning, Montana. The BNSF is currently considering a term of 25 years. The Service specifically requests comment on the term of a permit.

In 1991, the BNSF entered into an agreement with the State and Federal agencies that have relevant jurisdiction in the Middle Fork Flathead River Corridor to form the Great Northern Environmental Stewardship Area (GNESA). The GNESA fosters a positive working relationship among industry, government, and conservation interests. The cooperators recognize that the Middle Fork Flathead River corridor is an area with unique natural values. They also recognize that commerce has an important place in the area. Accordingly, they seek to promote proper stewardship so that these two aspects are compatible. In addition to BNSF, the GNESA cooperators include the Flathead National Forest; Lewis and Clark National Forest; Glacier National Park; U.S. Fish and Wildlife Service; Blackfeet Indian Nation; Montana Fish, Wildlife and Parks; Montana Department of Natural Resources and Conservation; Montana Department of Transportation; Flathead County; Glacier County; the Great Bear Foundation; the Flathead Land Trust; The Nature Conservancy; and, two citizen members.

The BNSF has indicated that the HCP will emphasize conservation of grizzly bears. The BNSF also has indicated that they will develop and implement the HCP in close cooperation with GNESA and its member agencies. This approach will ensure that the HCP is well coordinated with other conservation programs that are currently in place in the Middle Fork Flathead River Corridor.

For the proposed HCP, the BNSF will develop specific conservation measures to be implemented within the framework of existing railroad operations and/or in cooperation with conservation programs for which another GNESA member agency has primary responsibility.

In cooperation with GNESA, the BNSF has implemented an operating protocol that includes several railroad operation and maintenance procedures intended to minimize train-bear incidents and ensure a rapid response and removal of attractants from the railroad right-of-way. In addition to the protocol, the GNESA agreement includes the provision for developing a $1 million conservation trust fund for the purpose of assisting the GNESA cooperators to implement a variety of grizzly bear conservation activities in the Middle Fork Flathead River corridor. The BNSF anticipates that the HCP will update and build upon this existing agreement.

As currently envisioned, the HCP will incorporate active adaptive management features, with an emphasis on documenting all human-caused grizzly bear mortality in the corridor, evaluating factors that contribute to each mortality, and evaluating methods to reduce the potential for human-caused mortality. Applied research and monitoring will help determine the effectiveness of the HCP, validate models used to develop the HCP, and

provide the basic information used to implement "mid-course corrections" if necessary.

The Service will conduct an Environmental Review of the proposed HCP and prepare an EA. The Environmental Review will analyze the proposal as well as a full range of reasonable alternatives and the associated impacts of each. The Service and BNSF are currently in the process of developing alternatives for analysis. The scoping process will be used to identify reasonable alternatives in addition to the No Action alternative.

The Environmental Review of this project will be conducted in accordance with the requirements of the NEPA (42 U.S.C. 4321 *et seq.*), Council of Environmental Quality regulations (40 CFR parts 1500–1508), other appropriate Federal laws and regulations, and policies and procedures of the Service for compliance with all of the above-mentioned regulations. It is estimated that the draft EA will be available for public review during the third quarter of calendar year 2004.

Comments and suggestions are invited from all interested parties to ensure that all significant issues are identified and the full range of issues related to the proposed action are addressed. Comments or questions concerning this proposed action and the Environmental Review should be directed to the Service (see **ADDRESSES**).

Dated: January 27, 2004.

John A. Blankenship,

Deputy Regional Director, Denver, Colorado.

[FR Doc. 04–2952 Filed 2–10–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–500–0777–XM–241A]

Notice of Amendment of Meeting Date, Front Range Resource Advisory Council (Colorado)

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) Front Range Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held on March 18, 2004 at the Holy Cross Abbey Community Center, 2951 E. Highway 50, Canon City, Colorado beginning at 9:15 a.m. The public comment period will begin at approximately 9:30 a.m. and the meeting will adjourn at approximately 4 p.m.

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 Front Range Center, Colorado. Planned agenda topics include: Manager updates on current land management issues; a status report on the San Luis Valley Travel Management Plan; the San Luis Valley Program of Work for FY 04; and a briefing on the Arkansas Headwaters Recreation Area Integrated Concept Plan.

All meetings are open to the public. The public is encouraged to make oral comments to the Council at 9:30 a.m. or written statements may be submitted for the Councils consideration. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Summary minutes for the Council Meeting will be maintained in the Front Range Center Office and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management (BLM), Attn: Ken Smith, 3170 East Main Street, Canon City, Colorado 81212. Phone (719) 269–8500.

Dated: February 4, 2004.

Roy L. Masinton,

Front Range Center Manager.

[FR Doc. 04–2970 Filed 2–10–04; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–154–1610–DQ–GGCA]

Notice of Availability of the Proposed Resource Management Plan and Final Environmental Impact Statement, Gunnison Gorge National Conservation Area, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability of the Proposed Resource Management Plan and Final Environmental Impact Statement (PRMP/FEIS), Gunnison Gorge National Conservation Area (NCA), Colorado.

SUMMARY: In accordance with Section 202 of the National Environmental Policy Act (NEPA) of 1969, and under authority of the Federal Land Policy and Management Act of 1976 (FLPMA), the BLM has prepared a PRMP/FEIS for the Gunnison Gorge National Conservation Area. The planning area lies in Montrose and Delta Counties, Colorado. The PRMP/FEIS provides direction and guidance for the management of public lands and resources of the NCA, as well as monitoring and evaluation requirements. The PRMP/FEIS would also amend the Uncompahgre RMP (189) for the affected lands in the planning area. Some decisions in the existing planning and management documents may be carried forward into the new NCA Resource Management Plan (RMP). Once approved in a Record of Decision (ROD), the RMP for the NCA would supercede all existing management plans for the public lands within the NCA. Tetra Tech, Inc., an environmental consulting firm in Boulder, Colorado, is assisting the BLM in the preparation of these documents and in the planning process for the NCA.

DATES: BLM Planning Regulations (43 CFR 1610.5–2) state that any person may protest the proposed land use planning decisions in the PRMP/FEIS, if he/she participated in the planning process, and has an interest that may be adversely affected. The protest must be postmarked within 30 days of the date that the Environmental Protection Agency publishes this notice in the **Federal Register**. Instructions for filing a protest are described in the Dear Reader letter in the PRMP/FEIS and are also included in the **SUPPLEMENTARY INFORMATION** section of this notice. For Further Information, and/or to have your name added to our mailing list, contact Bill Bottomly (970) 240–5337, Planning and Environmental Coordinator (*bill_bottomly@co.blm.gov*), or Karen Tucker at (970) 240–5309 (*karen_tucker@co.blm.gov*), Gunnison Gorge NCA Manager. The address for both individuals is: Bureau of Land Management, Gunnison Gorge National Conservation Area, 2465 South Townsend Avenue, Montrose, CO 81401. Do not send protests to these individuals—see **SUPPLEMENTARY INFORMATION** below for instructions on submitting a protest.

Persons who are not able to inspect the PRMP/FEIS either on-line or at the information repository locations may request one of a limited number of printed or CD copies. Requests for copies of the PRMP/FEIS should be directed to Mr. Bottomly, and should

clearly state that the request is for a printed copy or CD of the Gunnison Gorge NCA PRMP/FEIS, and include the name, mailing address and phone number of the requesting party.

The BLM has sent copies of the PRMP/FEIS to affected Federal, State, and Local Government agencies and to interested parties. The planning documents and direct supporting record for the analysis for the PRMP/FEIS will be available for inspection at the offices of Tetra Tech, Inc. in Boulder or at the NCA offices during nomral working hours. Copies of the PRMP/FEIS are also available for public inspection at the Bureau of Land Management, Gunnison Gorge NCA office, 2465 South Townsend Avenue, Montrose, Colorado. Interested persons may also review the PRMP/FEIS on the Internet at *http://www.gunnison-gorge-eis.com*. Copies will also be available at the following local libraries.

- Montrose Public Library, 320 South 2nd Street, Montrose, CO 81401.
- Delta Public Library, 211 West 6th Street, Delta, CO 81416.
- Crawford Public Library, 425 Highway 92, Crawford, CO 81415.
- Hotchkiss Public Library, 1st and Main Street, Hotchkiss, CO 81419.

SUPPLEMENTARY INFORMATION: The Black Canyon of the Gunnison National park and Gunnison Gorge National Conservation Act (Act) of 1999 designated the Gunnison Gorge NCA and Wilderness the 1999 designated NCA contains 55,745 acres of public lands, including the 17,784-acre Gunnison Gorge Wilderness. The boundary of the 1999 NCA also included 2,031 acres of private lands. Then on November 17, 2003, the President of the United States signed The Black Canyon of the Gunnison Boundary Revision Act of 2003 (S. 677) which expanded the boundary of the NCA. This act added approximately 7,108 acres of public land and 191 acres of private land within and adjacent to the NCA. The private lands would not be affected as a result of the revision in the boundary, other than, subject to valid existing rights, all Federal mineral estate lands underneath private surface lands would be withdrawn from all forms of entry, appropriation or disposal under the public land laws; from location, entry, and patent under the mining laws; and from disposition under all laws relating to mineral and geothermal leasing. The BLM's Uncompahgre Field Office (UFO) in Montrose, Colorado, manages these lands. The Act directs the BLM to develop a comprehensive plan for the long-range protection and management of the Conservation Area.

The planning area that the PRMP/FEIS addresses consists of lands both within and outside the NCA boundary. The planning area is larger than the NCA boundary so as to consider and provide for consistent management on adjacent and nearby public lands. There are 62,844 acres of BLM-managed lands within the 2003 amended NCA boundary and 2,225 acres of private land. Outside the 2003 amended NCA boundary, the planning area contains 32,936 additional acres of other BLM managed lands, 666 acres of state-managed lands at Sweitzer Lake State Park, and 97,519 acres of private land. The proposed decisions of the PRMP/FEIS would only apply to federal lands, though the planning area boundary contains federal, state, and private lands.

The Draft Resource Management Plan/Draft EIS (DRMP/DEIS), published on March 14, 2003, addressed four alternatives: Alternative A (Continuation of Current Management); Alternative B (Conservation), Alternative C (Mixed use), and Alternative D (Agency Preferred Alternative). The PRMP/FEIS still includes Alternative D as the Agency Preferred Alternative. However, the PRMP/FEIS reflects the comments that the public and BLM reviewers made on the DRMP/DEIS.

When formulating alternatives, the BLM worked with planning participants to address the following planning themes:

1. Preservation of natural and wilderness resources of the NCA and Wilderness, promoting conservation of fish and wildlife, including special status species;
2. Management of human activities and uses;
3. Integration of NCA management with other agency and community plans;
4. Determination of facilities and infrastructure needed to provide visitor services and administration of the NCA;
5. Management of transportation and access; and,
6. Consideration of private property in the planning area.

Some of the issues within the planning themes above that have been identified during the scoping for the NCA planning process include: motorized and non-motorized vehicle use, livestock grazing management, allocation of commercial and private river and upland recreation use, river-related resource management, water quantity and quality, land health, riparian and aquatic habitat protection, threatened and endangered and special status species and critical habitat protection, wildlife habitat quality and fragmentation, declining biodiversity, reintroduction of native species, and noxious weed control. Other factors considered include recreation and resource use, protection of wilderness, riparian, and scenic values, the level and intensity of dispersed and developed recreation management, cultural resource protection and interpretation, management of the mineral estate on adjacent areas not withdrawn from mineral entry and location, public access, transportation and utility corridors, and woodland product harvest.

The PRMP/FEIS recommends the retention of an existing Area of Critical Environmental Concern (ACEC) and the designation of new ACECs. The effects of retaining and/or recommending designations of ACECs regarding restrictions on surface disturbing activities will occur only to the degree necessary to prevent damage and disturbance to the features and resources for which the area was designated. ACEC recommendations in the PRMP/FEIS are as follows: (1) Retain the existing designation of the 161-acre Fairview Research Natural Area/Area of Critical Environmental Concern (RNA/ACEC); (2) Establish the Gunnison Sage Grouse Important Bird Area/ACEC (IBA/ACEC—16,531 acres outside the NCA boundary and 5,669 acres inside the NCA boundary for 22,200 acres total); and, (3) Establish the Native Plant Community ACEC/Outstanding Natural Area (3,785 acres inside NCA.

BLM implemented an extensive public collaboration program for this effort. The agency distributed newsletters, hosted public open houses, an facilitated a public collaboration focus group. The BLM also collaborated with parties after the public comment period on the DRMP/EIS to help resolve issues dealing with wild and scenic river recommendations, rights-of-way utility corridors, and off-highway vehicle use. The resource management planning process includes an opportunity for public, administrative review of proposed land use plan decisions during a 30-day protest period of the PRMP/FEIS. Any person who participated in the planning process for this PRMP/FEIS, and has an interest which is or may be adversely affected, may protect approval of this PRMP/FEIS and land use plan decisions contained within it (See 43 CFR 1610.5–2) during this 30-day period. Only those persons or organizations who participated in the planning process leading to the PRMP/FEIS may protest. A protesting party may raise only those issues submitted for the record during the planning process leading up to the publication of this PRMP/FEIS. These issues may have

been raised by the protesting party or others. New issues may not be brought into the record at the protest stage. The 30-day period for filing a plan protest begins when the Environmental Protection Agency publishes in the **Federal Register** its Notice of Availability of the final environmental impact statement containing the PRMP/FEIS. There is no provision for any extension of time. To be considered "timely," your protest, along with all attachments, must be postmarked no later than the last day of the protest period. A letter of protest must be filed in accordance with the planning regulations, 43 CFR 1610.5–2(a)(1). Protests must be in writing. E-mail and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, BLM will consider the e-mail or faxed protest as an advance copy and it will receive full consideration. If you wish to provide BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at 202–452–5112, and e-mails to *Brenda_Hudgens-Williams@blm.gov*. If sent by regular mail, send to: Director (210), Attention: Brenda Williams, P.O. Box 66538, Washington DC 20035. For overnight (*i.e.*, Federal Express) mailing, send protests to: Director (210), Attention: Brenda Williams, 1620 L Street, NW., Suite 1075, Washington, DC 20036. In order to be considered complete, your protest must contain, at a minimum, the following information:

1. the name, mailing address, telephone number, and interest of the person filing the protest.
2. A statement of the issue or issues being protested
3. A statement of the part or parts of the PRMP/FEIS being protested. To the extent possible, this should be done by reference to specific pages, paragraphs, sections, tables, maps, etc., included in the document.
4. A copy of all documents addressing the issue or issues that you submitted during the planning process, or a reference to the date the issue or issues were discussed by you for the record.
5. A concise statement explaining why the Colorado BLM State Director's proposed decision is believed to be incorrect. This is a critical part of your protest. Take care to document relevant facts.

As much as possible, reference or cite the planning documents, environmental analysis documents, or available planning records (*i.e.*, meeting minutes or summaries, correspondence, *etc.*) A protest that merely expresses disagreement with the Colorado BLM State Director's proposed decision, without any data, will not provide us with the benefit of your information and insight. In this case, the Director's review will be based on the existing analysis and supporting data. At the end of the 30-day protest period and after the Governor's consistency review, the PRMP/FEIS, excluding any portions under protest, will become final. Approval will be withheld on any portion of the PRMP/FEIS under protest until final action has been completed on such protest.

Freedom of Information Act Considerations/Confidentiality

Public comments submitted for this planning review, including names and street addresses of respondents, will be available for public review at the Gunnison Gorge National Conservation Area, Uncompahgre Field Office, in Montrose, Colorado, during regular business hours (7:45 a.m. to 4:30 p.m.), Monday through Friday, except holidays. Comments, including names and addresses of respondents, will be retained on file in the same office as part of the public record for this planning effort. Individual respondents may request confidentiality. If you wish to withhold your name or address from public inspection or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

Dated: January 7, 2004.

Dave Kauffman,

Acting Field Manager, Uncompahgre Field Office.

[FR Doc. 04–2910 Filed 2–10–04; 8:45 am]

BILLING CODE 4310–JB–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 17, 2004.

Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW, 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, (202) 371–6447. Written or faxed comments should be submitted by February 26, 2004.

Carol D. Shull,

Keeper of the National Register of Historic Places.

CALIFORNIA

Humboldt County

Falk Historic District, Address Restricted, Eureka, 04000067

COLORADO

Prowers County

Holly SS Ranch Barn, 407 West Vinson, Holly, 04000068

ILLINOIS

Champaign County

Kappa Kappa Gamma Sorority House. (Fraternity and Sorority Houses at the Urbana-Champaign Campus of the University of Illinois MPS) 1102 S. Lincoln Ave., Urbana, 04000074

Phi Delta Theta Fraternity House, (Fraternity and Sorority Houses at the Urbana-Champaign Campus of the University of Illinois MPS) 309 E. Chalmers St., Champaign, 04000070

Cook County

Maynard, Isaac N., Rowhouses, (Land Subdivisions with Set-Aside Parks, Chicago, IL MPS) 119,121,123 W. Delaware Place, Chicago, 04000077

Schorsch Irving Park Gardens Historic District, (Chicago Bungalows MPS) Roughly bounded by Grace St., Patterson Ave., N. Austin Ave., and N. Melvena Ave., Chicago, 04000075

South Park Manor Historic District, (Chicago Bungalows MPS) Roughly bounded by S. King Dr., S. State St., 75th St. and 79th St., Chicago, 04000076

Logan County

Downey Building, 110–112 Southwest Arch St., Atlanta, 04000069

KANSAS

Franklin County

Pleasant Valley School District #2, 2905 Thomas Rd., Wellsville, 04000078

Johnson County

Ensor Farm, 18995 W. 183rd St., Olathe, 04000079

KENTUCKY

Jessamine County

Brownwood Farm, 5655 Harrodsburg Rd., Nicholasville, 04000073

LOUISIANA

Concordia Parish

Concordia Parish Courthouse, 405 Carter St., Vidalia, 04000081

Jefferson Davis Parish

Camp Hamilton House, (Louisiana's French Creole Architecture MPS) 2200 E. Academy Ave., Jennings, 04000072

Lafourche Parish

Bayou Boeuf Elementary School, 4138 LA 307, Thibodaux, 04000082

St. Landry Parish

Plaisance School, 3264 LA 167, Plaisance, 04000080

Vernon Parish

Kurth, Joseph H., Jr. House, 351 LA 465, Leesville, 04000071

MASSACHUSETTS

Barnstable County

Waquoit Historic District, Roughly bounded by Childs R., Carriage Shop Rd., Waquoit Hwy., Moonakis R., Moonakis Rd., Waquoit Bay, Waquoit Lndng., Falmouth, 04000086

Franklin County

Bissell Bridge, Heath Rd., MA 8A over Mill Brook, Charlemont, 04000083

Hampshire County

Center Cemetery, Sam Hill Rd., Worthington, 04000084

Suffolk County

Haskell, Edward H., Home for Nurses, 220 Fisther Ave., 63 Parker Hill Ave., Boston, 04000085

MISSISSIPPI

Grenada County

Yalobusha Line Defensive Trench, Address Restricted, Grenada, 04000087

MISSOURI

Lafayette County

Hicklin School, MO 24, Lexington, 04000088

St. Louis County

Greenwood Cemetery, 6571 St. Louis Ave., Hillsdale, 04000090

St. Louis Independent City

Seven-Up Company Headquarters, 1300–16 Convention Plaza (Formerly Delmar), St. Louis (Independent City), 04000089

NEW YORK

Chenango County

District School 2, Cty Rte 27, Coventryville, 04000096

Herkimer County

Snells Bush Church and Cemetery, Snells Bush Rd., Manheim, 04000092

Otsego County

Fly Creek Grange No. 844, 208 Cemetery Rd., Fly Creek, 04000097

Kenyon Residences, 60 and 62 Main St., Mt. Vision, 04000093

Rensselaer County

Earl, Gardner, Memorial Chapel and Crematorium, 50 101st St., Troy, 04000091

Westchester County

Peekskill Downtown Historic District, Main, Division, South, Park, Bank, Brown, First and Esther Sts., Central and Union Aves., Peekskill, 04000095

St. Peter's Church, Old, and Old Cemetery at Van Cortlandtville, Oregon Rd. at Locust Ave., Van Cortlandtville, 04000094

OHIO

Richland County

Rock Road Bridge, Former Erie Railroad over Rock Rd., Ontario, 04000062

PENNSYLVANIA

Clarion County

Sutton—Ditz House, 18 Grant St., Clarion, 04000063

Luzerne County

Luzerne County Fresh Air Camp, Middle Rd., approx. 0.25 mi. NE of jct. of Middle Rd. and PA 3021, Butler Township, 04000064

Montgomery County

Breyer, Henry W., Sr., House, 8230 Old York Rd., Eilkins Park, Cheltenham, 04000065

TEXAS

Brown County

Fisk, Greenleaf, House, 418 Milton Ave., Brownwood, 04000103

Comal County

Gruene Historic District (Boundary Increase), Gruene Rd. W. from Sequin St. to the W side of Gruene Bridge, New Braunfels, 04000066

Cooke County

Bomar, E.P. and Alice, House, 417 S. Denton St., Gainesville, 04000099

Dallas County

Harlan Building, 2018 Cadiz St., Dallas, 04000102

Harrison County

Todd—McKay—Wheat House, 506 W. Burleson St., Marshall, 04000101

Live Oak County

Live Oak County Jaoil, Public square in Oakville, Oakville, 04000098

Presidio County

Building 98, Fort D.A. Russell, West Bonnie St., Marfa, 04000100

VIRGINIA

Arlington County

Lee Gardens North Historic District, (Garden Apartments, Apartment Houses and Apartment Complexes in Arlington County, Virginia MPS), 2300–2341 N. 11th St., Arlington, 04000109

Penrose Historic District, Roughly bounded by Arlington Blvd., S. Courthouse Rd., S. Fillmore St., S. Barton St. S, and Columbia Pike, Arlington, 04000112

Stratford Junior High School, 4100 Vacation Ln., Arlington, 04000110

Waverly Hills Historic District, Roughly bounded by 20th Rd. N, N. Utah St, I–66, N. Glebe Rd. and N. Vermont St., Arlington, 04000111

Pittsylvania County

Hill Grove School, 2580 Wards Rd., Hurt, 04000104

Staunton Independent City

Cobble Hill Farm, 101 Woodlee Rd., Staunton, 04000105

WISCONSIN

Columbia County

Columbus Fireman's Park Complex, 1049 Park Ave., Columbus, 04000106

Kenosha County

Isermann, Anthony and Caroline, House, 6416 Seventh Ave., Kenosha, 04000108

Isermann, Frank and Jane, House, 6500 Seventh Ave., Kenosha, 04000107

A request for comment is made for the following:

The National Historic Landmarks Survey program has completed a draft theme study entitled "The Earliest Americans Theme Study for the Eastern United States." The draft study is available for review and comment until February 26, 2004, at *http://www.cr.nps.gov/nhl/design/REALEA2.wpd*. You will need to enter a username (crweb) and password ($yeap77). You may also contact Erika Martin Seibert by phone at (202) 354–2217, or through e-mail at *erika_seibert@nps.gov* for questions about the document.

A request for removal has been made for the following resources:

KANSAS

Allen County

Schleichers Branch Stone Arch Bridge (Masonry Arch Bridges in Kansas TR) Unnamed Rd. over Slack Cr. Humboldt vicinity, 95000620

Cowley County

Gladstone Hotel, N. Summit St., Arkansas City vicinity, 83000422

Reno County

Plevna General Store, 3rd and Main, Plevna, 88002968

Rooks County

Thomas Barn, NE of Woodston, near Osborne Co. Line, Woodston vicinity, 91001104

WISCONSIN

Waukesha County

Friederich Farmstead Historic District, N96 W15009 County Line Rd., Menomonee Falls, 88001631

[FR Doc. 04–2903 Filed 2–10–04; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 24, 2004. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, (202) 371–6447. Written or faxed comments should be submitted by February 26, 2004.

Carol D. Shull,

Keeper of the National Register of Historic Places.

ALABAMA

Baldwin County

Fairhope Downtown Historic District, Roughly bounded by Equality St., Fairhope Ave., Morphy Ave., School St., Summit St., Fairhope, 04000115

DISTRICT OF COLUMBIA

District of Columbia

Grant Road Historic District, 4400 and 4500 blks of Grant Rd., NW., Washington, 04000116

Plymouth Theater, 1365 H St., NE., Washington, 04000117

Surratt, Mary E., House, 604 H St., NW., Washington, 04000118

LOUISIANA

Orleans Parish

Xavier University Main Building, Convent and Library, 1 Drexel Dr., New Orleans, 04000114

MASSACHUSETTS

Hampshire County

North Cemetery, Cold St., Worthington, 04000121

Middlesex County

Asland Town House, 101 Main St., Ashland, 04000120

Suffolk County

YWCA Boston, 140 Clarendon St., Boston, 04000119

OHIO

Butler County

High Street Commercial Block, 228, 232, 236 High St., Hamilton, 04000113

OKLAHOMA

Beckham County

Sayre Champlin Service Station, (Route 66 and Associated Resources in Oklahoma AD MPS) 126 West Main, Sayre, 04000130

Sayre City Park, 200 yds S of jct. of E1200 Rd. and N1870 Rd., Sayre, 04000127

Canadian County

Avant's Cities Service Station, (Route 66 and Associated Resources in Oklahoma AD MPS) 220 S. Choctaw, El Reno, 04000131

Bridgeport Hill—Hydro OK 66 Segment, (Route 66 and Associated Resources in Oklahoma AD MPS) OK 66 from Hydro E to Spur U.S. 281, Hydro, 04000129

Jackson Conoco Service Station, (Route 66 and Associated Resources in Oklahoma AD MPS) 301 S. Choctaw, (121 W. Wade), El Reno, 04000132

Creek County

West Sapulpa Route 66 Roadbed, Jct. of Ozark Trail of OK 66, 0.25 W of Sahoma Lake Rd., Sapulpa, 04000128

Lincoln County

Captain Creek Bridge, (Route 66 and Associated Resources in Oklahoma AD MPS) W of jct. of Hickory St. and OK 66B, Wellston, 04000134

Muskogee County

St. Thomas Primitive Baptist Church, 5th St., N of jct. with Chimney Mountain Rd., Summit, 04000123

Oklahoma County

Gatewood East Historic District, NW 16th to N of NW 22nd, N. Classen Blvd. to N. Blackwelder Ave. and N. Florida Ave., Oklahoma City, 04000126

Gatewood West Historic District, NW 16th to NW 23rd, N Blackwelder Ave. and N. Florida Ave. to Pennsylvania Ave., Oklahoma City, 04000125

Lake Overholser Bridge, (Route 66 in Oklahoma MPS) N. Overholser Dr., 0.5 mi. W of N. Council Rd., Oklahoma City, 04000133

Lincoln Terrace East Historic District, Roughly bounded by Kelley Ave, NE 16th St., Philips Ave., NE 14th St., Linday Ave., Culbertston Dr., and NE 21st St., Oklahoma City, 04000124

Ottawa County

Ottawa County Courthouse, (County Courthouses of Oklahoma TR) 102 East Central, Miami, 04000122

Tulsa County

Vickery Phillips 66 Station, (Route 66 in Oklahoma MPS) 602 S. Elgin, Tulsa, 04000135

A request for REMOVAL has been made for the following resource:

SOUTH DAKOTA

Custer County

Archeological Site No. 39CU890 (Prehistoric Rock Art of South Dakota MPS) Address Restricted Hermosa vicinity, 93000803

[FR Doc. 04–2904 Filed 2–10–04; 8:45 am]

BILLING CODE 4312–51–U

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–492]

In the Matter of Certain Plastic Grocery and Retail Bags; Notice of Decision Not To Review an Initial Determination Terminating the Investigation as to One Respondent on the Basis of a Consent Order; Issuance of Consent Order

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (ID) issued by the presiding administrative law judge (ALJ) in the above-captioned investigation terminating respondent Spectrum Plastics, Inc. ("Spectrum") from the investigation on the basis of a consent order.

FOR FURTHER INFORMATION CONTACT: Andrea Casson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–3105. Copies of all nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 1, 2003, based on a complaint filed by Superbag Corp. ("Superbag") of Houston, Texas, against four respondents, including Spectrum, of Cerritos, California. 68 FR 24755. Superbag's complaint alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and/or sale within the United States after importation of certain T-styled plastic grocery and retail bags that infringe one or more of claims 1–8 and 15–19 of Superbag's U.S. Patent No. 5,188,235. On August 22, 2003, the ALJ issued an

ID (Order No. 7) granting complainant's motion to amend the complaint to add six additional respondents. That ID was not reviewed by the Commission. 68 FR 54740 (Sept. 18, 2003).

On December 23, 2003, pursuant to Commission rule 210.21(c), Superbag moved to terminate the investigation with respect to Spectrum on the basis of a proposed consent order. On January 2, 2004, the Commission investigative attorney filed a response supporting the motion.

On January 8, 2004, the ALJ issued an ID (Order No. 23) granting the motion. No petitions for review of the ID were filed.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's rules of practice and procedure (19 CFR 210.42).

Issued: February 5, 2004.

By order of the Commission.

Marilyn R. Abbott,

Secretary.

[FR Doc. 04–2942 Filed 2–10–04; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

Notice is hereby given that on January 29, 2004, a proposed Consent Decree in *United States* v. *Aervoe Industries, Inc.*, et al., Civil Action No. C–04–00382, was lodged with the United States District court for the Northern District of California.

In this action, the United States sought reimbursement of response costs, pursuant to section 107(a) of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9607(a), incurred in connection with the cleanup of the Lorentz Barrel and Drum Site in San Jose, CA. Aervoe Industries, Inc., D.A. Stuart Co., Ford Motor Company, General Mills, Inc., Golden Gate Petroleum Company, K–M Industries Holding Co., Inc., Pennzoil-Quaker State Company, Salz Leathers, Inc., Sunsweet Growers, Inc., and Textron Inc. ("Defendants") are signatories to the proposed Consent Decree. In addition, the proposed Consent Decree resolves a potential counterclaim by providing for a payment on behalf of the United States Navy. Under the proposed Consent Decree, the Defendants and the United States Navy, collectively, are required to pay $4,200,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044–7611, with a copy to Matthew A. Fogelson, Trial Attorney, U.S. Department of Justice, Environment and Natural Resources Division, Environmental Enforcement Section, 301 Howard Street, Suite 1050, San Francisco, CA 94105, and should refer to *United States* v. *Aervoe Industries, Inc.*, et al., D.J. Ref. 90–11–2–467/3. Commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The Consent Decree may be examined at the Office of the United States Attorney, 280 South First Street, Room 371, San Jose, CA, and at U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/open.html*. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library. P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $7.25 (25 cents per page reproduction cost) payable to the U.S. Treasury.

Ellen M. Mahan,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 04–2978 Filed 2–10–04; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with 28 U.S.C. section 50.7 and section 122 of the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 9622, notice is hereby given that on January 13, 2004, a proposed Consent Decree in *United States* v. *AFG Industries, Inc., et al.*, Civil Action No. 1:04–cv–172, was lodged with the United States District Court for the District of New Jersey.

In this action the United States, on behalf of the United States Department of the U.S. Environmental Protection Agency ("EPA"), seeks reimbursement of certain response costs incurred and to be incurred in connection with response actions at the Cinnaminson Groundwater Contamination Superfund Site (the "Site"), located in Townships of Cinnaminson and Delran, Burlington County, New Jersey. The Complaint alleges that defendants AFG Industries, Inc., Atlantic Metals Corporation, the BOC Group, Inc., Del Val Ink & Color, Inc., EPEC Polymers, Inc., Ford Motor Company, Hoeganaes Corporation, Honeywell International, Inc., L&L Redi-Mix, Inc., Sherman Wire Company, Tennessee Gas Pipeline Company, Twentieth Century Refuse Removal Co., SC Holdings, Inc., Waste Management of New Jersey, Inc., Waste Management of Pennsylvania, Inc., and Waste Management Disposal Services of Pennsylvania, Inc., are liable under section 107(a) of CERCLA, 42 U.S.C. 9607(a). Pursuant to the Consent Decree, the defendants will reimburse the plaintiff United States certain response costs incurred and to be incurred by the plaintiff in remediating the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044–7611, and should refer to *United States* v. *AFG Industries, Inc., et al.*, D.J. Ref. 90–11–2–661B.

The Consent Decree may be examined at the Office of the United States Attorney for the District of New Jersey, 970 Broad Street, Room 400, Newark, New Jersey 07102, and at the offices of EPA Region II, 290 Broadway, New York, New York 10007. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/open.html*. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check

in the amount to $49.75 (25 cents per page reproduction cost), payable to the U.S. Treasury.

Ronald Gluck,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 04–2977 Filed 2–10–04; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act

In accordance with Departmental Policy, 28 U.S.C. 50.7, notice is hereby given that on January 29, 2004, a proposed Consent Decree in *United States Exelon* v. *Mystic,* Civil Action No. 04–10213–PBS, was lodged with the United States District Court for the District of Massachusetts.

In this action the United States, on behalf of the United States Environmental Protection Agency ("EPA"), filed a complaint against Exelon Mystic alleging various violations of the Clean Air Act and the Massachusetts State Implementation Plan, concerning Exelon Mystic's power plant located in Everett, Massachusetts. Under the terms of the proposed settlement, Exelon Mystic will pay a civil penalty of $1 million and fund Supplemental Environmental Projects providing environmental benefits for the greater Boston area at a cost in excess of $5.1 million.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States Exelon* v. *Mystic,* D.J. Ref. 90–5–2–1–07948.

The Consent Decree may be examined at the Office of the United States Attorney, District of Massachusetts, 1 Courthouse Way, Boston, Massachusetts 02210, and at the United States Environmental Protection Agency, Region I—New England, One Congress Street, Boston, Massachusetts 02114. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/open.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov),* fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $10.50 (25 cents per page reproduction cost) payable to the U.S. Treasury.

Ronald Gluck,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 04–2979 Filed 2–10–04; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on April 9, 2003, American Radiolabeled Chemical, Inc., 104 ARC Drive, St. Louis, Missouri 63146, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenylacetone (8501)	II

The firm plans to bulk manufacture small quantities of the listed controlled substances as radiolabled compounds.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than April 12, 2004.

Dated: January 16, 2004.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 04–2951 Filed 2–10–04; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; U.S. National Administrative Office; North American Agreement on Labor Cooperation; Notice of Determination Regarding Review of U.S. Submission #2003–01

AGENCY: Office of the Secretary of Labor.

ACTION: Notice.

SUMMARY: The U.S. National Administrative Office (NAO) give notice that on February 5, 2004, U.S. Submission #2003–01 was accepted for review. The submission was filed with the NAO on September 30, 2003, by the U.S.-based United Students Against Sweatshops (USAS) and the Mexico-based Centro de Apoyo al Trabajador (CAT). An amendment to the submission was filed by the submitters on November 10, 2003. The submitters allege that the Government of Mexico has failed to fulfill its obligations under the North American Agreement on Labor Cooperation (NAALC) to effectively enforce its labor law in connection with freedom of association and protection of the right to organize, the right to bargain collectively, minimum employment standards, occupational safety and health, and access to fair, equitable and transparent labor tribunal proceedings related to events at two garment manufacturing plants located in the State of Puebla, Mexico.

Article 16(3) of the NAALC provides for the review of labor law matters in Canada and Mexico by the NAO. The objectives of the review of the submission will be to gather information to assist the NAO to better understand and publicly report on the Government of Mexico's compliance with the obligations set forth in the NAALC.

EFFECTIVE DATE: February 5, 2004.

FOR FURTHER INFORMATION CONTACT: Lewis Karesh, Acting Secretary, U.S. National Administrative Office, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–5205, Washington, DC 20210. Telephone: (202) 693–4900 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On September 30, 2003, U.S. Submission #2003–01 was filed by the United States Against Sweatshops (USAS) and the Centro de Apoyo al Trabajador (CAT) under the North American Agreement on Labor Cooperation (NAALC) concerning the enforcement of labor law by the Government of Mexico. An amendment to the submission was filed

by the submitters on November 10, 2003. The submission focuses on events at Matamoros Garment S.A. d C.V. and Tarrant México located in the State of Puebla, Mexico.

The submitters allege that the Government of Mexico has failed to fulfill its obligations under the NAALC to effectively enforce its labor law under Article 3 in connection with freedom of association and protection of the right to organize, the right to bargain collectively, minimum employment standards, occupational safety and health, and Article 4 and 5 on access to fair, equitable and transparent labor tribunal proceedings.

The submission focuses on union organizing attempts by workers at both Matamoros Garment S.A. de C.V. and Tarrant México, allegedly hindered by the Government of Mexico, specifically the Puebla Conciliation and Arbitration Board, due to its failure to provide a fair union registration process. Allegations also include failure to pay minimum wages, back wages, and severance compensation; forced overtime; illegal suspensions and layoffs; and unsanitary conditions in the factories' cafeterias and bathrooms. The submitters assert that the Government of Mexico has repeatedly failed to fulfill its obligations under Part 2 of the NAALC to effectively enforce its labor law.

The Procedural Guidelines for the NAO, published in the **Federal Register** on April 7, 1994, 59 FR 16660, specify that, in general, the Secretary of the NAO shall accept a submission for review if it raises issues relevant to labor law matters in Canada or Mexico and if a review would further the objectives of the NAALC.

U.S. Submission #2003–01, which alleges that Mexico has failed to effectively enforce its labor law under Articles 3, 4, and 5, relates to labor law matters in Mexico. A review would further the objectives of the NAALC, as set out in Article 1 of the NAALC, among them improving working conditions and living standards in each Party's territory, promoting the NAALC's labor principles, and encouraging publication and exchange of information, data development, and coordination to enhance mutually beneficial understanding of the laws and institutions governing labor in each Party's territory.

Accordingly, this submission has been accepted for review under Section G of the NAO Procedural Guidelines.

The NAO's decision is not intended to indicate any determination as to the validity or accuracy of the allegations contained in the submission. The objectives of the review will be to gather information to assist the NAO to better understand and publicly report on the issues of freedom of association and protection of the right to organize, the right to bargain collectively, minimum employment standards, occupational safety and health, including the Government of Mexico's compliance with the obligations agreed to under Articles 3, 4, and 5 of the NAALC. The review will be completed, and a public report issued, within 120 days, or 180 days if circumstances require an extension of time, as set out in the Procedural Guidelines of the NAO.

Signed at Washington, DC, on February 5, 2004.

Lewis Karesh,

Acting Secretary, U.S. National Administrative Office.

[FR Doc. 04–2900 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–28–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W–50,953]

Advanced Energy, Including Leased Workers of Adecco, Voorhees, New Jersey; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 28, 2003, applicable to workers of Advanced Energy, Voorhees, New Jersey. The notice was published in the **Federal Register** on May 9, 2003 (68 FR 25061).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New information shows that leased workers of Adecco were employed at Advanced Energy to produce radio frequency power generation equipment at the Voorhees, New Jersey location of the subject firm.

Based on these findings, the Department is amending this certification to include leased workers of Adecco working at Advanced Energy, Voorhees, New Jersey.

The intent of the Department's certification is to include all workers employed at Advanced Energy who were adversely affected by a shift in production to China.

The amended notice applicable to TA-W–50,953 is hereby issued as follows:

All workers of Advanced Energy, Voorhees, New Jersey, and leased workers of Adecco producing radio frequency power generation equipment at Advanced Energy, Voorhees, New Jersey, who became totally or partially separated from employment on or after February 19, 2002, through April 28, 2005, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed in Washington, DC this 22nd day of January, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–248 Filed 02–10–04;8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,161]

ATC Distribution Group, McKees Rocks, PA; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at ATC Distribution Group, McKees Rocks, Pennsylvania. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–53,161; ATC Distribution Group McKees Rocks, Pennsylvania (January 23, 2003)

Signed at Washington, DC this 5th day of February 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 04–3011 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,023]

Cardinal Glass Industries, Inc., Sextonville, Wi; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of December 17, 2003, a petitioner requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment

Assistance and Alternative Trade Adjustment Assistance (ATAA), applicable to workers of the subject firm. The determination was signed on November 19, 2003. The determination notice was published in the **Federal Register** on December 29, 2003 (68 FR 74977).

The Department reviewed the request for reconsideration and has determined that the petitioner has provided additional information. Further review of the initial investigation revealed that the Department erred in its description of the subject firm's product during the customer survey. Therefore, the Department will conduct a new customer survey to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed in Washington, DC, this 29th day of January, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3013 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W–40,568]

Carlisle Engineered Products, Erie, PA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 29, 2002, applicable to workers of Carlisle Engineered Products, Erie, Pennsylvania. The notice was published in the **Federal Register** on February 13, 2002 (67 FR 6748).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of engine-cooling components.

New information shows that workers will be retained at the subject firm beyond the January 29, 2004, expiration date of the certification. These employees will complete the close-down process until their termination no later than May 31, 2004. Based on these findings, the Department is amending the certification to extend the January 29, 2004, expiration date for TA–W–40,568 to read May 31, 2004.

The intent of the Department's certification is to include all workers of Carlisle Engineered Products who were adversely affected by increased imports.

The amended notice applicable to TA–W–40,568 is hereby issued as follows:

All workers of Carlisle Engineered Products, Erie, Pennsylvania, who became totally or partially separated from employment on or after October 25, 2000, through May 31, 2004, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 29th day of January, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–249 Filed 02–10–04;8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,636]

CFM Harris Systems, Skokie, IL; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 25, 2003 in response to a petition filed by a company official on behalf of workers at CFM Harris Systems, Skokie, Illinois.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 5th day of December, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3005 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–U

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,252]

Cytec Industries, Woodbridge, NJ; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Cytec Industries, Woodbridge, New Jersey. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–53,252; Cytec Industries, Woodbridge, New Jersey (January 30, 2003)

Signed at Washington, DC this 5th day of February 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 04–3009 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,221]

Intermetro Industries, A Division of Emerson Electric Wilkes-Barre, PA; Notice of Revised Determination on Reconsideration Regarding Eligibility To Apply for Alternative Trade Adjustment Assistance

On December 17, 2003, the Department issued a Notice of Affirmative Determination Regarding Application for Reconsideration, applicable to workers of the subject firm. The notice will soon be published in the **Federal Register.**

The initial investigation determined that workers at the subject firm possessed easily transferable skills.

The reconsideration investigation revealed that the workers possess skills that are not easily transferable. Additional investigation revealed that a significant number of workers in the workers' firm are fifty years of age or older. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that the requirements of Section 246 of the Trade Act of 1974, as amended, have been met for workers at the subject firm.

In accordance with the provisions of the Act, I make the following certification:

All workers of at Intermetro Industries, A Division of Emerson Electric, Wilkes-Barre, Pennsylvania, who became totally or partially separated from employment on or after October 10, 2002 through November 6, 2005, are eligible to apply for adjustment assistance under Section 223 of the Trade Act

of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed in Washington, DC, this 16th day of January, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3010 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,374]

Manufacturers' Services, Ltd., Charlotte, North Carolina; Notice of Negative Determination Regarding Application for Reconsideration

By application received on December 3, 2003, a petitioner requested administrative reconsideration of the Department's negative determination regarding eligibility for workers and former workers of the subject firm to apply for Trade Adjustment Assistance (TAA). The denial notice applicable to workers of Manufacturer's Services, Ltd., Charlotte, North Carolina, was signed on November 18, 2003, and published in the **Federal Register** on December 29, 2003 (68 FR 74978).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

The TAA petition was filed on behalf of workers at Manufacturer's Services, Ltd. (MSL), Charlotte, North Carolina. Subject firm workers were engaged in support activities such as information technology, quality assurance and program management. The petition was denied because the petitioning workers did not produce an article within the meaning of Section 222 of the Act.

The petitioner alleges that the subject firm is the "assembler and finisher of products", whose workers were separated as a result of a shift of production to Canada.

A company official was contacted for clarification in regard to the nature of the work performed at the subject facility. The official informed that system unit assembly and testing is indeed performed at the subject facility. However, a company official further stated that workers separated during the relevant period were specifically involved in information technology solution, quality engineering, program management and data entry.

Information technology solution, quality engineering, program management and data entry do not constitute production. In order for the worker group to be considered for TAA certification, the workers must be either (1) producing a product or (2) be on site in support of a facility whose workers are currently under TAA certification.

The petitioner's allegation of a shift in work functions from the subject facility to Canada appears to stem from the fact that Manufacturer's Services, Ltd., is being bought by a company in Canada. The petitioner contends that "this action in itself suggests that production has been shifted to foreign countries."

A company official, who was questioned on this issue, stated that the allegation of the shift of production from the subject facility is a mere speculation of the workers based on an unofficial announcement which was circulated among workers of the subject firm about a potential merger of the MSL with a Canadian-based company. However, the merger has never materialized and there are no plans of the merger in the near future. Consequently, no production has been shifted from the subject facility to Canada.

The petitioner further alleges that workforce reduction at the subject firm is also attributed to a reduction of orders from IBM, subject firm's main customer, who in its turn has shifted jobs and production to foreign countries.

In order to meet eligibility requirements, the petitioning worker group must be engaged in production; information technology, quality engineering, program management and data entry do not constitute production within the meaning of Section 222(3) of the Trade Act.

Only in very limited instances are service workers certified for TAA, namely the worker separations must be caused by a reduced demand for their services from a parent or controlling firm or subdivision whose workers produce an article and who are currently under certification for TAA.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 2nd day of February, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3008 Filed 2–10–04; 8:45 am]

BILLING CODE 4310–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 23, 2004.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than February 23, 2004.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 5th day of February, 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[Petitions instituted between 12/29/2003 and 01/16/2004]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
53,885	NTN–BCA Corp. (Comp)	Greensburg, IN	12/29/2003	12/23/2003
53,886	Fishing Vessel (F/V) Pacific Pacer (Comp)	Cordova, AK	12/29/2003	12/22/2003
53,887	Regal Beloit Corp. (Wkrs)	Grafton, WI	12/29/2003	12/23/2003
53,888	Artesyn Technologies (MN)	Redwood Falls, MN	12/29/2003	12/23/2003
53,889	PSC (Wkrs)	Eugene, OR	12/29/2003	12/26/2003
53,890	Arrow Terminals (USWA)	Aliquippa, PA	12/29/2003	12/04/2003
53,891	Kokusai Semiconductor Equipment Corp. (Co).	Portland, OR	12/29/2003	12/23/2003
53,892	IBM Global Services (Wkrs)	Costa Mesa, CA	12/29/2003	12/20/2003
53,893	Johnston Industries (Comp)	DeWitt, IA	12/29/2003	12/04/2003
53,894	Mediacopy (Wkrs)	El Paso, TX	12/29/2003	12/22/2003
53,895	Flexcon Company Inc. (Wkrs)	Spencer, MA	12/29/2003	12/17/2003
53,896	Hogslat, Inc. (Wkrs)	Newton Grove, NC	12/29/2003	12/18/2003
53,897	Louisiana Pacific Corp (Comp)	Deer Lodge, MT	12/29/2003	12/22/2003
53,898	Timken US Corporation (Wkrs)	Torrington, CT	12/30/2003	12/29/2003
53,899	Crane Lithography (Comp)	Cedarburg, WI	12/30/2003	12/28/2003
53,900	Pennsylvania Southwestern Railroad (USWA)	Midland, PA	12/30/2003	12/04/2003
53,901	Delaine Worsted Mills, Inc. (Comp)	Gastonia, NC	12/30/2003	12/29/2003
53,902	Technical Rubber Products, Inc. (Comp)	Rockford, TN	12/30/2003	12/15/2003
53,903	Carolina Shoe Co. (Wkrs)	Morganton, NC	12/30/2003	12/22/2003
53,904	Secutronex (53704)	Miami, FL	12/30/2003	12/29/2003
53,905	Finotex USA Corporation (FL)	Miami, FL	12/30/2003	12/16/2003
53,906A	Dixie Chips, Inc. (Comp)	Brundidge, AL	12/30/2003	12/29/2003
53,906	Dixie Chips, Inc. (Comp)	Evergreen, AL	12/30/2003	12/29/2003
53,907	Phillips Plastics Corp. (Wkrs)	Menomonie, WI	12/30/2003	12/22/2003
53,908	Cal-Jac, Inc. (Comp)	Macon, MS	12/31/2003	12/19/2003
53,909	Lancer Partnership, Ltd. (Comp)	San Antonio, TX	12/31/2003	12/15/2003
53,910	American Standard (Comp)	Tiffin, OH	12/31/2003	12/19/2003
53,911	Scripto-Tokai Corp. (Wkrs)	Rancho Cucam., CA	12/31/2003	12/18/2003
53,912	AK Steel (Wkrs)	Butler, PA	12/31/2003	12/31/2003
53,913	Smead Manufacturing (Wkrs)	Hastings, MN	12/31/2003	12/22/2003
53,914	InterMetro Industries Corp. (Comp)	Cucamonga, CA	12/31/2003	12/19/2003
53,915	First Source Furniture Group (Wkrs)	Nashville, TN	12/31/2003	12/26/2003
53,916	Diamond Crown Co., Inc. (Comp)	New York, NY	12/31/2003	12/03/2003
53,917	Kincaid Furniture Co. (Wkrs)	Hudson, NC	12/31/2003	12/23/2003
53,918	BMC Software, Inc. (Wkrs)	Houston, TX	12/31/2003	12/23/2003
53,919	Senco Products, Inc. (Comp)	Cincinnati, OH	12/31/2003	12/23/2003
53,920	Eaton Corporation (PACE)	Cleveland, OH	12/31/2003	12/17/2003
53,921	Pac-Tec, Inc. (Wkrs)	Heath, OH	12/31/2003	12/19/2003
53,922	K and R Products (CA)	Santa Cruz, CA	12/31/2003	12/18/2003
53,923	Agilent Technologies—QPO (Comp)	Portsmouth, NH	12/31/2003	12/15/2003
53,924	National Carbide Die (USWA)	McKeesport, PA	12/31/2003	12/17/2003
53,925	Avery Dennison (Comp)	Flowery Branch, GA	12/31/2003	12/30/2003
53,926	Shuler Brothers Chip Mill (State)	Opp, AL	01/02/2004	12/29/2003
53,927	Dixie Chips Inc. (Comp)	Evergreen, AL	01/02/2004	12/29/2003
53,928	Tech-Tran Corp. (Wkrs)	Rancocas, NJ	01/02/2004	12/20/2003
53,929	Fishing Vessel (F/V) Viking (Comp)	Cordova, AK	01/02/2004	12/17/2003
53,930	Medcases Inc. (Wkrs)	Philadelphia, PA	01/02/2004	12/29/2003
53,931	Service Corporation International (Wkrs)	Houston, TX	01/02/2004	12/29/2003
53,932	Corex Products Inc. (Comp)	Springfield, MA	01/05/2004	01/02/2004
53,933	Homak Professional Manufacturing Co (Comp).	Bedord Park, IL	01/05/2004	01/02/2004
53,934	Phillips Plastics Corps. (Wkrs)	Eau Claire, WI	01/05/2004	12/31/2003
53,935	Hiddenite Woodworks, Inc. (Comp)	Hiddenite, NC	01/05/2004	12/26/2003
53,936	Analytical Surveys Inc. (State)	San Antonio, TX	01/05/2004	12/22/2003
53,937	Johnson Controls Inc. (Comp)	Laurel Hill, NC	01/05/2004	12/30/2003
53,938A	Oshkosh B'Gosh Retail, Inc. (Wrks)	Oshkosh, WI	01/05/2004	12/29/2003
53,938B	OBG Product Development and Sales (Wrks)	Oshkosh, WI	01/05/2004	12/29/2003
53,938	Oshkosh B'Gosh Corp. (Wkrs)	Oshkosh, WI	01/05/2004	12/29/2003
53,939	Tippins Inc. (Wkrs)	Pittsburgh, PA	01/05/2004	01/05/2004
53,940	PolyOne Corporation (Comp)	DeForest, WI	01/05/2004	12/29/2003
53,941	Murata Electronics North America (Wkrs)	State College, PA	01/06/2004	01/06/2004
53,942	Winalta USA (Wkrs)	Linton, IN	01/06/2004	12/15/2003
53,943	Teletech Holdings, Inc. (Wkrs)	Uniontown, PA	01/06/2004	12/28/2003
53,944	Universal Lighting Technologies (Comp)	Madison, AL	01/06/2004	12/30/2003
53,945	BASF Corp. (Wkrs)	Belvidere, NJ	01/06/2004	01/05/2004
53,946	Tyco Healthcare/Ludlow (Comp)	Huntington Bch., CA	01/06/2004	01/05/2003
53,947	James Kenney Vineyards (Wkrs)	Giants Pass, OR	01/06/2004	01/05/2003
53,948	Seagate Technology (Wkrs)	Oklahoma City, OK	01/06/2004	01/05/2003
53,949	American Fast Print (Wkrs)	Greenville, SC	01/06/2004	12/19/2003

APPENDIX—Continued

[Petitions instituted between 12/29/2003 and 01/16/2004]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
53,950	F/V Lisa Lynn (Comp)	Anchorage, AK	01/12/2004	12/31/2003
53,951	Millennium A.R. Haire (Comp)	Thomasville, NC	01/07/2004	01/06/2004
53,952	Pass and Symour/Legrand (Comp)	San Antonio, TX	01/07/2004	01/05/2003
53,953	Cooper Standard Automotive (Wkrs)	Griffin, GA	01/07/2004	01/06/2004
53,954	Sappi Fine Paper (ME)	Skowhegan, ME	01/07/2004	01/06/2004
53,955	American Steel and Aluminum Corp. (Comp)	Middletown, PA	01/07/2004	01/07/2004
53,956	Tomken Enterprises, Inc. (Comp)	Hildebran, NC	01/07/2004	12/28/2003
53,957	H. Warshow and Sons, Inc. (Comp)	Tappahannock, VA	01/07/2004	01/05/2004
53,958	Motorola (Comp)	San Jose, CA	01/07/2004	10/06/2003
53,959	Bayer Corporation (Wkrs)	Pittsburgh, PA	01/08/2004	01/06/2004
53,960	Waukesha Kramer, Inc. (Wkrs)	Milwaukee, WI	01/08/2004	01/07/2004
53,961	Tyco Safety Products (Wkrs)	Westlake, OH	01/08/2004	12/29/2003
53,962	Wagner Plastics, Inc. (Comp)	Clinton, MA	01/08/2004	01/06/2004
53,963	YKK (USA), Inc. (Wkrs)	Macon, GA	01/08/2004	12/30/2003
53,964	Merit Knitting Mills Corp. (Wkrs)	Glen Dale, NY	01/08/2004	12/23/2003
53,965	Sangamon, Inc. (IL)	Taylorville, IL	01/08/2004	01/07/2004
53,966	Wellington Synthetic Fibers (Comp)	Leesville, SC	01/08/2004	12/31/2003
53,967	OSRAM Sylvania, Inc. (Wkrs)	Warren, PA	01/08/2004	12/30/2003
53,968	FMC Corporation (ICWU)	Tonawanda, NY	01/08/2004	12/22/2003
53,969	Flint River Textiles, Inc. (Comp)	Albany, GA	01/09/2004	01/07/2004
53,970	Tyson Foods, Inc. (Comp)	Augusta, ME	01/09/2004	12/16/2003
53,971	Bailey Manufacturing Corp. (ME)	Fryeburg, ME	01/09/2004	11/25/2003
53,972	Colonial Metals Co. (Comp)	Columbia, PA	01/09/2004	01/08/2004
53,973	Warner Electric, Inc. (USWA)	Roscoe, IL	01/09/2004	01/05/2004
53,974	General Chemical (DE)	Wilmington, DE	01/09/2004	01/08/2004
53,975	Weavexx Corp. (Comp)	Farmville, VA	01/09/2004	12/19/2003
53,976	Fieldstone Ltd./Central Notion Co. (Wkrs)	Providence, RI	01/09/2004	12/31/2003
53,977	Risdon-AMS (Comp)	Danbury, CT	01/12/2004	01/08/2004
53,978	Academy Die Casting and Plating Co. (Comp)	Edison, NJ	01/12/2004	01/05/2004
53,979	Gorecki Manufacturing (Wkrs)	Pierz, MN	01/12/2004	01/12/2004
53,980	Backsplash (Comp)	White Salmon, WA	01/12/2004	12/18/2003
53,981	Marine Accessories Corp. (Comp)	Tempe, AZ	01/12/2004	01/06/2004
53,982	Bassett Furniture Industries, Inc. (Comp)	Hiddenite, NC	01/12/2004	01/08/2004
53,983	Archibald Candy Co. d/b/a Fannie May (IBT)	Chicago, IL	01/12/2004	01/07/2004
53,984	GA Financial Assurance (VA)	Lynchburg, VA	01/12/2004	01/05/2004
53,985	Vishay BLH, Inc. (Wkrs)	Canton, MA	01/12/2004	01/08/2004
53,986	Retango West, Inc. (Comp)	Brooklyn, NY	01/12/2004	01/06/2004
53,987	Air Products and Chemicals, Inc. (Comp)	Pace, FL	01/12/2004	12/31/2003
53,988	Coperion Corporation (NJ)	Ramsey, NJ	01/12/2004	01/05/2004
53,989	Wellington Die Division (Wkrs)	Wellington, OH	01/12/2004	12/29/2003
53,990	Quadelle Textile Corp. (Comp)	W. New York, NJ	01/12/2004	12/12/2003
53,991	Omni Tech. Corporation (Wkrs)	Pewaukee, WI	01/12/2004	01/09/2004
53,992	Twin City Leather Co., Inc. (UNITE)	Gloversville, NY	01/13/2004	01/12/2003
53,993	Newell Rubbermaid (USWA)	Wooster, OH	01/13/2004	01/12/2004
53,994	Union Tools, Inc (AFLCIO)	Frankfort, NY	01/13/2004	01/12/2004
53,995	Lake Region Manufacturing, Inc. (Wkrs)	Pittsburgh, PA	01/13/2004	01/12/2004
53,996	Eljer Plumbingware (Comp)	Salem, OH	01/13/2004	01/12/2004
53,997	Hollister, Inc. (UAW)	Kirksville, MO	01/13/2004	01/07/2004
53,998	Tri Star Knitting (AL)	Cedar Bluff, AL	01/14/2004	01/12/2004
53,999	Collins and Aikman (Wkrs)	Greenville, SC	01/14/2004	01/07/2004
54,000	Arkansas Catfish Growers (Comp)	Hollandale, MS	01/14/2004	01/12/2004
54,001	Yellow Book USA (Wkrs)	Effingham, IL	01/14/2004	01/07/2004
54,002	Axiohm TPG (Wkrs)	Riverton, WY	01/14/2004	01/05/2004
54,003	MDF Moulding and Mill Work (Comp)	Idabel, OK	01/14/2004	01/12/2004
54,004	Maxxim Medical (Comp)	Columbus, MS	01/14/2004	12/18/2003
54,005	Vermont Fasteners Mfg. (VT)	Swanton, VT	01/14/2004	01/09/2004
54,006	American Safety Razor (IUE)	Verona, VA	01/14/2004	01/13/2004
54,007	M and M Manufacturing Industries (IBT)	Bensenville, IL	01/14/2004	01/07/2004
54,008	Unifine Dohler America (NJ)	Monmouth Junc., NJ	01/14/2004	01/12/2004
54,009	Oxford Drapery, Inc. (Comp)	Timmonsville, SC	01/14/2004	01/12/2004
54,010	Tri-Molded Plastic, Inc. (Wkrs)	Bayshore, NY	01/14/2004	01/07/2004
54,011	Owens Illinois (Wkrs)	Erie, PA	01/14/2004	12/27/2003
54,012	Perry/Judd's (GCIU)	Waterloo, WI	01/15/2004	01/14/2004
54,013	Sappi Fine Paper (Wkrs)	Cloquet, MN	01/15/2004	01/12/2004
54,014	Badger Equipment Co. (UAW)	Winona, MN	01/15/2004	01/14/2004
54,015	Sanmina-SCI (Comp)	Durham, NC	01/15/2004	01/14/2004
54,016	Doncasters New England Airfoil Products (Wkrs).	Farmington, CT	01/15/2004	01/10/2004
54,017	Pearson Performance Solutions (Wkrs)	Butler, PA	01/15/2004	01/12/2004
54,018	Tyco Plastics (Wkrs)	Fairmont, MN	01/15/2004	01/14/2004

APPENDIX—Continued

[Petitions instituted between 12/29/2003 and 01/16/2004]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
54,019	Manchester Foundry (USWA)	N. Manchester, IN	01/15/2004	01/10/2004
54,020	Tri Star Precision, Inc. (Comp)	Gilberts, IL	01/15/2004	01/14/2004
54,021	Honeywell (Comp)	Pottsville, PA	01/15/2004	01/14/2004
54,022	Advanced Micro Devices (Wkrs)	Austin, TX	01/15/2004	01/13/2004
54,023	J and J Knitting Corp. (Wkrs)	Ridgewood, NY	01/15/2004	01/08/2004
54,024	Milford Marketing, Inc. (MI)	Franklin, MI	01/15/2004	01/04/2004
54,025	Columbia Showcase, Inc. (Wkrs)	Sun Valley, CA	01/15/2004	12/22/2004
54,026	Central Textiles, Inc. (Wkrs)	Pickens, SC	01/15/2004	01/07/2004
54,027	St. George Crystal Ltd. (Wkrs)	Jeannette, PA	01/15/2004	01/13/2004
54,028	Means Industries (PACE)	Vassar, MI	01/15/2004	01/14/2004
54,029	Symtech, Inc. (Wkrs)	Spartansburg, SC	01/15/2004	01/08/2004
54,030	Interstate Industries of Miss, LLC (Comp)	Kosciusko, MS	01/16/2004	01/15/2004
54,031	Del Monte, Inc. (IBT)	Toppenish, WA	01/16/2004	01/15/2004
54,032	Thermotech Co. (Comp)	El Paso, TX	01/16/2004	01/12/2004
54,033	Aluminum Color Industries (UAW)	Lowellville, OH	01/16/2004	01/14/2004
54,034	Andrew Corporation (Comp)	Dallas, TX	01/16/2004	01/05/2004
54,035	Hi-Country Foods (IBT)	Selah, WA	01/16/2004	01/15/2004

[FR Doc. 04–2901 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,873]

Olympic West Sportswear, Inc., Cascada De Mexico, Inc., Cascade West Sportswear, Inc., Puyallup, WA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 2, 2004, applicable to workers of Olympic West Sportswear, Inc., a division of Cascade West Sportswear, Inc., Puyallup, Washington. The notice will be published soon in the **Federal Register**.

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of outerwear.

New information shows that Cascade West Sportswear, Inc. is the parent firm of Olympic West Sportswear, Inc. and Cascada de Mexico, Puyallup, Washington. Workers of Cascada de Mexico, Inc. and Cascade West Sportswear provide administrative, marketing and management consulting services supporting the production of outerwear at Olympic West Sportswear, Inc., Puyallup, Washington.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Olympic West Sportswear, Inc., Puyallup, Washington, who were adversely affected by a shift in production to Mexico.

The amended notice applicable to TA–W–53,873 is hereby issued as follows:

All workers of Olympic West Sportswear, Inc., including workers of Cascada de Mexico, Inc., and Cascade West Sportswear, Puyallup, Washington, who became totally or partially separated from employment on or after December 22, 2002, through January 2, 2006, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under section 246 of the Trade Act of 1974.

Signed in Washington, DC, this 12th day of January, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–243 Filed 02–10–04; 8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,557]

Paxar Americas, Inc., Formerly Paxar Corporation, Monarch Marking Systems Printed Label Division (Snow Hill Tape), Snow Hill, NC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on November 24, 2003, applicable to workers of Paxar Americas, formerly Paxar Corporation, Printed Label Division (Snow Hill Tape), Snow Hill, North Carolina. The notice was published in the **Federal Register** on December 29, 2003 (68 FR 74979).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of woven tape.

New information shows that some workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account for Monarch Marking Systems, Inc.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Paxar Americas, Inc., formerly Paxar Corporation, Monarch Marking Systems,

Inc., Printed Label Division (Snow Hill Tape), Snow Hill, North Carolina, who were adversely affected by a shift in production to Mexico, Honduras and the Dominican Republic.

The amended notice applicable to TA–W–53,557 is hereby issued as follows:

All workers of Paxar Americas, Inc., formerly Paxar Corporation, Monarch Marking Systems, Inc., Printed Label Division (Snow Hill Tape), Snow Hill, North Carolina, who became totally or partially separated from employment on or after November 17, 2002, through November 24, 2005, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 29th day of January, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–244 Filed 02–10–04; 8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–52,862]

Paxar Americas, Inc., Formerly Paxar Corporation, Monarch Marking Systems, Fabric Label Group, Lenoir, NC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 23, 2003, applicable to workers of Paxar Corporation, Fabric Label Group, Lenoir, North Carolina. The notice was published in the **Federal Register** on November 28, 2003 (68 FR 66880).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of printed labels.

New information shows that some workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account for Paxar Americas, Inc., Monarch Marking Systems, Inc.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Paxar Americas, Inc., formerly Paxar Corporation, Monarch Marking Systems, Inc., Fabric Label Group, Lenoir, North Carolina, who were adversely affected by a shift in production to Mexico, Honduras and the Dominican Republic.

The amended notice applicable to TA–W–52,862 is hereby issued as follows:

All workers of Paxar Americas, Inc., formerly Paxar Corporation, Monarch Marking Systems, Inc., Fabric Label Group, Lenoir, North Carolina, who became totally or partially separated from employment on or after August 26, 2002, through September 23, 2005, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 29th day of January, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–246 Filed 02–10–04; 8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,461]

Symtech, Inc., Spartanburg, SC; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of January 7, 2003, a petitioner requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers of the subject firm. The Department's determination notice was signed on November 18, 2003. The notice was published in the **Federal Register** on December 29, 2003 (68 FR 74978).

The Department reviewed the request for reconsideration and has determined that the petitioner has provided additional information. Therefore, the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 28th day of January 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3007 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–U

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,515D]

Thomasville Furniture Industries, Inc., Plant E, Thomasville, North Carolina; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 13, 2003 in response to a petition filed by a company official on behalf of workers of Thomasville Furniture Industries, Inc., Plant E, Thomasville, North Carolina (TA–W–53,515D).

The petitioning group of workers is covered by an active certification issued on March 10, 2003, and which remains in effect (TA–W–50,150A). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 13th day of January 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3006 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–U

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–52,770]

Tower Mills, Inc., Burlington, NC; Notice of Revised Determination on Reconsideration

By application of December 12, 2003, a petitioner requested administrative reconsideration regarding the Department's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to the workers of the subject firm.

The initial investigation resulted in a negative determination issued on November 3, 2003, based on the finding that imports of hosiery, spandex tights, pantyhose and trouser socks did not contribute importantly to worker separations at the subject plant and no shift of production to a foreign source

occurred. The denial notice was published in the **Federal Register** on November 28, 2003 (68 FR 66878).

To support the request for reconsideration, the company official supplied additional major declining customers to supplement those that were surveyed during the initial investigation. Upon further review and contact with these customers of the subject firm, it was revealed that they increased their import purchases of socks and hosiery during the relevant period. The imports accounted for a meaningful portion of the subject plant's lost sales and production.

It was further revealed that U.S. aggregate imports of socks and hosiery increased significantly during the relevant period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with those produced at Tower Mills, Inc., Burlington, North Carolina, contributed importantly to the declines in sales or production and to the total or partial separation of workers at the subject firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Tower Mills, Inc., Burlington, North Carolina, who became totally or partially separated from employment on or after August 27, 2002, through two years from the date of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 31st day of January, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–247 Filed 02–10–04; 8:45 am]

BILLING CODE 4510–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,106]

Tree Source Industries, Inc., Portland, Oregon; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Tree Source Industries, Inc., Portland, Oregon. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–53,106; Tree Source Industries, Inc. Portland, Oregon (February 2, 2003)

Signed at Washington, DC, this 5th day of February 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 04–3012 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–53,989]

Wellington Die Division, a Subsidiary of Shiloh Industries, Inc., Wellington, Ohio; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on January 12, 2004, in response to a petition filed on behalf of workers at Wellington Die Division, a subsidiary of Shiloh Industries, Inc., Wellington, Ohio.

All workers were separated from the subject firm more than one year before the date of the petition. Section 223(b) of the Act specifies that no certification may apply to any worker whose last separation occurred more than one year before the date of the petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 16th day of January, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 04–3004 Filed 2–10–04; 8:45 am]

BILLING CODE 4510–30–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 04–024]

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, March 24, 2004, 8:30 a.m. to 4 p.m.; and Thursday, March 25, 2004, 8:30 a.m. to 12 noon.

ADDRESSES: National Aeronautics and Space Administration, 300 E Street, SW., Room 6H46 (MIC–6), 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

—Agency Reorganization

—Aeronautics Enterprise Overview

—Subcommittee Reports

—Enterprise Plans for FY 2005

—Joint Planning Office Update

—Recommendations and Actions from June 25–26, 2003, Meeting

—Closing Comments

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); employer/affiliation information (name of institution, address, county, phone); and title/position of attendee. To expedite admittance, attendees can provide identifying information in advance by contacting Ms. Mary-Ellen McGrath via e-mail at *mary.E.mcgrath@nasa.gov* or by telephone at (202) 358–4729. Persons with disabilities who require assistance should indicate this.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participant.

Michael F. O'Brien,

Assistant Administrator for External Relations, National Aeronautics and Space Administration.

[FR Doc. 04–2961 Filed 2–10–04; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 04–023]

NASA Space Science Advisory Committee, Solar System Exploration Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: The National Aeronautics and Space Administration announces a meeting of the NASA Space Science Advisory Committee (SScAC), Solar System Exploration Subcommittee (SSES).

DATES: Wednesday, February 25, 2004, 8:30 a.m. to 5:30 p.m.; Thursday, February 26, 2004, 8:30 a.m. to noon.

ADDRESSES: University of Arizona, Student Union Memorial Center, Picacho Room, 1303 East University Boulevard, Tucson, AZ 85719.

FOR FURTHER INFORMATION CONTACT: Dr. Jay Bergstralh, Code SE., National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–0313, *Jay.T.Bergstralh@nasa.gov.*

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:

—Status of Solar System Exploration
—Status of Mars Exploration Program
—Early Results from Mars Exploration Rovers
—Science Requirements for Jupiter Icy Moons Orbiter (JIMO)
—Status of Planetary Data System

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Michael F. O'Brien,

Assistant Administrator for External Relations, National Aeronautics and Space Administration.

[FR Doc. 04–2962 Filed 2–10–04; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency has submitted to OMB for approval the information collection described in this notice. The public is invited to comment on the proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted to OMB at the address below on or before March 12, 2004, to be assured of consideration.

ADDRESSES: Comments should be sent to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mr. Jonathan Womer, Desk Officer for NARA, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number (301) 837–1694 or fax number (301) 837–3213.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on November 25, 2003 (68 FR 66129). No comments were received. NARA has submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed collection information is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collections; (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 the use of information technology. In this notice, NARA is soliciting comments concerning the following information collection:

Title: Customer Comment Form.
OMB number: 3095–0007.
Agency form number: NA Form 14045.
Type of review: Regular.
Affected public: Individuals.
Estimated number of respondents: 9,600.
Estimated time per response: 5 minutes.
Frequency of response: On occasion.
Estimated total annual burden hours: 800 hours.
Abstract: The information collection is a customer comment form made available to persons who use NARA services or visit NARA museums. The form is voluntary and is used to record comments, complaints, and suggestions from NARA customers about our services, products, and the objectivity, usefulness, or integrity of our information. NARA uses the information collected from our customers to correct problems and improve service.

Dated: January 30, 2004.

L. Reynolds Cahoon,

Assistant Archivist for Human Resources and Information Services.

[FR Doc. 04–2943 Filed 2–10–04; 8:45 am]

BILLING CODE 7515–01–U

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* Policy Statement for the "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof By States Through Agreement." Maintenance of Existing Agreement State Programs, Request for Information through the Integrated Materials Performance Evaluation Program (IMPEP) Questionnaire, and Agreement State Participation in IMPEP.

2. *Current OMB approval number:* 3150–0183.

3. *How often the collection is required:* There are four activities that occur under this collection: information collection activities required by the IMPEP questionnaire in preparation for an IMPEP review conducted no less frequently than every four years; while the following activities are all collected on an annual basis—policy statement addressing requirements for new Agreement States; participation by Agreement States in the IMPEP reviews; and annual requirements for Agreement States to maintain their programs.

4. *Who is required or asked to report:* 33 Agreement States who have signed Section 274b Agreements with NRC.

5. *The estimated number of annual respondents:* 33.

6. *The number of hours needed annually to complete the requirement or request:* For States interested in becoming an Agreement State: Approximately 4,300 hours. For Agreement State participation in 11 IMPEP reviews (9 State, 1 NRC Region and 1 Follow-up Review): 396 hours (an average of 36 hours per review). For maintenance of existing Agreement State programs: 252,000 hours (an average of approximately 7,636 hours per State for 33 Agreement States). For Agreement State response to 9 IMPEP questionnaires annually: 477 hours (an average of 53 hours per program). The total number of hours expended annually is 257,173 hours.

7. *Abstract:* States wishing to become an Agreement State are requested to provide certain information to the NRC as specified by the Commission's Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof By States Through Agreement." Agreement States need to ensure that the Radiation Control Program under the Agreement remains adequate and compatible with the requirements of Section 274 of the Atomic Energy Act (Act) and must maintain certain information. NRC conducts periodic evaluations through IMPEP to ensure that these programs are compatible with the NRC's, meet the applicable parts of the Act, and are adequate to protect public health and safety.

Submit, by April 12, 2004, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html*. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–5 F52, Washington, DC 20555–0001, by telephone at (301) 415–7233, or by Internet electronic mail to *infocollects@nrc.gov*.

Dated at Rockville, Maryland, this 4th day of February, 2004.

For the Nuclear Regulatory Commission.

Brenda Jo Shelton,

NRC Clearance Officer Office of the Chief Information Officer.

[FR Doc. 04–2935 Filed 2–10–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–143]

Notice of Issuance of License Amendment 47 for Blended Low-Enriched Uranium Processing Facility for Nuclear Fuel Services, Inc., Erwin, TN

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of license amendment.

FOR FURTHER INFORMATION CONTACT: Michael Lamastra, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: (301) 415–8139; fax number: (301) 415–5390; e-mail: *mxl2@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to 10 CFR 2.106, the U.S. Nuclear Regulatory Commission (NRC) is providing notice of the issuance of Amendment 47 to Special Nuclear Material License SNM–124 to Nuclear Fuel Services, Inc. (NFS) authorizing the possession and use of special nuclear material in the Blended Low-Enriched Uranium (BLEU) Preparation Facility (BPF) at the licensee's site in Erwin, Tennessee. The NFS' request for the proposed action was previously noticed in the **Federal Register** on January 7, 2003 (68 FR 796) along with a notice of opportunity to request a hearing.

This amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended, and NRC's rules and regulations as set forth in 10 CFR chapter 1. Accordingly, this amendment was issued on January 13, 2004, and was effective immediately.

II. Further Information

The NRC has prepared a non-proprietary (public) version of the Safety Evaluation Report (SER) that documents the information that was reviewed and NRC's conclusion. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," details with respect to this action, including the non-proprietary version of the SER and accompanying documentation included in the license amendment package, are available for inspection at the NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html* (ADAMS accession numbers ML040280502, ML040280209, ML040130574, and ML040130530). These documents may also be viewed electronically on the computers located at the NRC Public Document Room (PDR), O1F21 One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee. Persons who do not have access to ADAMS should contact the NRC PDR Reference Staff by telephone at 1–800–397–4209 or (301) 415–4737, or by e-mail at *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 4th day of January, 2004.

For the Nuclear Regulatory Commission.

Michael Lamastra,

Project Manager, Fuel Manufacturing Section, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 04–2933 Filed 2–10–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–27]

Pacific Gas and Electric Company; Notice of Docketing, Notice of Proposed Action, and Notice of Opportunity for a Hearing for a Materials License for the Humboldt Bay Independent Spent Fuel Storage Installation

The Nuclear Regulatory Commission (NRC or Commission) is considering an application dated December 15, 2003, for a materials license under the provisions of 10 CFR part 72, from Pacific Gas and Electric Company (the applicant or PG&E) to possess spent fuel and other radioactive materials associated with spent fuel in an independent spent fuel storage installation (ISFSI) located on the site of the Humboldt Bay Power Plant (HBPP).

If granted, the license will authorize the applicant to store spent fuel from HBPP in a dry storage cask system at the ISFSI which the applicant proposes to construct and operate on the site of HBPP. This application was docketed under 10 CFR part 72; the ISFSI Docket No. is 72–27. The HBPP ISFSI will be located in Humboldt County, California. If granted, the license will authorize the applicant to store spent fuel for a term of twenty (20) years.

Prior to issuance of the requested license, the NRC will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and by the NRC's rules and regulations. The issuance of the materials license will not be approved until the NRC has reviewed the application and has concluded that issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public. The NRC will complete an environmental evaluation, in accordance with 10 CFR part 51, to determine if the preparation of an environmental impact statement is warranted or if an environmental assessment and finding of no significant impact are appropriate. This action will be the subject of a subsequent notice in the **Federal Register**.

Pursuant to 10 CFR 2.105, within thirty (30) days from the date of publication of this notice in the **Federal Register**, the applicant may file a request for a hearing; and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene with respect to the subject materials license in accordance with the provisions of 10 CFR 2.714. If a request for hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition, and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order. In the event that no request for hearing or petition for leave to intervene is filed by the above date, the NRC may, upon satisfactory completion of all required evaluations, issue the materials license without further prior notice.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which the petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend a petition, without requesting leave of the Atomic Safety and Licensing Board, up to fifteen (15) days prior to the holding of the first pre-hearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the action under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

A request for a hearing or petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudication Staff or may be delivered to the Commission's Public Document Room, One White Flint North Building, 11555 Rockville Pike, Rockville, MD, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the NRC by a toll-free telephone call (800–368–5642 Extension 415–8500) to E. William Brach, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, with the following message: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Assistant General Counsel for Materials Litigation and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Lawrence F. Womack, Vice President, Nuclear Services, Humboldt Bay Power Plant, P.O. Box 56, Avila Beach, California 93424.

Non-timely filings of petitions for leave to intervene, amended petitions, supplemental petitions, and/or requests for hearing will not be entertained absent a determination by the Commission, the Presiding Officer, or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

The Commission hereby provides notice that this is a proceeding on an application for a license falling within the scope of section 134 of the Nuclear Waste Policy Act of 1982 (NWPA), 42 U.S.C. 10154. Under section 134 of the NWPA, the Commission, at the request of any party to the proceeding, must use hybrid hearing procedures with respect to "any matter which the Commission determines to be in controversy among the parties."

The hybrid procedures in section 134 provide for oral argument on matters in controversy, preceded by discovery under the Commission's rules and the designation, following argument, of only those factual issues that involve a genuine and substantial dispute, together with any remaining questions of law, to be resolved in an adjudicatory hearing. Actual adjudicatory hearings are to be held on only those issues found to meet the criteria of section 134 and set for hearing after oral argument.

The Commission's rules implementing section 134 of the NWPA are found in 10 CFR part 2, subpart K, "Hybrid Hearing Procedures for Expansion of Spent Fuel Storage Capacity at Civilian Nuclear Power Reactors' (published at 50 FR 41662 dated October 15, 1985). Under those rules, any party to the proceeding may invoke the hybrid hearing procedures by filing with the presiding officer a written request for oral argument under 10 CFR 2.1109. To be timely, the request must be filed within ten (10) days of an order granting a request for hearing or petition to intervene. The presiding officer must grant a timely request for oral argument. The presiding officer may grant an untimely request for oral argument only upon a showing of good cause by the requesting party for the failure to file on time and after providing the other parties an opportunity to respond to the untimely request. If the presiding officer grants a request for oral argument, any hearing held on the application must be conducted in accordance with the hybrid hearing procedures. In essence, those procedures limit the time available for discovery and require that an oral argument be held to determine whether any contentions must be resolved in an adjudicatory hearing. If no party to the proceeding requests an oral argument, or if all untimely requests for oral argument are denied, then the proceeding shall be conducted in accordance with 10 CFR part 2, subpart G.

For further details with respect to this application, see the application dated December 15, 2003, which is available for public inspection at the Commission's Public Document Room (PDR), One White Flint North Building, 11555 Rockville Pike, Rockville, MD or from the publicly available records component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* (the Public Electronic Reading Room). Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 2nd day of February, 2004.

For the Nuclear Regulatory Commission.

Stephen C. O'Connor, Sr.

Project Manager, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 04–2934 Filed 2–10–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Seeking Qualified Candidates for the Advisory Committee on Reactor Safeguards

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Request for résumés.

SUMMARY: The U.S. Nuclear Regulatory Commission is seeking qualified candidates for appointment to its Advisory Committee on Reactor Safeguards (ACRS).

ADDRESSES: Submit résumés to: Ms. Sherry Meador, Administrative Assistant, ACRS/ACNW, Mail Stop T2E–26, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or e-mail *SAM@NRC.gov*.

SUPPLEMENTARY INFORMATION: Congress established the ACRS to provide the NRC with independent expert advice on matters related to the safety of existing and proposed nuclear power plants and on the adequacy of proposed reactor safety standards. The Committee work currently emphasizes safety issues associated with the operation of 103 commercial nuclear units in the United States; the pursuit of a risk-informed and performance-based regulatory approach; license renewal applications; risk-informed revisions to 10 CFR Part 50; power uprates; transient and accident analysis codes; materials degradation issues; use of mixed oxide and high burnup fuels; and advanced reactor designs.

The ACRS membership includes individuals from national laboratories, academia, and industry who possess specific technical expertise along with a broad perspective in addressing safety concerns. Committee members are selected from a variety of engineering and scientific disciplines, such as nuclear power plant operations, nuclear engineering, mechanical engineering, electrical engineering, chemical engineering, metallurgical engineering, risk assessment, structural engineering, materials science, and instrumentation and process control systems. At this time, candidates are specifically being sought who have 15 years of experience in the areas of nuclear engineering, probabilistic risk assessment, and/or plant operations. Candidates with pertinent graduate level experience will be given additional consideration. Individuals should have a demonstrated record of accomplishments in the area of nuclear reactor safety.

Criteria used to evaluate candidates include education and experience, demonstrated skills in nuclear safety matters, and the ability to solve problems. Additionally, the Commission considers the need for specific expertise in relationship to current and future tasks. Consistent with the requirements of the Federal Advisory Committee Act, the Commission seeks candidates with varying views so that the membership on the Committee will be fairly balanced in terms of the points of view represented and functions to be performed by the Committee.

Because conflict-of-interest regulations restrict the participation of members actively involved in the regulated aspects of the nuclear industry, the degree and nature of any such involvement will be weighed. Each qualified candidate's financial interests must be reconciled with applicable Federal and NRC rules and regulations prior to final appointment. This might require divestiture of securities issued by nuclear industry entities, or discontinuance of industry-funded research contracts or grants.

A résumé describing the educational and professional background of the candidate, including any special accomplishments, professional references, current address, and telephone number should be provided. All qualified candidates will receive careful consideration. Appointment will be made without regard to such factors as race, color, religion, national origin, sex, age, or disabilities. Candidates must be citizens of the United States and be able to devote approximately 80–100 days per year to Committee business. Applications will be accepted until March 15, 2004.

Dated: February 5, 2004.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 04–2936 Filed 2–10–04; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical

utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection:

Supplement to Claim of Person Outside the United States; OMB 3220–0155.

Under the Social Security Amendments of 1983 (Public Law 98–21), which amends Section 202(t) of the Social Security Act, the Tier I or the O/M (overall minimum) portion of an annuity and Medicare benefits payable under the Railroad Retirement Act to certain beneficiaries living outside the U.S., may be withheld effective January 1, 1985. The benefit withholding provision of P.L. 98–21 applies to divorced spouses, spouses, minor or disabled children, students, and survivors of railroad employees who (1) initially became eligible for Tier I amounts, O/M shares, and Medicare benefits after December 31, 1984; (2) are not U.S citizens or U.S. nationals; and (3) have resided outside the U.S for more than six consecutive months starting with the annuity beginning date. The benefit withholding provision does not apply, however to a beneficiary who is exempt under either a treaty obligation of the U.S., in effect on August 1, 1956, or a totalization agreement between the U.S. and the country in which the beneficiary resides, or to an individual who is exempt under other criteria specified in Pub. L. 98–21.

RRB Form G–45, Supplement to Claim of Person Outside the United States, is currently used by the RRB to determine applicability of the withholding provision of Pub. L. 98–21. Completion of the form is required to obtain or retain a benefit. One response is requested of each respondent. The RRB estimates that 100 Form G–45's are completed annually. The completion time for Form G–45 is estimated at 10 minutes per response.

The RRB proposes no changes to Form G–45.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to *Charles.Mierzwa@RRB.GOV*. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or send an e-mail to *Ronald.Hodapp@RRB.GOV*. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. 04–2945 Filed 2–10–04; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Rule 17a–12, SEC File No. 270–442, OMB Control No. 3235–0498.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 17a–12 under the Securities Exchange Act of 1934 is the reporting rule tailored specifically for OTC derivatives dealers, and Part IIB of Form X–17A–5, the Financial and Operational Combined Uniform Single Report, is the basic document for reporting the financial and operational condition of OTC derivatives dealers.

At this point there are three registered OTC derivatives dealers and the staff expects that three additional firms will register as OTC derivatives dealers within the next three years. Rule 17a–12 requires OTC derivatives dealers to file quarterly Part IIB of the Financial and Operational Combined Uniform Single Report ("FOCUS" report)—Form X–17A–5.[1] Rule 17a–12 also requires that OTC derivatives dealers file audited financial statements annually. The staff estimates that the average amount of time necessary to prepare and file the quarterly reports required by the rule is eighty hours per OTC derivatives dealer[2] and that the average amount of time for the annual audit report is 100 hours per OTC derivatives dealer, for a total of 180 hours per OTC derivatives dealer annually. Thus the staff estimates that the total number of hours necessary for six OTC derivatives dealers to comply with the requirements of Rule 17a–12 on an annual basis is 1,080 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: February 4, 2004.

Margaret F. McFarland,

Deputy Secretary.

[FR Doc. 04–2949 Filed 2–10–04; 8:45 am]

BILLING CODE 8010–01–U

[1] Form X–17A–5 [17 CFR 249.617].

[2] Based upon an average of 4 responses per year and an average of 20 hours spent preparing each response.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–49185; File No. SR–CTA/CQ–2003–01]

Consolidated Tape Association; Order Approving the Fifth Substantive Amendment to the Second Restatement of the Consolidated Tape Association Plan and the Third Substantive Amendment to the Restated Consolidated Quotation Plan and Amendment No. 1 Thereto

February 4, 2004.

I. Introduction

On November 28, 2003, the Consolidated Tape Association ("CTA") Plan and Consolidated Quotation ("CQ") Plan Participants ("Participants")[1] submitted to the

[1] Each Participant executed the proposed amendments. The Participants are the American Stock Exchange LLC; Boston Stock Exchange, Inc.; Chicago Board Options Exchange, Inc.; Chicago Stock Exchange, Inc.; Cincinnati Stock Exchange,

Securities and Exchange Commission ("Commission") a proposal to amend the CTA and CQ Plans (collectively, the "Plans"), pursuant to Rule 11Aa3–2[2] under the Securities Exchange Act of 1934 ("Act"). On December 23, 2003, the Participants submitted Amendment No. 1 to the proposed amendments.[3] The proposal represents the 5th substantive amendment made to the Second Restatement of the CTA Plan ("5th Amendment") and the 3rd substantive amendment to the Restated CQ Plan ("3rd Amendment"), and reflects several changes unanimously adopted by the Participants. The proposed amendments would delete the provisions of the Plans that exempt any Participant in the Plans from paying market data fees for the receipt of data on its trading floor for regulation or surveillance or for other specifically approved purposes ("Participant Fee Exemptions"). Notice of the proposed amendments was published in the **Federal Register** on December 31, 2003.[4]

The Commission received no comments on the proposed amendments. This order approves the 5th Amendment to the CTA Plan and the 3rd Amendment to the CQ Plan.

II. Description of the Proposed Amendments

Currently, the Plans specify that each Participant is exempt from certain market data charges (other than access fees) if it is in compliance with the requisite market data contract. According to the Participant Fee Exemptions, the market data contract must require the Participant (1) to receive market data solely at premises that it occupies or on its "trading floor or trading floors" (as that term is generally understood), and (2) to use the data solely for regulatory, surveillance and other approved purposes.

The Participants propose to amend the Plans to require each Participant to pay the same fees for its receipt and use of market data as other market participants pay, regardless of whether the Participant receives the data on its trading floor or elsewhere or uses the data for surveillance or other purposes.

The Participants believe that eliminating the Participant Fee Exemptions will eliminate disputes that have arisen among the Participants regarding what constitutes a "trading floor" and will eliminate a perceived competitive advantage that the Participant Fee Exemptions give Participant markets over non-exchange markets (such as electronic communications networks and other alternative trading systems), over NASD market makers and, in the case of Participants that trade options, over non-Participant options markets.

The Participants have represented that once the proposed amendments are approved by the Commission, they will commence payment of the fees that were subject to the Participant Fee Exemptions in the billing cycle that follows the Commission's approval of the proposed amendments.

III. Discussion

The Commission finds that the proposed amendments to the Plans are consistent with the requirements of the Act and the rules and regulations thereunder,[5] and, in particular, section 11A(a)(1)[6] of the Act and Rule 11Aa3–2 thereunder.[7]

The Commission notes that, under the proposed amendments, all Participants will be required to pay for market data like other market participants, regardless of how they receive or use it. The Commission believes that deleting the Participant Fee Exemptions from the Plans will eliminate any potential disputes over the applicability of the Participant Fee Exemptions and should help to eliminate any perceived competitive inequities between the Participants who currently benefit from the Participant Fee Exemptions and other market participants who pay for market data. The Commission notes that payment of fees subject to the Participant Fee Exemption will commence in the billing cycle that follows Commission approval of the proposed amendments. The Commission finds that the proposed amendments to delete the Participant Fee Exemptions from the Plans are consistent with section 11A of the Act[8] and the rules and regulations thereunder.

IV. Conclusion

It is therefore ordered, pursuant to section 11A of the Act[9] and paragraph (c)(2) of Rule 11Aa3–2[10] thereunder, that the proposed 5th Amendment to the CTA Plan and the proposed 3rd Amendment to the CQ Plan are approved, as amended.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–2906 Filed 2–10–04; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–49187; File No. SR–CTA/CQ–2003–02]

Consolidated Tape Association; Order Approving the Sixth Substantive Amendment to the Second Restatement of the Consolidated Tape Association Plan and the Fourth Substantive Amendment to the Restated Consolidated Quotation Plan and Amendment No. 1 Thereto

February 4, 2004.

I. Introduction

On November 28, 2003, the Consolidated Tape Association ("CTA") Plan and Consolidated Quotation ("CQ") Plan Participants ("Participants")[1] submitted to the Securities and Exchange Commission ("Commission") a proposal to amend the CTA and CQ Plans (collectively, the "Plans"), pursuant to Rule 11Aa3–2[2] under the Securities Exchange Act of 1934 ("Act"). On December 23, 2003, the Participants submitted Amendment No. 1 to the proposed amendments.[3] The proposal represents the 6th substantive amendment made to the Second Restatement of the CTA Plan ("6th Amendment") and the 4th

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Inc. (now known as the National Securities Exchange, Inc.); National Association of Securities Dealers, Inc. ("NASD"); New York Stock Exchange, Inc.; Pacific Exchange, Inc.; and Philadelphia Stock Exchange, Inc.

[2] 17 CFR 240.11Aa3–2.

[3] *See* letter to Jonathan G. Katz, Secretary, Commission, from Thomas E. Haley, Chairman, CTA, dated December 22, 2003 ("Amendment No. 1"). Amendment No. 1 makes a technical correction to the proposed amendments.

[4] *See* Securities Exchange Act Release No. 48987 (December 23, 2003), 68 FR 75661 (December 31, 2003).

[5] In approving the proposed plan amendments, the Commission has considered the proposed amendments' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78k–1(a)(1).

[7] 17 CFR 240.11Aa3–2.

[8] 15 U.S.C. 78k–1.

[9] 15 U.S.C. 78k–1.

[10] 17 CFR 240.11Aa3–2(c)(2).

[11] 17 CFR 200.30–3(a)(27).

[1] Each Participant executed the proposed amendments. The Participants are the American Stock Exchange LLC ("Amex"); Boston Stock Exchange, Inc.; Chicago Board Options Exchange, Inc.; Chicago Stock Exchange, Inc.; Cincinnati Stock Exchange, Inc. (now known as the National Stock Exchange, Inc.); National Association of Securities Dealers, Inc.; New York Stock Exchange, Inc. ("NYSE"); Pacific Exchange, Inc.; and Philadelphia Stock Exchange, Inc.

[2] 17 CFR 240.11Aa3–2.

[3] *See* letter to Jonathan G. Katz, Secretary, Commission, from Thomas E. Haley, Chairman, CTA, dated December 22, 2003 ("Amendment No. 1"). Amendment No. 1 makes a technical correction to the proposed amendments.

substantive amendment to the Restated CQ Plan ("4th Amendment"), and reflects several changes unanimously adopted by the Participants. The proposed amendments would separate the functions of administering the contracts into which vendors and others enter for the purpose of receiving and using market data. Notice of the proposed amendments was published in the **Federal Register** on December 31, 2003.[4]

The Commission received no comments on the proposed amendments. This order approves the 6th Amendment to the CTA Plan and the 4th Amendment to the CQ Plan.

II. Description of the Proposed Amendments

Since 1989, NYSE has performed certain administrative functions on behalf of the Amex, which is the Network B Administrator.[5] These functions include procuring and maintaining the contracts by which vendors and others receive and use the market data that both Network A and Network B make available.[6] NYSE executes the Consolidated Vendor Form on behalf of itself, the Network B administrator and the other Plan Participants.

The Participants propose to once again divide the contract-administration function between the Network A administrator (NYSE) (for the receipt and use of Network A market data) and the Network B administrator (Amex) (for the receipt and use of Network B market data). To make the separation of contract functions possible, the amendments propose to replace the Consolidated Vendor Form with two new forms, a "Network A Consolidated Vendor Form" and a "Network B Consolidated Vendor Form."

Under the proposal, the Amex would assume all contract-administration functions for the Network B Consolidated Vendor Form and would execute those forms on behalf of itself and the other Network B Participants. The NYSE would continue to perform the contract-administration functions for Network A and would execute the Network A Consolidated Vendor Form on behalf of itself and the other Network A Participants.

In terms of substance, the Network A Consolidated Vendor Form and the Network B Consolidated Vendor Form would offer the same terms and conditions as does the Consolidated Vendor Form. The only difference would be that the Consolidated Vendor Form governs the receipt and use of both Network A and Network B market data, whereas the Network A Consolidated Vendor Form governs the receipt and use of Network A market data and the Network B Consolidated Vendor Form will govern the receipt and use of Network B market data.

The Participants originally submitted the Consolidated Vendor Form to the Commission on October 16, 1989.[7] They made certain revisions to the form in response to changes recommended by commenters and re-filed the Consolidated Vendor Form for immediate effectiveness in August 1990.[8] In conjunction with its submission of amended and restated CTA and CQ Plans in December 1995, the Participants submitted a revised version of the Consolidated Vendor Form to the Commission. That revised version made non-substantive changes to conform the form's language to the language in the Plans and to provide greater clarity and standardization in the definitions. The Commission approved the restated Plans, including the revised version of the Consolidated Vendor Form, in May 1996.[9] The amendments propose the first changes to the Consolidated Vendor Form since then.

Under the proposal, the Amex would assume Network B contract-administration functions within 90 days from the Commission's approval of these proposed amendments. The network administrators would commence to use the Network A consolidated Vendor Form and the Network B Consolidated Vendor Form at that time. The Participants state that they intend to notify vendors and other interested parties, both in writing and through verbal contact, of the two new forms.

III. Discussion

The Commission finds that the proposed amendments to the Plans are consistent with the requirements of the Act and the rules and regulations thereunder,[10] and, in particular, section 11A(a)(1)[11] of the Act and Rule 11Aa3–2 thereunder.[12]

The Commission believes that separating the Network A and Network B functions of administering the contracts into which vendors and others enter for the purpose of receiving and using market data should help to facilitate the proper administration of the Plans. More specifically, the Commission believes that the proposed amendments should ease the administrative burden on the NYSE, which currently administers the Consolidated Vendor Form on behalf of both Network A and Network B Participants, by transferring the Network B Contract functions to the Amex, the Network B administrator. The Commission notes that the new Network A Consolidated Vendor Form and the new Network B Consolidated Vendor Form are substantially similar to, and offer the same terms and conditions as, the current Consolidated Vendor Form. The Commission further notes that the separation of the Network A and Network B contract-administration functions and the use of the new forms will be implemented 90 days from the date of this approval order, and that the Participants will notify vendors and other interested parties of the new forms. The Commission therefore finds that the proposed amendments to divide the contract-administration function between the Network A administrator and the Network B administrator are

[4] *See* Securities Exchange Act Release No. 48984 (December 23, 2003), 68 FR 75662 (December 31, 2003).

[5] In 1989, the Participants introduced the "Consolidated Vendor Form" and that form of vendor agreement is still in use. *See* Securities Exchange Act Release No. 27498 (December 4, 1989), 54 FR 50828 (December 11, 1989). The Consolidated Vendor Form applies to the receipt and use of Network B market data, as well as Network A market data. Pursuant to delegated authority, NYSE has administered that Consolidated Vendor Form on behalf of the Network B Participants as well as on behalf of the Network A Participants. Before the introduction of that form of vendor agreement, NYSE administered the Network A vendor agreements on behalf of the Network A Participants and the Amex administered the Network B vendor agreements on behalf of the Network B Participants.

[6] The form of contract that is the subject of the proposal is the form of contract (the Consolidated Vendor Form) that the Participants require "Customers" to enter into for their receipt and use of the market data that the Participants make available under the Plans. "Customers" include (1) vendors, (2) internal and other data redistributors, and (3) those that internally use market data for the purposes that are subject to the Plans' program classification charges. The Consolidated Vendor Form constitutes Exhibit C to each Plan.

End users that do not redistribute data and do not use it for the purposes that are the subject of the program classification charges receive the data pursuant to "subscriber" forms of the agreement. NYSE, as the Network A administrator, currently administers the Network A form of that agreement. The Amex, as the Network B administrator, currently administers a Network B form of that agreement. The proposed amendments do not propose any change to those subscriber forms.

[7] *See* Securities Exchange Act Release No. 27498 (December 4, 1989), 54 FR 50828 (December 11, 1989).

[8] *See* Securities Exchange Act Release No. 28407 (September 6, 1990), 55 FR 37276 (September 10, 1990).

[9] *See* Securities Exchange Act Release No. 37191 (May 9, 1996), 61 FR 24842 (May 16, 1996).

[10] In approving the proposed plan amendments, the Commission has considered the proposed amendments' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78k–1(a)(1).

[12] 17 CFR 240.11Aa3–2.

consistent with section 11A of the Act[13] and the rules and regulations thereunder.

IV. Conclusion

It is therefore ordered, pursuant to section 11A of the Act[14] and paragraph (c)(2) of Rule 11Aa3–2[15] thereunder, that the proposed 6th Amendment to the CTA Plan and the proposed 4th Amendment to the CQ Plan are approved, as amended.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–2907 Filed 2–10–04; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48991A; File No. SR–NASD–2003–44]

Self-Regulatory Organizations; Order Granting Approval to Proposed Rule Change and Amendment Nos. 1 and 2 Thereto and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 3 Thereto by the National Association of Securities Dealers, Inc. To Modify an Existing Pilot Program Relating to the Bid Price Test of the Nasdaq Maintenance Listing Standards

February 5, 2004.

Correction

On March 18, 2003, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, the Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") a proposed rule change to modify an existing pilot program relating to the bid price test of Nasdaq's maintenance listing standards. On December 23, 2003, the Commission approved the proposed rule change, as amended. This order corrects and supercedes the order that appeared in the **Federal Register** on December 31, 2003 (FR Doc. 03–32171).[1]

These corrections reflect the fact that, prior to the Commission's approval of SR–NASD–2003–44, NASD Rule 4450(e)(2) offered Nasdaq National Market issuers only one 180-calendar-day grace period for bid price non-compliance, not two as stated in the original approval order. In SR–NASD–2003–44, Nasdaq proposed an amendment to NASD Rule 4450(e)(2) that would offer National Market issuers a second 180-calendar-day grace period for bid price non-compliance, if certain conditions are met. The Commission approved this proposal on a pilot basis. Therefore, the theoretical maximum period for bid price non-compliance for an issuer listed on the Nasdaq National Market is now approximately 1.0 years, not 1.5 years as stated in the original approval order. The corrected order is as follows:

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I. Introduction

On March 18, 2003, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, the Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") a proposed rule change to modify an existing pilot program relating to the bid price test of Nasdaq's maintenance listing standards. Nasdaq submitted amendments to the proposed rule change on March 24, 2003,[2] and September 26, 2003.[3] On October 10, 2003, the Commission published notice of the proposal in the **Federal Register**.[4] No comments were received on the proposed rule change. On November 26, 2003, Nasdaq submitted Amendment No. 3 to the proposed rule change.[5] This notice and order solicits comment on Amendment No. 3 and approves the proposed rule change, as amended, on an accelerated basis.

II. Description of the Proposal

To obtain a listing on the Nasdaq Stock Market, an issuer must meet the initial listing standards; to keep a listing on Nasdaq, an issuer must meet the maintenance listing standards on an ongoing basis.[6] One of these standards relates to the bid price of the issuer's security. On either the Nasdaq National Market or the SmallCap Market, the security must maintain a bid price of at least $1.00 or face delisting.[7] Nasdaq's listing rules provide that a failure to meet the bid price standard exists if the bid price remains less than $1.00 for 30 consecutive business days.[8] After 30 consecutive business days of the security failing the bid price test, Nasdaq would notify the issuer of the deficiency.[9] Nasdaq's listing rules would then provide for certain "grace periods" during which the issuer is expected to regain compliance with the bid price standard or be subject to delisting.

On the Nasdaq SmallCap Market, an issuer that fails the bid price test automatically receives a 180-calendar-day grace period.[10] An issuer need not meet any special requirements to qualify for this grace period. If the issuer still fails the bid price test at the end of the 180 days,[11] it could be granted an additional 180-day grace period if it meets one of the quantitative initial listing standards (rather than the lesser maintenance standards) of the SmallCap Market.[12] If the issuer were still deficient at the end of the second 180-day grace period, it could be granted an additional 90-calendar-day grace period if the issuer again meets one of the quantitative initial listing standards of the SmallCap Market. At the end of the 90 days (or of any other grace period where the issuer does not qualify for an additional grace period), Nasdaq would delist the security, subject to the procedural requirements of the NASD Rule 4800 Series. Thus, Nasdaq's maintenance listing standards currently allow a SmallCap issuer a theoretical maximum of approximately 1.25 years of non-compliance with the bid price standard before facing delisting.

On the Nasdaq National Market, like on the SmallCap Market, an issuer that fails the bid price test would automatically receive a 180-calendar-

[13] 15 U.S.C. 78k–1.

[14] 15 U.S.C. 78k–1.

[15] 17 CFR 240.11Aa3–2(c)(2).

[16] 17 CFR 200.30–3(a)(27).

[1] Securities Exchange Act Release No. 48991 (December 23, 2003), 68 FR 75677 (December 31, 2003).

[2] *See* letter from Sara Nelson Bloom, Associate General Counsel, Nasdaq, to Katherine A. England, Division of Market Regulation, Commission, dated March 21, 2003 ("Amendment No. 1"). In Amendment No. 1, Nasdaq made minor revisions to the original proposal.

[3] *See* letter from Edward S. Knight, Executive Vice President, Nasdaq, to Katherine A. England, Division of Market Regulation, Commission, dated September 25, 2003 ("Amendment No. 2"). In Amendment No. 2, Nasdaq revised the length of the grace periods available to issuers not in compliance with the bid price test and added to the criteria that issuers would have to meet to avail themselves of such periods.

[4] *See* Securities Exchange Act Release No. 48592 (October 3, 2003), 68 FR 58732.

[5] *See* letter from Sara Nelson Bloom, Associate General Counsel, Nasdaq, to Katherine A. England, Division of Market Regulation, Commission, dated November 25, 2003. In Amendment No. 3, Nasdaq made minor revisions to the proposal.

[6] *See* NASD Rules 4300 *et seq.* and 4400 *et seq.*

[7] *See* NASD Rule 4310(c)(4) (for SmallCap); NASD Rules 4450(a)(5) and (b)(4) (for National Market).

[8] *See* NASD Rule 4310(c)(8)(D) (for SmallCap); NASD Rule 4450(e)(2) (for National Market).

[9] *See id.*

[10] *See* NASD Rule 4310(c)(8)(D).

[11] An issuer is deemed to be back in compliance with the bid price standard if it maintains a bid price of over $1 for ten consecutive business days, *see id.*, although Nasdaq in its discretion may extend the ten-day requirement to as long as 20 consecutive business days, *see id.*

[12] *See id.* (requiring issuer to meet any of the three criteria for initial listing set forth in NASD Rule 4310(c)(2)(A)).

day grace period without having to meet any special requirements.[13] A National Market security that meets the maintenance listing standards for the SmallCap Market could "phase down" to the SmallCap Market to take advantage of the additional grace period offered there.[14]

The second 180-day grace period and the additional 90-day grace period on the SmallCap Market were established by pilot rules adopted by Nasdaq in February 2002 and modified in March 2003.[15] Also as part of the pilot program, Nasdaq extended the grace period on the National Market from 90 days to 180 days.[16] This pilot program expires on December 31, 2004. Nasdaq has committed to study the effect of these changes to the maintenance listing standards during the pilot period.[17]

Nasdaq is now proposing to amend the pilot program by further extending the bid price grace periods. For the National Market, Nasdaq would provide an issuer with a second 180-calendar-day grace period if, at the end of the first 180-day period, the issuer meets all of the initial listing standards of the National Market (except for the bid price test). Thus, a National Market issuer could fail the bid price test for a theoretical maximum of approximately 1.0 years before being subject to delisting. For the SmallCap Market, Nasdaq would replace the current 90-day grace period (which comes after the two 180-day grace periods), with a grace period that would last up to the issuer's next shareholder meeting,[18] provided four conditions are met: (1) The issuer meets all of the initial listing standards for the SmallCap Market (other than the bid price test); (2) the shareholder meeting is scheduled to occur no later than two years from the original notification of the bid price deficiency; (3) the issuer obtains shareholder approval at the meeting to carry out the reverse stock split; and (4) the issuer executes the reverse stock split promptly after the shareholder meeting. If the issuer fails to timely propose, obtain approval for, or promptly execute the reverse stock split, Nasdaq would immediately institute delisting proceedings. Thus, Nasdaq's proposal would allow SmallCap issuers to fail the bid price test for a theoretical maximum of 2.0 years before being subject to delisting.[19]

In addition, Nasdaq is proposing to amend the second of the two 180-day grace periods in the SmallCap Market by requiring that an issuer, at the end of the first 180-day period, meet all of the initial listing requirements to the SmallCap Market before entering the second grace period. Currently, the issuer need meet only one of the quantitative initial listing requirements of the SmallCap Market to receive the second grace period. The first 180-day grace period would continue to be available without any stipulations.

Special provisions would apply during the transition period between the old and new rules. An issuer currently in the delisting process for bid price deficiency could avail itself of any grace period to which it would have been entitled had the new pilot rules been in effect when the issuer received the original notification of the deficiency.[20] Furthermore, upon Commission approval of the new pilot rules, an issuer that is currently using a grace period offered by the old rules could remain listed for the duration of the period even though such period would be eliminated under the new rules. For example, a SmallCap issuer currently in the final 90-day grace period under the old rules would be permitted to maintain its listing on the SmallCap Market at least until the end of this period. At the end of the 90 days, the issuer could avail itself of the new rules and remain listed up to its next shareholder meeting, provided that it meets all of the initial listing criteria of the SmallCap Market (except the bid price test) and commits to seek shareholder approval for a reverse stock split, receives such approval, and promptly thereafter carries out the reverse stock split. However, in no event would a SmallCap issuer be afforded a cumulative grace period longer than two years from the date of the notification of the original bid price deficiency, absent "extraordinary circumstances."[21]

This proposal would not change the termination date of the pilot program. The pilot program will expire on December 31, 2004.

Finally, Nasdaq is proposing to amend NASD Rule 4820(a) to reference the "Staff Warning Letter" described in the proposed amendments to paragraph (e)(2) of NASD Rule 4450 and to make other minor, technical revisions.

III. Discussion

A. Approval of Revised Pilot Program

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the regulations thereunder applicable to the NASD.[22] In particular, the Commission believes that the proposal is consistent with Section 15A(b)(6) of the Act.[23] Section 15A(b)(6) requires, among other things, that the rules of a national securities association be designed to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to remove impediments to and

[13] *See* NASD Rule 4450(e)(2).

[14] *See* NASD Rule 4450(i).

[15] *See* Securities Exchange Act Release No. 45387 (February 4, 2002), 67 FR 6306 (February 11, 2002) (SR–NASD–2002–13); Securities Exchange Act Release No. 47482 (March 11, 2003), 68 FR 12729 (March 17, 2003) (SR–NASD–2003–34).

[16] *See id.*

[17] *See* letter from Sara Nelson Bloom, Nasdaq, to Katherine A. England, Division of Market Regulation, Commission, dated January 31, 2002; letter from Florence Harmon, Division of Market Regulation, Commission, to Sara Nelson Bloom, Nasdaq, dated April 4, 2003.

[18] As originally proposed, the second year of the grace period would have lasted until the next annual shareholder meeting of the issuer. In Amendment No. 3, Nasdaq deleted the word "annual" and clarified that the shareholder meeting at which the reverse stock split is approved could be a special meeting rather than a regular annual meeting.

[19] In most cases, a SmallCap issuer would have a grace period of less than the two full years that is theoretically available. This can be demonstrated with the following example. Assume a SmallCap issuer receives an initial notice of bid price deficiency from Nasdaq on October 16, 2004. The issuer uses the first and the second 180-day grace periods, so the date is now October 11, 2005 (*i.e.*, 360 days after October 16, 2004). Assume further that the issuer's annual shareholder meeting is scheduled to occur on November 16, 2005. Although there is a theoretical maximum grace period of two years, the grace period in this case would extend only to November 16, 2005—a total of one year and one month. Now assume instead that the issuer holds its next annual shareholder meeting on October 10, 2006. The third grace period, therefore, could last until this annual meeting, if there is no intervening shareholder meeting. However, if there is a special shareholder meeting before October 10, 2006, authorization for the reverse stock split must be obtained at that meeting, because the pilot rule provides that the third grace period for the SmallCap Market extends only until the next shareholder meeting in the two-year window, not a shareholder meeting of the issuer's choosing. *See* e-mail from Sara Bloom, Nasdaq, to Michael Gaw, Division of Market Regulation, Commission, dated December 9, 2003.

[20] Nasdaq has stated that, during the pendency of this rule proposal, panels convened pursuant to the NASD Rule 4800 Series to consider delistings have been granting exemptions from the bid price rules consistent with the new pilot grace periods.

[21] Existing NASD Rule 4810(b) provides that Nasdaq may grant exceptions to its listing rules. In Amendment No. 3, Nasdaq clarified that it would be unwilling to exercise this discretion to allow a SmallCap issuer to maintain its listing beyond two years from the date of the notification of the original bid price deficiency, absent "extraordinary circumstances." Nasdaq stated that adverse financial developments affecting the issuer would not support a finding of "extraordinary circumstances." Rather, the term "extraordinary circumstances" is intended to refer to a *force majeure* event that, in the opinion of Nasdaq, makes it impossible for the issuer to effect the actions necessary to achieve compliance within the specified compliance period.

[22] In approving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78o–3(b)(6).

perfect the mechanism of a free and open market and a national market system; and, in general, to protect investors and the public interest.

During the 1980s, there was widespread concern about the occurrence of so-called penny stock fraud which prompted Congress to enact the Securities Enforcement Remedies and Penny Stock Reform Act of 1990.[24] This legislation provided the Commission with expanded authority to regulate the market in securities with a low bid price. In light of these developments and that fact that the provisions of the Penny Stock Reform Act do not apply to any security listed on Nasdaq, the Commission in January 1990 wrote the NASD urging it to carefully scrutinize Nasdaq listing applications to ensure that low-priced securities fully complied with all applicable standards.[25] Nasdaq responded with a proposal to raise its listing standards by, among other things, adopting for the first time a requirement that an issuer maintain a minimum bid price. In its September 1991 approval order for that proposal, the Commission noted that there were two competing interests present. First, small, thinly capitalized companies had an interest in listing on Nasdaq to further their efforts to raise capital and grow their businesses. Second, Nasdaq had an interest in preventing suspect issuers from evading the Penny Stock Reform Act by allowing them to list on Nasdaq.[26] More broadly, Nasdaq has an interest in establishing and maintaining investor confidence in the quality of securities that it allows to trade on its market. Nasdaq's listing regime is an ongoing effort to balance these two considerations, particularly with respect to the SmallCap Market, which is designed to allow smaller companies access to the capital markets.

Nasdaq's original bid price rules allowed a perpetual exemption from the $1 bid price minimum if the issuer met heightened requirements for the market value of its public float and for the amount of capital and surplus.[27] In 1997, Nasdaq proposed to eliminate this alternative method of compliance, providing several reasons for doing so. First, Nasdaq believed that removing the exemption and enforcing a maintenance standard of a $1 bid price for all Nasdaq issuers would "provide a safeguard against certain market activity associated with low-priced securities."[28] Second, Nasdaq pointed out that, when the exemption was adopted, it was intended to address "temporary adverse market conditions," not to create a permanent means of meeting the listing standards.[29] Third, Nasdaq believed that "a $1 minimum bid price would serve to increase investor confidence and the credibility of its market commensurate with its increased prominence."[30]

Nasdaq's present proposal is in some ways a return to the alternate standard that was in effect from 1991 to 1997 since, under both regimes, an issuer can remain listed on Nasdaq if it meets heightened quantitative standards. Although the Commission found the alternate standard to be consistent with the Act in its 1991 approval order, the Commission now shares the concerns that prompted Nasdaq to rescind the alternative standard in 1997. An investor who purchases a security on the Nasdaq Stock Market should have reason to assume that the security has met all of the minimum standards to obtain a listing there, including the bid price standard. Moreover, as Nasdaq observed in 1997, enforcing a minimum bid price helps deter abusive market activity sometimes associated with low-priced, thinly capitalized securities. The Commission agrees with the NASD's 1997 statement that the $1 minimum bid price generally "serve[s] to increase investor confidence and the credibility of its market."[31]

Furthermore, the Commission echoes Nasdaq's concern in rescinding the alternate standard that derogations from the bid price standard are meant to address "temporary adverse market conditions." The Commission agrees with Nasdaq that "at times companies experience temporary adverse market conditions that cause the share price of their security to fall below $1 without having a serious impact on the health or viability of the company."[32] On that basis, the Commission was able to approve the alternate standard of compliance that allowed for the original, indefinite exemption from the bid price test. Nevertheless, an issuer should not be permitted to rely for an extended period of time on an exemption premised on "temporary adverse market conditions." The Commission is concerned that the length of the grace periods for bid price deficiency in this case raises concerns about investor protection. Transparency is one of the fundamental aspects of any set of listing standards. If a listing standard is suspended for too long, the standard is not transparent and the investor protection principles underlying the listing standards could be compromised.

Despite these concerns, the Commission does not presently have reason to believe that Nasdaq's proposal is inconsistent with the Act. The present proposal differs from the earlier alternative to the bid price test in that the grace periods now are only temporary (up to 2.0 years for the SmallCap Market and 1.0 years for the National Market), whereas under the old rules an issuer that met the heightened quantitative standards could keep its listing indefinitely despite a bid price below $1. The present proposal also requires issuers that fail the bid price test to meet all of the initial listing criteria (except for the bid price test), whereas the old rules required issuers to meet just two heightened quantitative criteria (market value of the public float and amount of capital and surplus). These additional requirements that an issuer must meet to qualify for the grace periods should offer additional reassurance that the issuer remains a viable business vehicle despite its low bid price.

Nasdaq has provided the Commission with a discussion of its surveillance program for securities that fall below a $1 bid price. The Commission believes that this program, designed to detect fraudulent and abusive trading activity, should further the protection of investors and the public interest.

For these reasons, the Commission is approving this pilot proposal for extending the bid price grace periods. As noted above, Nasdaq previously has committed to study the effect of the pilot changes to its maintenance listing standards.[33] This data will be essential in analyzing—if and when Nasdaq seeks permanent approval for the rules allowing bid price grace periods—whether derogations from the bid price standards undermine the principles of the Act as they are reflected in Nasdaq's listing rules. Previously, the

[24] Pub. L. 101–429, 104 Stat. 931 (October 15, 1990).

[25] *See* Securities Exchange Act Release No. 29638 (August 30, 1991), 56 FR 44108, 44109 (September 6, 1991) (approval of SR–NASD–90–18) ("1991 Approval").

[26] *See* 1991 Approval, 56 FR at 44111.

[27] *See* Securities Exchange Act Release No. 38469 (April 2, 1997), 62 FR 17262, 17262, 17268 (April 9, 1997) (proposing SR–NASD–97–16) ("1997 Proposal") (showing 1991 rules providing exemption from bid price maintenance standard). For the SmallCap Market, an issuer could use the exemption if the market value of its public float was at least $1 million and it had capital and surplus of at least $2 million. For the National Market, an issuer could use the exemption if the market value of its public float was at least $3 million and it had capital and surplus of at least $4 million.

[28] 1997 Proposal, 62 FR at 17269.

[29] *Id.*

[30] *Id.*

[31] 1997 Proposal, 62 FR at 17269.

[32] 1991 Approval, 56 FR at 44111.

[33] *See supra* note 16.

Commission required that Nasdaq submit the study six months prior to the expiration of the pilot (*i.e.*, by June 30, 2004).[34] However, because only 12 months remain in the pilot period, the Commission now believes that it would be appropriate to allow Nasdaq to submit the study three months prior to the expiration of the pilot (*i.e.*, by September 30, 2004). In view of its concerns about the potential for manipulation in the market for low-priced, thinly capitalized securities, the Commission believes that it would be difficult to permit any extension of the pilot provisions without first analyzing the results of Nasdaq's study.[35]

B. Accelerated Approval of Amendment No. 3

Pursuant to Section 19(b)(2) of the Act,[36] the Commission finds good cause for approving the proposal, as revised by Amendment No. 3, prior to the thirtieth day after the date that the notice of the amended proposal was published in the **Federal Register**. No comments were received on the original proposal, and the Commission believes that Amendment No. 3 does not materially alter the proposal and is intended only to make certain technical clarifications. Accordingly, the Commission is accelerating approval of the proposal, as amended.

IV. Text of Amendment No. 3

In Amendment No. 3, Nasdaq proposed further amendments to NASD Rule 4310(c), noted below. The base text is that proposed in Amendment No. 2 (*i.e.*, how the rule would appear if only Amendment No. 2 were approved by the Commission). Changes made by Amendment No. 3 are in italic; deletions are in brackets.

* * * * *

4310. Qualification Requirements for Domestic and Canadian Securities

To qualify for inclusion in Nasdaq, a security of a domestic or Canadian issuer shall satisfy all applicable requirements contained in paragraphs (a) or (b), and (c) hereof.

(a)–(b) No change.

(c) In addition to the requirements contained in paragraph (a) or (b) above, and unless otherwise indicated, a security shall satisfy the following criteria for inclusion in Nasdaq:

(1)–(7) No change.

(8)(A)–(C) No change.

(D) A failure to meet the continued inclusion requirement for minimum bid price on The Nasdaq SmallCap Market shall be determined to exist only if the deficiency continues for a period of 30 consecutive business days. Upon such failure, the issuer shall be notified promptly and shall have a period of 180 calendar days from such notification to achieve compliance. If the issuer has not been deemed in compliance prior to the expiration of the 180 day compliance period, it shall be afforded an additional 180 day compliance period, provided, that on the 180th day of the first compliance period, the issuer demonstrates that it meets the criteria for initial inclusion set forth in Rule 4310(c) (except for the bid price requirement set forth in Rule 4310(c)(4)) based on the issuer's most recent public filings and market information. If the issuer has publicly announced information (*e.g.*, in an earnings release) indicating that it no longer satisfies the applicable initial inclusion criteria, it shall not be eligible for the additional compliance period under this rule.

[If on the 180th day of the second compliance period, the issuer has not been deemed in compliance during such compliance period but it satisfies the criteria for initial inclusion set forth in Rule 4310(c) (except for the bid price requirement set forth in Rule 4310(c)(4)), the issuer shall be provided with an additional compliance period up to its next annual shareholder meeting, provided: the issuer commits to seek shareholder approval for a reverse stock split to address the bid price deficiency at or before its next annual meeting, and to promptly thereafter effect the reverse stock split; and the shareholder meeting to seek such approval is scheduled to occur no later than two years from the original notification of the bid price deficiency. If the issuer fails to timely propose, or obtain approval for, or promptly execute the reverse stock split, Nasdaq shall immediately institute delisting proceedings upon such failure.] *If on the 180th day of the second compliance period, the issuer has not been deemed in compliance during such compliance period but it satisfies the criteria for initial inclusion set forth in Rule 4310(c) (except for the bid price requirement set forth in Rule 4310(c)(4)), the issuer shall be provided with an additional compliance period up to its next shareholder meeting scheduled to occur no later than two years from the original notification of the bid price deficiency, provided the issuer commits to seek shareholder approval at that meeting for a reverse stock split to address the bid price deficiency. If the issuer fails to timely propose, or obtain approval for, or promptly execute the reverse stock split, Nasdaq shall immediately institute delisting proceedings upon such failure.* Compliance can be achieved during any compliance period by meeting the applicable standard for a minimum of 10 consecutive business days.

* * * * *

Amendment No. 3 clarifies that the shareholder meeting referred to in the proposed changes to NASD Rule 4310(c)(8)(D) need not be the annual shareholder meeting, but could also be a special shareholder meeting. A special meeting could be called for the express purpose of seeking shareholder approval for a reverse stock split to cure the issuer's bid price deficiency within the grace period allowed by proposed NASD Rule 4310(c)(8)(D). Nasdaq noted in Amendment No. 3 that, in some circumstances, the next annual meeting could fall outside the two-year deadline for such action and a special meeting would therefore be required.

Amendment No. 3 also clarifies the meaning of the term "extraordinary circumstances" used in regard to whether Nasdaq would exercise its discretion under NASD Rule 4810(b) to grant additional exceptions to its bid price maintenance standard.

Amendment No. 3 can be obtained from the Commission's Public Reference Room or from the principal offices of Nasdaq.

V. Solicitation of Comments on Amendment No. 3

Interested persons are invited to submit written data, views, and arguments on Amendment No. 3, including whether the 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. Comments also may be submitted electronically at the following e-mail address: *rule-comments@sec.gov*. All comments should refer to File No. SR–NASD–2003–44. This file number should be included on the subject line if e-mail is used. To help the Commission process and review comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written

[34] *See* letter from Florence Harmon, Division of Market Regulation, Commission, to Sara Nelson Bloom, Nasdaq, dated April 4, 2003.

[35] In addition, following issuance of this approval order, staff of the Commission's Division of Market Regulation will send a letter to Nasdaq setting forth in more detail the data that Nasdaq should provide in its study.

[36] 15 U.S.C. 78s(b)(2).

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 Nasdaq. All submissions should refer to File No. SR–NASD–2003–44 and should be submitted by March 3, 2004.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[37] that the proposed rule change (SR–NASD–2003–44) and Amendment Nos. 1 and 2 are approved, and that Amendment No. 3 is approved on an accelerated basis.

* * * * *

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[38]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04–2950 Filed 2–10–04; 8:45 am]

BILLING CODE 8010–01–U

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–49193; File No. SR–Phlx–2004–12]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Member Organizations' Compliance With Phlx Rule 972

February 4, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1], and Rule 19b–4[2] thereunder, notice is hereby given that on February 3, 2004, the Philadelphia Stock Exchange, Inc. ("Phlx" 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx Rule 972, Continuation of Status After the Merger, to extend the filing period of a member organizations' qualifying permit holder pursuant to Phlx Rule 921(a), following the transition of the Exchange from a non-stock to a stock corporation (the "Demutualization").[3] Specifically, the Exchange proposes to extend the time period from 15 days to 45 days after the closing of the Demutualization. The text of the proposed rule change is available at the Exchange 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 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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to facilitate the administration of new Phlx Rule 972, which was recently adopted as part of the Exchange's Demutualization. The Exchange believes that the minor change proposed in this filing would make it easier for the Exchange to administer the new rule, because it allows more time for member organizations to comply.

Phlx Rule 972 currently establishes three deadlines for member organizations; two of the deadlines are within 15 days after the closing of Demutualization[4] and one is within 45 days after the closing of Demutualization. First, the requirement that member organizations specify the Member Organization Representative within 15 days is not being changed. Second, Rule 972 requires that member organizations provide the security required by Rule 909 within 45 days. Rule 909 requires member organizations provide security to the Exchange for the payment of any claims owed to the Exchange, the Stock Clearing Corporation of Philadelphia ("SCCP"),[5] and other Exchange members or member organizations (the "Security Requirement").[6] Third, Rule 972 requires member organizations to comply with Rule 921(a) within 15 days. Rule 921 requires that the member who proposes to qualify an entity as a member organization file a form with the Exchange.

The purpose of the proposed amendment to Rule 972 is to extend the time member organizations have to satisfy the requirements of 921(a) in order for member organizations to avoid suspension.[7] The Exchange is proposing to extend the 15-day time period to 45 days. The Exchange believes that this extension will provide member organizations with sufficient time to process and complete the tasks necessary to meet the requirements and avoid suspension.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market, and in general, protects investors and the public interest by allowing member organizations more time to comply with Rule 972, and thus, continue their status as a member organization without disruption.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

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[37] *Id.*

[38] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 49098 (January 16, 2004), 69 FR 3974 (January 27, 2004) (SR–Phlx–2003–73).

[4] The closing of the Demutualization, also referred to as the Merger, occurred on January 20, 2004.

[5] SCCP, a subsidiary of Phlx, is a registered clearing agency.

[6] The Exchange recently, in SR–Phlx–2004–06, extended the compliance date for the Security Requirement from 15 days to 45 days after the closing of Demutualization and provided an additional method of complying with the Security Requirement, which is by entering into an acceptable agreement among the Exchange, SCCP and the member organization (a "Security Agreement"). The Security Agreement establishes and assigns to the Exchange a first priority perfected lien on and continuing security interest in the excess margin funds held in such member organization's SCCP margin account.

[7] *See* Rule 972(a).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder,[11] because the proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate; and the Exchange has given the Commission written notice of its intention to file the proposed rule change. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Under Rule 19b–4(f)(6)(iii) of the Act,[12] the proposed rule change does not become operative for 30 days after the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange has requested that the Commission accelerate the thirty-day operative date of the proposal and also waive the requirement that the Exchange submit written notice of its intent to file the proposed rule change at least five business days prior to the filing date, in order to facilitate member organization compliance with new Phlx Rule 972 and to avoid disruption of their status as member organizations. The Commission, consistent with the protection of investors and the public interest, has determined to accelerate the 30-day operative date to February 3, 2004,[13] the date of filing of the proposed rule change. Such waiver would facilitate member organization compliance with new Phlx Rule 972 and thus would avoid disruption of their status as member organizations. In addition, the Commission has determined to waive the five-day pre-filing requirement.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Comments may also be submitted electronically at the following e-mail address: *rule comments@sec.gov*. All comment letters should refer to File No. SR–Phlx–2004–12. This file number should be included on the subject line if e-mail is used. To help the Commission process and review comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–2004–12 and should be submitted by March 3, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–2948 Filed 2–10–04; 8:45 am]

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[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of accelerating the 30-day operative period for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–49190; File No. SR–SCCP–2003–07]

Self-Regulatory Organizations; Stock Clearing Corporation of Philadelphia; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Equity Charges for Specialists

February 4, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on December 30, 2003, the Stock Clearing Corporation of Philadelphia ("SCCP") 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 primarily by SCCP. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

SCCP proposes to amend its schedule of dues, fees, and charges by eliminating the $.20 credit for Philadelphia Stock Exchange ("Phlx") equity specialists' trades against Phlx Automated Communication and Execution System ("PACE") executions [2] for trades settling on or after January 2, 2004.[3]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, SCCP 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. SCCP has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] PACE is Phlx's automated order entry, routing, and executing system. Phlx Rules 229 and 229A.

[3] SCCP previously implemented the $.20 PACE specialist credit effective June 1, 2000. Securities Exchange Act Release No. 42804 (May 19, 2000), 65 FR 34244 (May 26, 2000) (SR–Phlx–00–42). A copy of SCCP's schedule of dues, fees, and charges is attached as Exhibit 2 to its proposed rule filing.

[4] The Commission has modified the text of the summaries prepared by SCCP.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The PACE specialist credit currently applies to Phlx specialists for their trades against PACE executions. The purpose of the proposed rule change is to eliminate the PACE specialist credit, which should generate additional revenue for SCCP and simplify SCCP's billing structure. SCCP intends to eliminate the PACE specialist credit for trades settling on or after January 2, 2004.

SCCP believes that the proposed rule change is consistent with section 17A(b)(3)(D) of the Act[5] which requires that the rules of a registered clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges among its participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

SCCP 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

SCCP has not solicited or received any written comments relating to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act[6] and Rule 19b–4(f)(2)[7] thereunder because it changes a due, fee, or other charge. At any time within sixty days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the 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 5th Street NW, Washington, DC 20549–0069. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov*. All comment letters should refer to File No. SR–SCCP–2003–07. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the rule filing that are filed with the Commission, and all written communications relating to the rule filing between the Commission and any person, other than those that may be withheld from the public in accordance with provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in Washington, DC. Copies of such filing will also be available for inspection and copying at SCCP's principal office and on SCCP's Web site at *http://www.phlx.com/exchange/memos/SCCP/sccp_rules/122903.pdf*. All submissions should refer to File No. SR–SCCP–2003–07 and should be submitted by March 3, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–2908 Filed 2–10–04; 8:45 am]

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[5] 15 U.S.C. 78q–1(b)(3)(D).

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 17 CFR 240.19b–4(f)(2).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–49189; File No. SR–SCCP–2004–01]

Self-Regulatory Organizations; Stock Clearing Corporation of Philadelphia; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Extension of Fee Waivers for Electronic Communications Networks

February 4, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] notice is hereby given that on January 20, 2004, the Stock Clearing Corporation of Philadelphia ("SCCP") 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 primarily by SCCP. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1)

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

SCCP proposes to extend its one-year pilot program of waiving fees for electronic communications networks ("ECNs") for trades executed on the Philadelphia Stock Exchange, Inc. ("Phlx") for an additional year (through January 23, 2005)[2] and to change the definition of ECN. The pilot program was scheduled to expire on January 23, 2004.[3]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, SCCP 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. SCCP has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.[4]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

SCCP has waived fees (including trade recording fees, value fees, treasury transaction charges, and Nasdaq 100 Trust, Series 1 ("QQQ") charges for ECN trades[5] but not account fees, research fees, computer transmission/tape charges, or other charges on its fee schedule) since early 2001.[6] SCCP proposes to continue this fee waiver through January 23, 2005.

This proposal affects ECN trades that are not related to ECNs acting as Phlx specialists or floor brokers on Phlx. Currently, no ECN operates from Phlx's equity trading floor as a floor broker or specialist unit. If, however, an ECN

[2] A copy of SCCP's schedule of fees, which includes the fees proposed to be waived for ECNs, is attached as Exhibit 2 to SCCP's rule filing.

[3] Securities Exchange Act Release No. 47924 (May 23, 2003), 68 FR 33558 (June 4, 2003) (SR–SCCP–2002–06).

[4] The Commission has modified the text of the summaries prepared by SCCP.

[5] Certain provisions of the SCCP fee schedule do not apply to ECNs because they apply to specialists and/or relate to margin financing, such as specialist discount, margin account interest, P&L statement charges, buy-ins, specialist QQQ charges, and SCCP transaction charge (remote specialists only).

[6] Securities Exchange Act Release No. 45145 (Dec. 10, 2001), 66 FR 65017 (Dec. 17, 2001) (SR–SCCP–2001–01).

were to operate from the Phlx equity trading floor, it could be subject to various SCCP fees with respect to its non-ECN floor operation. In addition, an ECN's transactions as a floor broker would be subject to the applicable SCCP fee, as would any ECN's specialist trades.[7] Even if the ECN acts as a floor broker or specialist with respect to some trades, those trades for which it is not acting as a floor broker or specialist, but rather an ECN, would be eligible for this fee waiver.

SCCP also proposes to make minor changes to its definition of ECNs that appears on SCCP's fee schedule.[8]

SCCP believes that this proposed rule change is consistent with section 17A(b)(3)(D) of the Act[9] because it provides for the equitable allocation of dues, fees, and other charges.

B. Self-Regulatory Organization's Statement on Burden on Competition

SCCP 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

SCCP has not solicited or received written comments pertaining to its proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act[10] and Rule 19b–4(f)(2)[11] thereunder because it establishes or changes a due, fee, or other charge. At any time within sixty days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the 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 5th Street NW., Washington, DC 20549–0069. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov*. All comment letters should refer to File No. SR–SCCP–2004–01. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the rule filing that are filed with the Commission, and all written communications relating to the rule filing between the Commission and any person, other than those that may be withheld from the public in accordance with provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in Washington, DC. Copies of such filing will also be available for inspection and copying at SCCP's principal office and on SCCP's Web site at *http://www.phlx.com/SCCP/memindex_sccpproposals.html*. All submissions should refer to File No. SR–SCCP–2004–01 and should be submitted by March 3, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–2909 Filed 2–10–04; 8:45 am]

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[7] For example, an ECN acting as a specialist would be subject to the trade recording fee for specialist trades matching with PACE trades.

[8] SCCP's definition of ECN still generally conforms to the definition in Rule 11Ac1–1(a) (8) of the Act, 17 CFR 240.11Ac–1–(a)(8). As stated on SCCP's new proposed fee schedule, ECNs shall mean any electronic system that widely disseminates to third parties orders entered therein by a Phlx market maker or over-the-counter ("OTC") market maker, and permits such orders to be executed against in whole or in part. The term ECN shall not include: any system that crosses multiple orders at one or more specified times at a single price set by the ECN (by algorithm or by any derivative pricing mechanism) and does not allow orders to be crossed or executed against directly by participants outside of such times or any system operated by, or on behalf of, an OTC market maker or exchange market maker that executes customer orders primarily against the account of such market maker as principal, other than riskless principal.

[9] 15 U.S.C. 78q–1(b)(3)(D).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

[12] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Statement of Organization, Functions and Delegations of Authority

This statement amends Part T of the Statement of Organization, Functions and Delegations of Authority that covers the Social Security Administration (SSA). Chapter TA covers the Deputy Commissioner for Disability and Income Security Programs. Notice is hereby given that Chapter TA, which covers the Office of the Deputy Commissioner, Disability and Income Security Programs, is being amended to reflect the establishment of the Information Technology Support Staff as a separate line organization.

Chapter TA

Office of Disability and Income Security Programs

Section TA.10 *The Office of the Deputy Commissioner, Disability and Income Security Programs*—(Organization):

The Office of the Deputy Commissioner, Disability and Income Security Programs under the leadership of the Deputy Commissioner, Disability and Income Security Programs includes:

Establish:

K. The Information Technology Support Staff (TAX).

Section TA.20 *The Office of the Deputy Commissioner, Disability and Income Security Programs*—(Functions):

Delete the last part of sentence #3 in paragraph C: "* * * and the technology that supports them."

Delete the last two sentences from paragraph C: "Provides user support to all its subordinate components. Directs all systems activities supporting the Agency's electronic programmatic instructional system."

Add:

K. The Information Technology Support Staff (TAX) provides expert advice and support to the Deputy Commissioner and Assistant Deputy Commissioner on the technology that supports Agency-level projects and initiatives that impact the Agency's policymaking processes. It provides user support to all its ODISP components. It directs all systems activities supporting the Agency's electronic programmatic instructional system.

Establish:

Subchapter (TAX)

Information Technology Support Staff

Section (TAX).00 *The Information Technology Support Staff*—(Mission):

The Information Technology Support Staff provides expert advice and support to the Deputy Commissioner and Assistant Deputy Commissioner on the technology that supports Agency-level projects and initiatives that impact the Agency's policymaking processes. It provides user support to all ODISP components. It directs all systems activities supporting the Agency's electronic programmatic instructional system.

Section (TAX).10 *The Information Technology Support Staff*—(Organization):

The Information Technology Support Staff does not have a substructure.

Section (TAX).20 *The Information Technology Support Staff*—(Functions):

1. Provides expert advice and support to the Deputy Commissioner and Assistant

Deputy Commissioner on Agency-level projects and initiatives that impact the Agency's policymaking processes and the technology that supports them.

2. Represents ODISP on Agency-level steering and planning committees that develop and prioritize technology initiatives and/or funding that impact the Agency's programmatic policy development process.

3. Assesses the programmatic policy development processes to identify and recommend technology improvements and enhancements.

4. Develops, recommends, negotiates, implements, integrates and then supports broad automated systems strategies for ODISP components that take into account current and emerging technologies, Agency systems policies and standards and their impact on the ODISP environment.

5. Provides user and infrastructure support to all ODISP components, managing the desktop and computer room environments. Manages software and hardware inventories and oversees ODISP-wide rollouts and migrations. Provides application software training as needed.

6. Directs the preparation and management of ODISP's ITS budget, including development of procurement plans, cost data and analysis and justification of systems needs. Represents ODISP in negotiations with the Office of Systems on systems requirements, priority designations, delivery schedules and equipment arrival dates. Manages the identification, procurement and implementation of all IT items for ODISP components.

7. Provides expert advice and support to the Deputy Commissioner and ODISP Associate Commissioners on systems security policies, initiatives, best practices and implementation procedures. Performs data and system security audits, assessments and risk assessments on existing and proposed ODISP systems as required. Represents ODISP on Agency-level IT security workgroups and committees.

Dated: January 30, 2004.

Jo Anne B. Barnhart,

Commissioner of Social Security.

[FR Doc. 04–3003 Filed 2–10–04; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

Bureau of Oceans and International Environmental and Scientific Affairs; Certifications Pursuant to Section 609 of Public Law 101–162

[Public Notice 4621]

SUMMARY: On January 26, 2004, the Department of State certified, pursuant to Section 609 of Public Law 101–162 ("Section 609"), that 2 nations, Costa Rica and Honduras, have adopted programs to reduce the incidental capture of sea turtles in their shrimp fisheries comparable to the program in effect in the United States. The Department also withdrew certification for one country, Nigeria, due to concerns over the effectiveness of its program.

EFFECTIVE DATE: February 11, 2004.

FOR FURTHER INFORMATION CONTACT: James Story, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20520–7818; telephone: (202) 647–2335.

SUPPLEMENTARY INFORMATION: Section 609 of Public Law 101–162 prohibits imports of certain categories of shrimp unless the President certifies to the Congress not later than May 1 of each year either: (1) That the harvesting nation has adopted a program governing the incidental capture of sea turtles in its commercial shrimp fishery comparable to the program in effect in the United States and has an incidental take rate comparable to that of the United States; or (2) that the fishing environment in the harvesting nation does not pose a threat of the incidental taking of sea turtles. The President has delegated the authority to make this certification to the Department of State. Revised State Department guidelines for making the required certifications were published in the **Federal Register** on July 2, 1999 (Vol. 64, No. 130, Public Notice 3086).

On January 26, 2004, the Department certified Costa Rica and Honduras on the basis that their sea turtle protection program is comparable to that of the United States. These countries join 14 others certified by the Department in 2003 on the same basis.

The Department also withdrew certification for Nigeria, on the basis of a determination that the program in place in Nigeria was no longer comparable in effectiveness to the program in place in the United States. Imports of shrimp harvested by commercial fishing technology in Nigeria will not be eligible for importation into the United States, though products from artisanal fisheries or aquaculture production remain eligible for importation if accompanied by a properly executed DS–2031 Shrimp Importer's/Exporter's declaration. No other categories of shrimp produced in Nigeria are eligible for importation at this time.

The Department of State has communicated the certifications under Section 609 to the Office of Trade Program of the United States Customs Service.

Dated: February 4, 2004.

David A Balton,

Deputy Assistant Secretary for Oceans and Fisheries, Department of State.

[FR Doc. 04–2972 Filed 2–10–04; 8:45 am]

BILLING CODE 4710–09–U

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed Between the Week of January 19 and January 30, 2004

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days after the filing of the application.

Agreements filed during the week ending January 23, 2004.

Docket Number: OST–2004–16940.

Date Filed: January 20, 2004.

Parties: Members of the International Air Transport Association.

Subject: MV/PSC/005 dated January 15, 2004, Mail Vote Number S 077—Amended Version, Recommended Practice 1720a (R–1), Request for Form Code for Travel Agent Service Fee (TASF), Intended effective date: February 1, 2004.

Agreements filed during the week ending January 30, 2004.

Docket Number: OST–2004–17001.

Date Filed: January 30, 2004.

Parties: Members of the International Air Transport Association.

Subject: PTC12 USA–EUR Fares 0086 dated January 30, 2004, Resolution 015h USA Add-Ons between USA and UK, Intended effective date: April 1, 2004.

Andrea M. Jenkins,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 04–2997 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending January 2, 2004

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart B (formerly subpart Q) of the Department of Transportation's Procedural

Regulations (*See* 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–1998–3863.

Date Filed: January 2, 2004.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 23, 2004.

Description: Application of Continental Airlines, Inc., requesting renewal of its Route 758 certificate authorizing Continental to provide scheduled air transportation of persons, property, and mail between Houston and Sao Paulo and to combine authority on this certificate with other certificate and exemption authority held by Continental.

Andrea M. Jenkins,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 04–2991 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending January 23, 2004

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart B (formerly subpart Q) of the Department of Transportation's Procedural Regulations (*See* 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–2004–16946.

Date Filed: January 21, 2004.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: February 11, 2004.

Description: Application of Kitty Hawk Aircargo, Inc., requesting issuance of a certificate of public convenience and necessity authorizing Kitty Hawk to engage in scheduled foreign air transportation of property and mail between any point or points in the United States and any point in the countries listed in appendix A to this application. Kitty Hawk also requests authority to integrate this certificate authority with all services it is otherwise authorized to conduct.

Andrea M. Jenkins,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 04–2996 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Preparation of Alternatives/Technology Assessment with the Intent of Preparing an Environmental Impact Statement for the International Drive (I–Drive) Circulator; Orange County, FL

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Florida Department of Transportation (FDOT), in consultation with the Federal Transit Administration (FTA) and the Central Florida Regional Transportation Authority (locally known as LYNX), is issuing this notice to advise the public that FDOT and LYNX intend to conduct a Scoping Meeting and an Alternatives/Technology Assessment, leading to the preparation of an Environmental Impact Statement (EIS) that would comply with all FTA requirements and in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended and the regulations of the Council on Environmental Quality (CEQ) and all other relevant Federal, State and local regulations and requirements. This EIS will be prepared to evaluate a transit circulator described as the International Drive (I–Drive) Circulator system that would serve as a feeder/distributor system connected to the proposed regional rail transit system including the proposed North-South Light Rail Transit (LRT) system and the proposed Orlando International Airport (OIA) Connector system.

This Notice of Intent is being published at this time to notify interested parties and to solicit participation in the study. The objective of the Alternatives/Technology Assessment is to identify a Locally Preferred Alternative (LPA) that can then be evaluated further as part of the EIS phase of project development. The proposed project is planned to connect major attractions in the I–Drive area including the Belz Factory Outlet Mall, the Orange County Convention Center, numerous hotels and restaurants in the area, Sea World and a connection to the Universal Studios area. The proposed connection to the regional rail transit system will occur in the area of the Orange County Convention Center or the Belz Factory Outlet and will make I–Drive accessible by transit from the OIA. The project study area will be the International Drive corridor between Belz Factory Outlet on the north through Universal/Major Blvd. and Canadian Court Intermodal Center areas to the Sea World area on the south, including a possible connection to Universal Studios to the west of Interstate 4.

The following alternatives will be evaluated as part of this study: (1) A No Action (No Build) Alternative; (2) a Transportation Systems Management (TSM) Alternative/Baseline; and (3) two or more Fixed Guideway Alternatives; the assessment of alternative technologies is a part of this study effort.

DATES: *Comment Due Date:* Written comments on the scope of alternatives and impacts to be considered should be directed to Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida, 32720 by April 12, 2004. Scoping Meeting: Scoping for the study will be accomplished through review of previous studies and consultation with affected agencies, interested persons/key stakeholders through correspondence and at the public scoping meeting and other public meetings.

ADDRESSES: A Scoping Meeting will be conducted to provide the purpose and need for the study, describe the process that will be followed, define the limits of the study area, to answer any questions that may exist, and to receive comments, thoughts, and/or opinions relevant to the study. The meeting will be held on Wednesday, February 25, 2004 from 11 a.m. to 12 p.m. at the Orange County Convention Center in the Lecture Hall, Room W300, located at 9800 International Drive, Orlando, Florida 32819. Persons with disabilities, in accordance with the Americans with Disabilities Act of 1990, who may require special accommodations to participate in the Scoping Meeting should contact Mr. Steve Ferrell, P.E., Deputy Project Manager, at least seven (7) calendar days prior to the meeting

date. Please send a request to the following address: Mr. Steve Ferrell, Deputy Project Manager, Wilbur Smith Associates, 3535 Lawton Road, Suite 100, Orlando, Florida 32803, phone: (407) 896–5851; fax: (407) 896–9165; e-mail: *i-drive@wilbursmith.com.*

FOR FURTHER INFORMATION CONTACT: Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida, 32720, phone: (386) 943–5707, e-mail: *tawny.olore@dot.state.fl.us.* You may also contact Mr. Derek R. Scott, Community Planner, Federal Transit Administration, 61 Forsyth Street, SW., Suite 17T50, Atlanta, Georgia 30303, phone: (404) 562–3524.

SUPPLEMENTARY INFORMATION:

1. Notice of Intent

This Notice of Intent to prepare an Alternatives / Technology Assessment leading to an Environmental Impact Statement is being published at this time to advise interested parties of the study and to solicit comment from the general public. FTA regulations and guidance, in accordance with NEPA will be used in the analysis and preparation of the International Drive (I-Drive) Circulator Study.

2. Scoping

Both FTA and FDOT encourage you to provide comments at the Scoping Meeting as discussed previously and will accept written comments for up to 45 days following the meeting date. Comments should focus on the scope of the alternatives and any specific social, economic, or environmental impacts to be considered as part of this study.

Persons wishing to be placed on a mailing list to receive further information as the study progresses are encouraged to contact: Mr. Steve Ferrell, Deputy Project Manager, Wilbur Smith Associates, 3535 Lawton Road, Suite 100, Orlando, Florida 32803, phone: (407) 896–5851; fax: (407) 896–9165; e-mail: *i-drive@wilbursmith.com.*

3. Study Area and Project Need

The project study area includes the International Drive corridor between Belz Factory Outlet on the north through Universal/Major Blvd. and Canadian Court Intermodal Center areas to the Sea World area on the south, including a possible connection to Universal Studios to the west of Interstate 4. The proposed project is planned to connect major attractions/activity centers in the I-Drive area including the Belz Factory Outlet Mall, the Orange County Convention Center, numerous hotels and restaurants in the area, Sea World and a possible connection to the Universal Studios area. The proposed connection to the regional rail transit system will occur in the area of the Orange County Convention Center or the Belz Factory Outlet and will make I-Drive accessible by transit from the OIA.

The underlying purpose of the I-Drive Circulator Study is to enable the Florida Department of Transportation, District 5 and other local agencies to make an informed decision regarding the preferred investment strategy for transportation system improvements in the I-Drive Corridor. The I-Drive Circulator Study process will provide a forum to assess community concerns, financial and policy support, review alternative transit modes and technologies and explore the social, economic and environmental impact of a transportation investment in the corridor.

The I-Drive Circulator Study will also examine alignment and technology options that play an important role in improving access and mobility for local residents, employees and visitors to the I-Drive area. As part of this process, the I-Drive Circulator Study will integrate urban design, livable community principles, and economic development potential along with the transportation planning and engineering analyses. The I-Drive Circulator Study will culminate not only in transportation and public policy solutions that will enhance Central Florida's standing as a convention and tourist destination, but build sustainable civic infrastructure that will serve local resident, businesses and employees from future congestion problems in the I-Drive Corridor.

Previous studies by LYNX, the local public transportation authority, concluded that the local circulator service in the I-Drive area was a necessary and strategic element in the overall development of an effective regional transportation system. Factors that constitute the need for the I-Drive Circulator include meeting existing and future travel demands, loss of mobility due to the projected increase in traffic on the major roadways within the study area, and current and future projected expansion of the Orange County Convention Center and other proposed developments.

To keep up with the tremendous growth in the attractions in the study area and in south Orange County, METROPLAN ORLANDO (metropolitan planning organization (MPO) for the Orlando, Florida Transportation Management Area) has identified the need for this project. The need for the I-Drive Circulator is consistent with METROPLAN ORLANDO's 2020 Long Range Transportation Plan Update (adopted December 2000). However, this project is currently not listed in any local government comprehensive plans, including Orange County and the City of Orlando.

4. Alternatives

A number of transportation alternatives will be evaluated as part of this study. These include: (1) No Action (No Build) Alternative that consists of existing and programmed transportation improvements as identified in METROPLAN ORLANDO's Cost Feasible 2020 Long Range Transportation Plan Update, which includes the North-South LRT system. This alternative serves as the NEPA baseline. (2) The TSM Alternative includes enhanced LYNX bus services and facilities in addition to other TSM-related projects. This alternative is defined as low-cost operational improvements identified to address transportation problems in the corridor. (3) Fixed Guideway Transit Alternatives that may include a combination of feasible modes with various alternative alignments using both street and/or highway corridors. These alternatives would ultimately link to the proposed regional rail transit system.

As part of the Alternatives/Technology Assessment, capital, operating, and maintenance costs and other financial impacts will be evaluated. Upon the selection and screening of a set of initial alternatives, a set of conceptual alternatives will be identified and will undergo a comparative evaluation process to be further refined. A detailed analysis of the refined alternatives will be undertaken during the Alternatives/Technology Assessment and subsequent draft EIS phase of project development. These refined, conceptual viable alternatives will ultimately be presented to the public and agencies at a series of public workshops. Upon the selection of a Build Alternative, FDOT will then request that METROPLAN ORLANDO review and approve the LPA selection. Once the LPA is approved, the MPO will consider including the LPA in the Cost Feasible Plan of the MPO's Long Range Transportation Plan.

5. Probable Effects

Should the study proceed from the Alternatives/Technology Assessment to an Environmental Impact Statement, preliminary steps will be taken to allow FTA and FDOT to evaluate the project's potential for significant adverse impacts during construction and operation.

Analysis of socio-economic impacts would include the evaluation of land use and neighborhood impacts, parks and recreational areas, historic and archaeological resources, displacement and environmental justice (disproportionate adverse impacts on minority and low-income populations), visual and aesthetic impacts, transit (ridership, operations, and maintenance), traffic, and parking. Impacts to the natural environment would include Outstanding Florida Waters, Wild and Scenic Rivers, aquatic preserves, wetlands, and threatened and endangered species. The physical impact analysis would include the evaluation of noise and vibration, air quality, energy, potential hazardous materials, water quality, and coastal zone consistency. The environmental evaluation would consider construction and cumulative and secondary impacts. Measures to mitigate any adverse impacts would also be addressed.

In addition, this study is being coordinated with other transit initiative studies that are currently underway. These projects include: (1) Canadian Court Intermodal Center; (2) the Orlando International Airport Connector; and (3) the North-South Light Rail Transit project. Although the above-mentioned studies are freestanding and capable of independent utility, all projects will continue to be closely monitored to ensure project consistency. Additional information on these other independent transit initiatives, may be obtained from Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida 32720, phone: (386) 943–5707; e-mail: *tawny.olore@dot.state.fl.us.*

6. FTA Procedures

In accordance with FTA policy, all Federal laws, regulations, and executive orders affecting project development, including but not limited to the regulations of the Council on Environmental Quality and FTA for implementing NEPA (40 CFR parts 1500–1508, and 23 CFR part 771), the 1990 Clean Air Act Amendments, section 404 of the Clean Water Act, Executive Order 13274 on Environmental Streamlining (September 18, 2002), Executive Order 12898 regarding Environmental Justice, the National Historic Preservation Act, the Endangered Species Act, and section 4(f) of the DOT Act, will be addressed to the maximum extent practicable during the NEPA process. In addition, following selection and adoption of the LPA, FDOT may seek FTA Section 5309 New Starts funding for the LPA, and therefore, will be subject to the FTA New Starts Regulations (49 CFR part 611). This New Starts regulation requires submission of information specified by FTA to support FDOT's request to initiate Preliminary Engineering.

The Alternatives Analysis and subsequent Preliminary Engineering activities are to be executed in conjunction with the NEPA process.

Issued on: February 6, 2004.

George T. Thomson,

Acting FTA Regional Administrator.

[FR Doc. 04–2987 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Preparation of Alternatives Analysis With the Intent of Preparing an Environmental Impact Statement for the Orlando International Airport Connector; Orange County, FL

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Florida Department of Transportation (FDOT), in consultation with the Federal Transit Administration (FTA) and the Central Florida Regional Transportation Authority (CFRTA, locally known as LYNX), is issuing this notice to advise the public that FDOT and LYNX intend to conduct a Scoping Meeting and an Alternatives Analysis, leading to the preparation of an Environmental Impact Statement (EIS) that would comply with all FTA requirements and in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended and the regulations of the Council on Environmental Quality (CEQ) and all other relevant Federal, State and local regulations and requirements. This EIS will be prepared to evaluate a transit system that would connect the International Drive (I-Drive) Corridor to the Orlando International Airport (OIA) in Orange County, Florida.

This Notice of Intent is being published at this time to notify interested parties and to solicit participation in the study. The objective of the Alternatives Analysis is to identify a Locally Preferred Alternative (LPA) that can then be evaluated further as part of the EIS phase of project development. The proposed project is planned to link to the 22-mile North-South Light Rail Transit (LRT) system currently under evaluation. The proposed connection to the LRT system will occur in the area of the Orange County Convention Center or the Belz Factory Outlet. The project study area extends from the International Drive (I-Drive) Corridor to the Orlando International Airport (OIA). Alternatives will be studied for connecting to OIA from the south and from the north.

The following alternatives will be evaluated as part of this study: (1) A No Action (No Build) Alternative; (2) A Transportation Systems Management (TSM) Alternative; and (3) two or more Build Alternatives.

DATES: *Comment Due Date:* Written comments on the scope of alternatives and impacts to be considered should be directed to Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida, 32720 by April 12, 2004. Scoping Meeting: Scoping for the study will be developed during review of previous studies and consultation with affected agencies and interested persons through correspondence and at public meetings.

ADDRESSES: A Scoping Meeting will be conducted to provide the purpose of the study, describe the process that will be followed, define the limits of the study area, to answer any questions that may exist, and to receive comments, thoughts, and/or opinions relevant to the study. The meeting will be held on Wednesday, February 25, 2004 from 8:30 a.m. to 11 a.m. at the Orange County Convention Center in the Lecture Hall, Room W300, located at 9800 International Drive, Orlando, Florida 32819. Persons with disabilities, in accordance with the Americans and Disabilities Act of 1990, who may require special accommodations, to participate in the Scoping Meeting should contact Ms. Karen Campblin, Public Involvement Coordinator, at least seven (7) calendar days prior to the meeting date. Please send a request to the following address: Ms. Karen Campblin, Public Involvement Coordinator, Glatting Jackson, 33 East Pine Street, Orlando, Florida 32801, phone: (407) 843–6552; toll free: (800) 496–2768 extension 1006; fax: (407) 839–1789; e-mail: *kcampblin@glatting.com.*

FOR FURTHER INFORMATION CONTACT: Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida 32720, phone: (386) 943–5707, e-mail:

tawny.olore@dot.state.fl.us. You may also contact Mr. Derek R. Scott, Community Planner, Federal Transit Administration, 61 Forsyth Street, SW., Suite 17T50, Atlanta, Georgia 30303, phone: (404) 562–3524.

SUPPLEMENTARY INFORMATION:

1. Notice of Intent

This Notice of Intent to prepare an Alternatives Analysis leading to an Environmental Impact Statement is being published at this time to advise interested parties of the study and to solicit comment from the general public. FTA regulations and guidance, in accordance with NEPA, will be used in the analysis and preparation of the OIA Connector Transit Study.

2. Scoping

Both FTA and FDOT encourage you to provide comments at the Scoping Meeting as discussed previously and will accept written comments for up to 45 days following the meeting date. Comments should focus on the scope of the alternatives and any specific social, economic, or environmental impacts to be considered as part of this study.

Persons wishing to be placed on a mailing list to receive further information as the study progresses, please contact Ms. Karen Campblin, Public Involvement Coordinator, Glatting Jackson, 33 East Pine Street, Orlando, Florida 32801, phone: (407) 843–6552; toll free: (800) 496–2768 extension 1006; fax: (407) 839–1789; e-mail: *kcampblin@glatting.com*.

3. Study Area and Project Need

The project study area for the OIA Connector extends from the I-Drive Corridor to the Orlando International Airport. The study area is generally bounded by Hoffner Avenue on the north, the Central Florida GreeneWay (SR 417) on the south, Narcoossee Road on the east, and Interstate 4 on the west. The OIA Connector is planned to link to the 22-mile North-South LRT system currently under study. The proposed connection to the LRT system will occur in the area of the Orange County Convention Center in the I-Drive Corridor or the Belz Factory Outlet. The proposed project traverses the southern portion of unincorporated Orange County and passes through areas of the Cities of Orlando and Belle Isle.

The purpose of this study is to develop a multi-modal transit system that would provide system linkage in the Central Florida area and serve as an alternative mode of travel to highways. This project is expected to provide an approach to transportation solutions by evaluating several alternative alignments, which would ultimately identify a LPA for this proposed transit system. By integrating the multi-modal system into the overall transportation network within the OIA corridor, the integrity of the highway system is maintained, while improving local access to the surrounding community.

Factors that constitute the need for the OIA Connector include meeting existing and future travel demands, loss of mobility due to the projected increase in traffic on the major roadways within the corridor, and projected expansion at the Airport, as identified in the OIA Master Plan. To keep up with the tremendous growth in south Orange County, METROPLAN ORLANDO (metropolitan planning organization (MPO) for the Orlando, Florida Transportation Management Area) has identified the need for this project. The need for the OIA Connector is consistent with METROPLAN ORLANDO's 2020 Long Range Transportation Plan Update (adopted December 2000). However, this project is currently not listed in any local government comprehensive plans, including Orange County and the City of Orlando.

4. Alternatives

A number of transportation alternatives will be evaluated as part of this study. These include: (1) A No Action (No Build) Alternative that consists of existing and programmed transportation improvements as identified in METROPLAN ORLANDO's Cost Feasible 2020 Long Range Transportation Plan Update, which includes the North-South LRT system. This alternative serves as the NEPA baseline. (2) The TSM Alternative includes enhanced LYNX bus services and facilities in addition to other TSM-related projects. This alternative is defined as low-cost operational improvements identified to address transportation problems in the corridor. (3) Build Alternatives that may include a combination of the above modes with various alternative alignments using both street and/or highway corridors. These alternatives would ultimately link to the proposed North-South line.

As part of the Alternatives Analysis, capital, operating, and maintenance costs and other financial impacts will be evaluated. Upon the selection and screening of a set of initial alternatives, a set of conceptual alternatives will be identified and undergo an evaluation process to be further refined. A detailed analysis of the refined alternatives will be undertaken during the Alternatives Analysis and subsequent draft EIS phase of project development. These refined, conceptual viable alternatives will ultimately be presented to the public and agencies at a series of public workshops. Upon the selection of a Build Alternative, FDOT will then request that METROPLAN ORLANDO review and approve the LPA selection. Once the LPA is approved, the MPO will consider including the LPA in the Cost Feasible Plan of the MPO's Long Range Transportation Plan.

5. Probable Effects

Should the study proceed from the Alternatives Analysis to an Environmental Impact Statement, preliminary steps will be taken to allow FTA and FDOT to evaluate the project's potential for significant adverse impacts during construction and operation. Analysis of socio-economic impacts would include the evaluation of land use and neighborhood impacts, parks and recreational areas, historic and archaeological resources, displacement and environmental justice (disproportionate adverse impacts on minority and low-income populations), visual and aesthetic impacts, transit (ridership, operations, and maintenance), traffic, and parking. Impacts to the natural environment would include Outstanding Florida Waters, Wild and Scenic Rivers, aquatic preserves, wetlands, and threatened and endangered species. The physical impact analysis would include the evaluation of noise and vibration, air quality, energy, potential hazardous materials, water quality, and coastal zone consistency. The environmental evaluation would consider construction and cumulative and secondary impacts. Measures to mitigate any adverse impacts would also be addressed.

In addition, this study is being completed with other transit initiative studies that are currently underway. These projects include: (1) Canadian Court Intermodal Center; (2) International Drive Circulator; (3) Florida High Speed Rail; (4) Orlando International Airport (OIA) Intermodal Center; (5) North-South Light Rail Transit; and (6) Central Florida North/South Commuter Corridor Alternatives Analysis. Although the above-mentioned studies are freestanding and capable of independent utility, all projects will continue to be closely monitored to ensure project consistency. Additional information on these other independent transit initiatives, may be obtained from Ms. Tawny Olore, Rail Transit Project Manager, Florida Department of Transportation—District 5, 719 South Woodland Boulevard, MS 2–543, DeLand, Florida, 32720, phone: (386) 943–5707; e-mail: *tawny.olore@dot.state.fl.us*.

6. OIA Intermodal Center

As part of the OIA Connector Scoping Meeting, information on the OIA Intermodal Center will be presented. The FDOT in consultation with the FTA, and the Greater Orlando Aviation Authority (GOAA) is preparing NEPA documentation for a new Intermodal Center at OIA in order to accommodate high-speed rail, light rail, and other private/public modes of transportation. The study will comply with FDOT, FTA, Federal Aviation Administration (FAA), Federal Railroad Administration (FRA), and the Transportation Security Administration (TSA) requirements. The OIA Intermodal Center project is freestanding and capable of independent operation.

7. FTA Procedures

In accordance with FTA policy, all Federal laws, regulations, and executive orders affecting project development, including but not limited to the regulations of the Council on Environmental Quality and FTA implementing NEPA (40 CFR parts 1500–1508, and 23 CFR part 771), the 1990 Clean Air Act Amendments, section 404 of the Clean Water Act, Executive Order 12898 regarding Environmental Justice, the National Historic Preservation Act, the Endangered Species Act, and section 4(f) of the DOT Act, will be addressed to the maximum extent practicable during the NEPA process. In addition, following selection and adoption of the LPA, FDOT may seek FTA Section 5309 New Starts funding for the LPA, and therefore, will be subject to the FTA New Starts Regulations (49 CFR part 611). This New Starts regulation requires submission of information specified by FTA to support FDOT's request to initiate Preliminary Engineering. The Alternatives Analysis and subsequent Preliminary Engineering activities are to be executed in conjunction with the NEPA process.

Issued on: February 6, 2004.

George T. Thomson,

Acting FTA Regional Administrator.

[FR Doc. 04–2988 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Release of Waybill Data

The Surface Transportation Board has received a request from Steptoe & Johnson on behalf of CSX Transportation (WB567–4—1/30/04), for permission to use certain data from the Board's Carload Waybill Samples. A copy of the request may be obtained from the Office of Economics, Environmental Analysis, and Administration.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics, Environmental Analysis, and Administration within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

FOR FURTHER INFORMATION CONTACT: Mac Frampton, (202) 565–1541.

Vernon A. Williams,

Secretary.

[FR Doc. 04–2965 Filed 2–11–04; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Release of Waybill Data

The Surface Transportation Board has received a request from GATX Rail (WB512–9—1/14/04), for permission to use certain data from the Board's Carload Waybill Samples. A copy of these request may be obtained from the Office of Economics, Environmental Analysis, and Administration.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics, Environmental Analysis, and Administration within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Mac Frampton, (202) 565–1541.

Vernon A. Williams,

Secretary.

[FR Doc. 04–2966 Filed 2–10–04; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34363]

Central Midland Railway Company—Lease and Operation Exemption—Missouri Central Railroad Co.

Central Midland Railway Company (Central Midland), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41, *et seq.*, to lease from Missouri Central Railroad Co. (Missouri Central) and operate 243.8 miles of rail line between milepost 19.0 west of Vigus, MO, and milepost 262.8 at Pleasant Hill, MO.[1]

Central Midland certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier. The parties contemplated consummating the transaction on or after January 20, 2004.[2]

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34363, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John Broadley, 1054 31st Street, NW., Suite 200, Washington, DC 20007.

Board decisions and notices are available on our website at *http://www.stb.dot.gov.*

Decided: February 2, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–2591 Filed 2–10–04; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–290 (Sub–No. 249X)]

Norfolk Southern Railway Company—Discontinuance of Service Exemption—in McLean, Dewitt and Piatt Counties, IL

Norfolk Southern Railway Company (NSR) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over a 30.4-mile line of railroad between milepost UM–47.9 at or near Mansfield and milepost UM–78.3 at or near Bloomington, in McLean, Dewitt and

[1] Central Midland indicates that it has entered into a lease agreement with Missouri Central.

[2] Central Midland initially proposed consummation on or after January 19, 2004, but subsequently filed a letter correcting the proposed consummation date as above indicated (7 days after the exemption was filed).

Piatt Counties, IL.[1] The line traverses United States Postal Service Zip Codes 61701, 61702, 61704, 61709, 61710, 61736, 61752, 61791, 61799, 61842, and 61854.

NSR has certified that: (1) No traffic has moved over the line for at least 2 years; (2) any overhead traffic can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on March 12, 2004, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA for continued rail service under 49 CFR 1152.27(c)(2),[2] must be filed by February 23, 2004.[3] Petitions to reopen must be filed by March 2, 2004, with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to NSR's representative: James R. Paschall, General Attorney, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

[1] By letter filed January 27, 2004, NSR clarified that it does not seek exemption from the requirements of 49 U.S.C. 10904 or 49 U.S.C. 10905. The notice of exemption covers only an exemption from the requirements of 49 U.S.C. 10903.

[2] Each offer of financial assistance must be accompanied by the filing fee, which currently is set at $1,100. *See* 49 CFR 1002.2(f)(25).

[3] Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Likewise, no environmental or historical documentation is required here under 49 CFR 1105.6(c) and 1105.8(b), respectively.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: February 4, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–2805 Filed 2–10–04; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: The Gray Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 7 to the Treasury Department Circular 570; 2003 Revision, published July 1, 2003, at 68 FR 39186.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–1033.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued to the following Company under 31 U.S.C. 9304 to 9308. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2003 Revision, on page 39202 to reflect this addition:

Company Name: The Gray Insurance Company. *Business Address:* P.O. Box 6202, Metairie, Louisiana 70009–6202. *Phone:* (504) 888–7790. *Underwriting Limitation b/:* $5,349,000. *Surety Licenses* c/: AL, AK, AZ, AR, CA, CO, DE, FL, GA, ID, IL, IA, KS, KY, LA, MD, MI, MS, MT, NE, NV, NM, NC, ND, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, WA, WV, WI. *Incorporated in:* Louisiana

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list qualified companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licensed to transact surety business and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, Telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04643–2.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: February 2, 2004.

Wanda J. Rogers,

Director, Financial Accounting and Services Division, Financial Management Service.

[FR Doc. 04–2898 Filed 2–10–04; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8390

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8390, Information Return for Determination of Life Insurance Company Earnings Rate Under Section 809.

DATES: Written comments should be received on or before April 12, 2004 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the internet at *CAROL.A.SAVAGE@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Information Return for Determination of Life Insurance Company Earnings Rate Under Section 809.

OMB Number: 1545–0927.
Form Number: Form 8390.
Abstract: Life insurance companies are required to provide data so the Secretary of the Treasury can compute the (1) stock earnings rate of the 50 largest stock companies; and (2) average mutual earnings rate. These factors are used to compute the differential earnings rate which will determine the tax liability for mutual life insurance companies.
Current Actions: There are no changes being made to the form at this time.
Type of Review: Extension of a currently approved collection..
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 150.
Estimated Time Per Respondent: 65 hours, 7 minutes.
Estimated Total Annual Burden Hours: 9,767.
The following paragraph applies to all of the collections of information covered by this notice:
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 5, 2004.
Glenn P. Kirkland,
IRS Reports Clearance Officer.
[FR Doc. 04–2974 Filed 2–10–04; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[PS–27–97]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.
ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, PS–27–91 (TD 8442), Procedural Rules for Excise Taxes Currently Reportable on Form 720 (§§ 40.6302(c)–3(b)(2)(ii), 40.6302(c)–3(b)(2)(iii), and 40.6302(c)–3(e).
DATES: Written comments should be received on or before April 12, 2004 to be assured of consideration.
ADDRESSES: Direct all written comments to Glenn P. Kirkland. Shear, Internal Revenue Service, room 6411, 1111 Constitution Avenue NW., Washington, DC 20224.
FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the internet at *CAROL.A.SAVAGE@irs.gov*.
SUPPLEMENTARY INFORMATION:
Title: Procedural Rules for Excise Taxes Currently Reportable on Form 720.
OMB Number: 1545–1296.
Regulation Project Number: PS–27–91.
Abstract: Internal Revenue Code section 6302(c) authorizes the use of Government depositaries for the receipt of taxes imposed under the internal revenue laws. These regulations provide reporting and recordkeeping requirements related to return, payments, and deposits of tax for excise taxes currently reportable on Form 720.
Current Actions: There are no changes being made to this existing regulation.
Type of Review: Extension of a currently approved collection.
Affected Public: Business or other for-profit organizations.
Estimated Number of Recordkeepers: 4,000.
Estimated Time Per Recordkeepers: 60 hours.
Estimated Total Annual Recordkeeping Hours: 240,000.
Estimated Number of Respondents: 5,000.
Estimated Time Per Respondent: 22 minutes.
Estimated Total Annual Burden Hours: 1,850.
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.
Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 5, 2004.
Glenn P. Kirkland,
IRS Reports Clearance Officer.
[FR Doc. 04–2975 Filed 2–10–04; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–109704–97]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.
ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing notice of proposed rulemaking and temporary regulations, REG–109704–97, HIPAA Mental Health Parity Act (§ 54.9812).

DATES: Written comments should be received on or before April 12, 2004, to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Carol Savage at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: HIPPAA Mental Health Parity Act.

OMB Number: 1545–1577.

Regulation Project Number: Reg–109704–97.

Abstract: The regulations provide guidance for group health plans with mental health benefits about requirements relating to parity in the dollar limits imposed on mental health benefits and medical/surgical benefits.

Current Actions: There is no changes being made to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, State, local or tribal governments, and not-for-profit institutions.

Estimated Number of Respondents: 7,053.

Estimated Time Per Respondent: 28 min.

Estimated Total Annual Burden Hours: 3,280.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 5, 2004.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. 04–2976 Filed 2–10–04; 8:45 am]

BILLING CODE 4830–01–P

Federal Register

Wednesday,
February 11, 2004

Part II

Department of Transportation

Federal Transit Administration

FTA Fiscal Year 2004 Apportionments, Allocations and Program Information; Notice

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FTA Fiscal Year 2004 Apportionments, Allocations and Program Information

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The "Consolidated Appropriations Act, 2004", (Public Law 108–199), which was signed into law by President Bush on January 23, 2004, includes appropriations for the Department of Transportation for the fiscal year ending September 30, 2004, and provides FY 2004 appropriations for the Federal Transit Administration (FTA) transit assistance programs. Pending further consideration of a multi-year authorization, Congress has passed a five-month extension of the Transportation Equity Act for the 21st Century (TEA–21), known as the Surface Transportation Extension Act of 2003 (Public Law 108–88). This act, signed by President Bush on September 30, 2003, provides additional funding authorizations for transit and highway programs for the period October 1, 2003, through February 29, 2004. The previous authorizations, under TEA–21, were effective through September 30, 2003.

This notice contains (1) a listing of the full amount of the FY 2004 apportionments and allocations for the formula, capital, and transit planning and research programs, including both trust funds and general funds, based on the Consolidated Appropriations Act, 2004 and Federal transit laws; and (2) a listing of apportionments and allocations based on the FY 2004 available funding for formula, capital, and transit planning and research programs, in accordance with the Consolidated Appropriations Act, 2004 and the Surface Transportation Extension Act of 2003. This includes the total of general funds made available in the Consolidated Appropriations Act, 2004 and a portion of contract authority under the Surface Transportation Extension Act of 2003. As soon as authorizing legislation covering the remainder of the fiscal year, March 1, 2004, through September 30, 2004, or a portion of it has been enacted the entire apportionment or the additional authority will be made available. If the authorization act affects the distribution of funds within the programs, FTA will republish the apportionments and allocations in their entirety, taking the provisions of both the Consolidated Appropriations Act, 2004 and the authorization act into consideration.

In addition, prior year unobligated allocations for the section 5309 New Starts, Bus and Bus-Related and Job Access and Reverse Commute (JARC) programs are listed. The FTA policy regarding pre-award authority to incur project costs, Letter of No Prejudice Policy, and other pertinent program information are provided.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Administrator for grant-specific information and issues; Mary Martha Churchman, Director, Office of Resource Management and State Programs, (202) 366–2053, for general information about the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, the Rural Transit Assistance Program, the Elderly and Persons with Disabilities Program, the Clean Fuels Formula Program, the Over-the-Road Bus Accessibility Program, the Capital Investment Program, or the Job Access and Reverse Commute Program; Paul L. Verchinski, Chief, Planning Oversight Division, (202) 366–1626, for general information concerning the Metropolitan Planning Program and the Statewide Planning and Research Program; or Bruce Robinson, Office of Research, Demonstration and Innovation, (202) 366–4209, for general information about the National Planning and Research Program.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Metropolitan Planning funds are apportioned by statutory formula to the States for allocation to Metropolitan Planning Organizations (MPOs) in urbanized areas or portions thereof to provide funds for their Unified Planning Work Programs. Statewide Planning and Research funds are apportioned to States by statutory formula to provide funds for their Statewide Planning and Research Programs. Urbanized Area Formula Program funds are apportioned by statutory formula to urbanized areas and to Governors to provide capital, operating and planning assistance in urbanized areas. Nonurbanized Area Formula Program funds are apportioned by statutory formula to Governors for capital, operating and administrative assistance in nonurbanized areas. Elderly and Persons with Disabilities Program funds are apportioned by statutory formula to Governors to provide capital assistance to organizations providing transportation service for the elderly and persons with disabilities. Fixed Guideway Modernization funds are apportioned by statutory formula to specified urbanized areas for capital improvements in rail and other fixed guideways. New Starts identified in the Consolidated Appropriations Act, 2004 and Bus and Bus-Related Allocations identified in the Conference Report accompanying the Act are included in this notice. Congressional allocations of the Job Access and Reverse Commute Program (JARC) included in the Conference Report are also included, as provided for in the Consolidated Appropriations Act, 2004. Over-the-Road Bus Accessibility Program funds are allocated on a competitive basis.

FTA will honor those discretionary project designations included in Conference Report language for Bus and Bus-Related and JARC, to the extent that the projects meet the statutory intent of the specific program. Requests for reprogramming of funding for projects that are found not to be consistent with the statutory intent of the program or project activities outside the scope of the project designation included in report language should be directed to the House and Senate Committees on Appropriations for resolution.

II. Overview

A. General

Table 1 displays the appropriations and obligation limitation for the FTA programs. Also listed is the amount of FY 2004 funds currently available for obligation for each program. The amounts have been adjusted from the FY 2004 enacted levels to reflect an across-the-board .59 percent rescission proportionately applied to the discretionary budget authority and obligation limitation, and to each program, project and activity, as directed by Section 168 of Division H of the Consolidated Appropriations Act, 2004. The following text provides a narrative explanation of the funding levels and other factors affecting the apportionments and allocations.

B. Funds Available for Obligation

The Consolidated Appropriations Act, 2004 provides a combination of trust and general funds that total $7.309 billion for FTA programs. After applying the across-the-board .59 percent rescission, as directed by Section 168 of Division H of the Consolidated Appropriations Act, 2004, new funding for FTA programs is $7.266 billion.

Because the Surface Transportation Extension Act of 2003 only provides contract authority through February 29, 2004, FTA is publishing both (1) the apportionment and allocation tables that contain the full program levels in the Consolidated Appropriations Act, 2004; and (2) the apportionments and allocations based on FY 2004 funds available for the FTA program. The column labeled "Apportionment" or "Allocation" includes both trust funds (contract authority) and general funds, and reflects the total dollar amount of obligation limitation and appropriations in the Consolidated Appropriations Act, 2004, once a full year contract authority is made available. This amount does not represent the amount that is actually available for obligation at this time. The amount shown in the column labeled "Available Apportionment" or "Available Allocation" is available for obligation.

C. Project Management Oversight

Section 5327 of title 49 U.S.C., permits the Secretary of Transportation to use up to one-half percent of the funds made available under the Urbanized Area Formula Program and the Nonurbanized Area Formula Program, and three-quarters percent of funds made available under the Capital Investment Program to contract with any person to oversee the construction of any major project under these statutory programs; to conduct safety, procurement, management and financial reviews and audits; and to provide technical assistance to correct deficiencies identified in compliance reviews and audits. Section 319 of the FY 2002 DOT Appropriations Act increased the amount made available under the Capital Investment Program for oversight activities to one percent, for FY 2002 and thereafter.

III. Fiscal Year 2004 Focus Areas

FTA draws attention to the following areas of particular interest in FY 2004 relative to the FTA programs.

A. Transit Safety and Security

The Federal Transit Administration (FTA) has undertaken a series of major steps to help prepare the transit industry to counter terrorist threats. Key to these efforts is emergency preparedness, employee training and public awareness, three of the most important transit security priorities for the future. Transit security must remain in the forefront as the immediacy of September 11, 2001, fades over time. To that end, FTA is continuing to provide security and emergency planning technical assistance to transit agencies, updating transit employee training courses as well as developing new curricula and will continue to hold "Connecting Communities" security forums across the country. In addition, FTA has launched a nationwide safety and security public awareness program, "TransitWatch", that encourages the active participation of transit passengers and employees in maintaining a safe transit environment.

Although the transit industry has made great strides in strengthening security and emergency preparedness, there is much more to do. Detailed information about these three areas and other important actions can be found in FTA's list of Top 20 Security Program Action Items for transit agencies. These 20 action items are based on good security practices identified through FTA's Security Assessments and the technical assistance program. The Top 20 Security Program Action Items can be found on FTA's Web site at *http://transit-safety.volpe.dot.gov/security/SecurityInitiatives/Top20/default.asp*. FTA will work with transit agencies to assist them as they incorporate these practices into their programs.

B. Ridership

FTA's strategic business plan establishes FTA's core values and identifies a number of strategic goals for sustaining these values over the next three years. Specifically, FTA seeks to deliver products and services that are valued by its customers and to assist transit agencies in better meeting the needs of their customers. Increasing transit ridership is a key measure of success in achieving this objective. FTA has further identified a goal of achieving an average 2.0 percent increase in the number of transit passenger boardings per transit agency, controlling for changes in local economic conditions by adjusting ridership by employment levels. FTA is continuing work on a range of research, guidance, and other technical assistance to support State and local transit efforts to increase ridership. FTA encourages all transit agencies to focus attention on ways to increase transit ridership, and will be issuing further information about the FTA ridership initiative throughout FY 2004.

C. Transportation Coordination

Without adequate transportation services, many older Americans, persons with disabilities, and individuals with low-incomes are often unable to access work, medical services, educational resources or recreation opportunities. The social and economic consequences of inadequate transportation can be enormous.

In June of 2003, the General Accounting Office issued a report on Transportation for Disadvantaged Populations. This report highlights the complex nature of coordinating multiple funding resources for a variety of client populations. Because of the complex issues related to coordinating resources to improve human service transportation, DOT has been actively working with other Federal agencies including the Departments of Health and Human Services, Labor, and Education. While the broad collaborative efforts focus on cross-cutting issues, there are also subcommittees and distinct activities addressing the unique needs of older adults, people with disabilities, and low-income populations, and issues related to medical transportation services. FTA is encouraging transportation and human service leaders in every community to work together to assess existing transportation services, determine unmet needs and institute resource strategies that will help bridge the gaps. Using available Federal transportation funds in the most effective coordinated manner has become especially important as States and communities deal with budget shortfalls.

To assist States and communities in moving forward, FTA and our federal partners have introduced a five point initiative, including, technical assistance, State recognition awards, and the issuance of a Framework for Action, a self-assessment tool for both States and communities. FTA encourages States and communities to use the Framework for Action (available on the FTA Web site at *http://www.fta.dot.gov/CCAM/framework.html*) as a planning tool to improve service coordination.

D. Special Transit Provisions in the Consolidated Appropriations Act, 2004

Procurement Pilot Program—Section 166 of the FTA general provisions in the Consolidated Appropriations Act, 2004 directs that a procurement pilot program be established to determine the benefits of encouraging cooperative procurement of major capital equipment under sections 5307, 5309, and 5311. The program will consist of three pilot projects, which may be carried out by grantees, consortiums of grantees, or members of the private sector acting as agents of grantees. The Federal share for a grant under this pilot program will be 90 percent of net project cost. FTA is working to develop procedures and guidance to implement this program. Details will be forthcoming.

Restriction on Advertisements for Controlled Substances—Section 177 of the FTA general provisions in the Consolidated Appropriations Act, 2004 provides that none of the funds made available in this Act shall be available to any Federal transit grantee after February 1, 2004, involved directly or indirectly, in any activity that promotes the legalization or medical use of any substance listed in schedule I of section 202 of the Controlled Substance Act (21 U.S.C. 812 *et seq.*).

IV. Metropolitan Planning Program and State Planning and Research Program

A. Metropolitan Planning Program

The Consolidated Appropriations Act, 2004 provides $60,029,325 to the Metropolitan Planning Program (49 U.S.C. 5303) after the across-the-board .59 percent rescission. The FY 2004 Metropolitan Planning Program apportionment to States for MPOs' use in urbanized areas totals $61,456,193. This amount includes $60,029,325 in FY 2004 funds, and $1,426,868 in prior year funds available for reapportionment under this program. A basic allocation of 80 percent of this amount ($49,164,954) is distributed to the States based on the State's urbanized area population as defined by the U.S. Census Bureau for subsequent State distribution to each urbanized area, or parts thereof, within each State. A supplemental allocation of the remaining 20 percent ($12,291,238) is also provided to the States based on an FTA administrative formula to address planning needs in the larger, more complex urbanized areas. Table 2 displays the State apportionments for the combined basic and supplemental allocations. Table 2 also shows the amount of a State's apportionment that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

All States have either reaffirmed or developed, in consultation with their MPOs, new allocation formulas as a result of the 2000 Census. These formulas may be changed annually, but require approval by the FTA regional office prior to grant approval.

B. Statewide Planning and Research Program

The Consolidated Appropriations Act, 2004 provides $12,539,975 to the Statewide Planning and Research Program (49 U.S.C. 5313(b)) after the across-the-board .59 percent rescission. The FY 2004 apportionment for the Statewide Planning and Research Program (SPRP) totals $13,259,049. This amount includes $12,539,975 in FY 2004 funds, and $719,074 in prior year funds available for reapportionment under this program. Final State apportionments for this program are also contained in Table 2. Table 2 also shows the amount of a State's apportionment that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

These funds may be used for a variety of purposes such as planning, technical studies and assistance, demonstrations, management training, and cooperative research. In addition, a State may authorize a portion of these funds to be used to supplement metropolitan planning funds allocated by the State to its urbanized areas, as the State deems appropriate.

C. FHWA Metropolitan Planning Program and State Planning and Research Program

For informational purposes, the FY 2004 apportionments for the FHWA Metropolitan Planning Program (PL) that are available under the Surface Transportation Extension Act of 2003 are contained in Table 3. Apportionments for the FY 2004 FHWA

State Planning and Research Program (SPRP) and for the full 12 months of the PL were not available at the time of publication of this notice. When the information becomes available it will be posted on the FHWA Web site at *http://www.fhwa.dot.gov/legsregs/directives/notices/n4510511.htm.*

D. Local Match Waiver for Specified Planning Activities

Job Access and Reverse Commute Planning. Federal, State and local welfare reform initiatives may require the development of new and innovative public and other transportation services to ensure that former welfare recipients have adequate mobility for reaching employment opportunities. In recognition of the key role that transportation plays in ensuring the success of welfare-to-work initiatives, FTA and FHWA permit the waiver of the local match requirement for Job Access and Reverse Commute planning activities undertaken with both FTA and FHWA Metropolitan Planning Program and State Planning and Research Program funds. FTA and FHWA will support requests for waivers when they are included in Metropolitan Unified Planning Work Programs and State Planning and Research Programs and meet all other requirements.

E. Planning Emphasis Areas for Fiscal Year 2004

The FTA and FHWA identify Planning Emphasis Areas (PEAs) annually to promote priority themes for consideration, as appropriate, in metropolitan and statewide Unified Planning Work Programs proposed for FTA and FHWA funding in FY 2004. While we try to make the PEAs available at the beginning of the Federal fiscal year, we realize even the October 1 date may be too late for some planning organizations to address the PEAs in their upcoming work programs. In such a case, the FY 2004 PEAs can be considered in the development of UPWPs during FY 2004 even though the UPWP might not be approved until early in FY 2005. FTA and FHWA provide support for the PEAs through the Transportation Planning Capacity Building Program, which can be accessed at *http://www.planning.dot.gov/.* Opportunities for exchanging ideas and experiences on innovative practices in these topical areas also will be provided throughout the year. For FY 2004, five key planning themes have been identified: (1) Consideration of safety and security in the transportation planning process; (2) integration of planning and environmental processes; (3) consideration of management and operations within planning processes; (4) State DOT consultation with non-metropolitan local officials; and (5) enhancing the technical capacity of planning processes.

1. Safety and Security in the Transportation Planning Process. TEA–21 emphasizes the safety and security of transportation systems as a national priority and calls for transportation projects and strategies that "increase the safety and security of transportation systems." This entails integration of safety and security into all stages of the transportation planning process.

FTA and FHWA are working together to advance the state-of-practice in addressing safety and security in the metropolitan and statewide planning process through forums, training, research, workshops, and case studies. A report prepared by the Transportation Research Board (TRB), Transportation Research Circular E–C02, "Safety-Conscious Planning," January 2001, describes the issues and recommendations identified at a Safety in Planning workshop held earlier. The report is available on the TRB Web site at *http://www.nas.edu/trb.* Also, the Institute of Transportation Engineers (ITE) has prepared a discussion paper on the topic, entitled "The Development of the Safer Network Transportation Planning Process," which is posted to their Web site at *http://www.ite.org.*

2. Integrated Planning and Environmental Processes. TEA–21 mandated the elimination of the Major Investment Study as a stand-alone requirement, while integrating the concept within the planning and project development/environmental review processes. A training course entitled "Linking Planning and NEPA" has been piloted and will be made available in FY 2004 at the National Transit Institute Web site, *http://www.ntionline.com.* The course will also be posted on the National Highway Institute Web site *http://www.nhi.fhwa.dot.gov/.*

3. Consideration of Management and Operations within Planning Processes. TEA–21 challenges FHWA and FTA to move beyond traditional capital programs for improving the movement of people and goods—focusing on the need to improve the way transportation systems are managed and operated. FTA and FHWA have convened a working group and have commissioned discussion papers on the topic. This information is available at *http://plan2op.fhwa.dot.gov.*

4. State DOT Consultation With Non-Metropolitan Local Officials. On January 23, 2003, the FTA and FHWA issued a final Rule on consultation, followed by a technical correction on February 14, 2003, which can be accessed at *http://www.fta.dot.gov/library/legal/federalregister/2003/fr12303.html* and *http://www.fta.dot.gov/library/legal/federalregister/2003/fr21403.html.* This final rule amends the 1993 Joint FTA/FHWA Planning regulation published in the **Federal Register**, Volume 58, No. 207, on October 28, 1993. Consultation is a vital issue within the transportation planning process. Each State shall have a documented process(es) that implements consultation with non-metropolitan local officials in the statewide planning process and development of the statewide transportation improvement program by February 24, 2004. The documented process(es) must be separate and discrete from the State's public involvement process. The FTA and FHWA have worked with each State to help facilitate development of the documented process(es), but will not review or approve the documented process(es). However, the FTA and FHWA in the State Planning Finding will comment on progress toward accomplishing the documented process(es) and its implementation. Since consultation is a vital issue, each State shall review its documented process and solicit comments regarding the effectiveness of its consultation process within two years of adopting its documented process, and thereafter, at least once every five years. The National Association of Development Organizations at *http://www.nado.org/rtoc/best_practices/index.html* has summaries of some State models for using regional planning and development organizations to help facilitate the input and involvement of rural local officials in the transportation planning and programming process.

5. Enhancing the Technical Capacity of Planning Processes. Reliable information on current and projected usage and performance of transportation systems is critical to the ability of planning processes to supply credible information to decision-makers to support preparation of plans and programs that respond to their localities' unique needs and policy issues. To ensure the reliability of usage and performance data, as well as the responsiveness of policy forecasting tools, an evaluation is needed of the quality of information provided by the technical tools, data sources, and forecasting models, as well as the expertise of staff to ensure its adequacy to support decision-making. If this expertise is found to be lacking, the responsible agencies within

metropolitan and statewide planning processes are encouraged to devote appropriate resources to enhance and maintain their technical capacity.

For further information on these PEAs, contact Candace Noonan, FTA Office of Planning and Environment, (202) 366–1648, or John Humeston, FHWA Office of Planning, (404) 562–3667.

F. Consolidated Planning Grants

Since FY 1997, FTA and FHWA have offered States the option of participating in a pilot Consolidated Planning Grant (CPG) program. Information concerning participation in the CPG program can be found on the FTA Web site at *http://www.fta.dot.gov/office/public/cpg.htm.* For further information on participating in the CPG Pilot, contact Candace Noonan, Office of Planning and Environment, FTA, at (202) 366–1648 or Anthony Solury, Office of Planning, FHWA, at (202) 366–5003.

V. Urbanized Area Formula Program

A. Total Urbanized Area Formula Apportionments

The Consolidated Appropriations Act, 2004 provides $3,425,608,562 to the Urbanized Area Formula Program (49 U.S.C. 5307) after the across-the-board .59 percent rescission. In addition, $3,039,008 in prior year funds became available for reapportionment under the Urbanized Area Formula Program as provided by 49 U.S.C. 5336(i).

After reserving $17,128,043 for oversight, the amount of FY 2004 funds available for apportionment is $3,408,480,519. The funds to be reapportioned, described in the previous paragraph, are then added and increase the total amount apportioned for this program to $3,411,519,527. Table 4 displays the amounts apportioned under the Urbanized Area Formula Program. Table 4 also shows, by urbanized area and State, the amount currently available for obligation in accordance with the Surface Transportation Extension Act of 2003. Table 12 contains the apportionment formula for the Urbanized Area Formula Program.

Additional funds in the amount of $4,821,335 are appropriated for the Alaska Railroad for improvements to its passenger operations after the across-the-board .59 percent rescission. After reserving $24,107 for oversight, $4,797,228 remains to finance Alaska Railroad projects. Of this amount $2,567,792 is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003. Funds appropriated for the Alaska Railroad are allocated in lieu of apportioning funds for the Anchorage, AK urbanized area under the fixed guideway tier of the section 5307 formula using data attributable to the Alaska Railroad Corporation.

B. Data Used for Urbanized Area Formula Apportionments

Data from the 2002 National Transit Database (NTD) Report Year were used to calculate the FY 2004 Urbanized Area Formula apportionments for urbanized areas with populations of 200,000 or more. The 2000 Census population and population density data are also used in calculating apportionments under the Urbanized Area Formula Program.

C. Urbanized Area Formula Apportionments to Governors

The total Urbanized Area Formula apportionment to the Governor (and the amount currently available for obligation in accordance with the Surface Transportation Extension Act of 2003) for use in areas under 200,000 in population for each State are shown in Table 4. This table also contains the apportionment amount attributable to each urbanized area within the State. The Governor may determine the allocation of funds among the urbanized areas under 200,000 in population with the following exception: as further discussed in Section F, below, funds attributed to an urbanized area under 200,000 in population and located within the planning boundaries of a Transportation Management Area, must be obligated to that small urbanized area.

D. Transit Enhancements

One percent of the Urbanized Area Formula Program apportionment in each urbanized area with a population of 200,000 or more must be made available only for transit enhancements. Table 4 shows the amount set aside for enhancements in these areas.

The term "transit enhancement" includes projects or project elements that are designed to enhance mass transportation service or use and are physically or functionally related to transit facilities. Eligible enhancements include the following: (1) Historic preservation, rehabilitation, and operation of historic mass transportation buildings, structures, and facilities (including historic bus and railroad facilities); (2) bus shelters; (3) landscaping and other scenic beautification, including tables, benches, trash receptacles, and street lights; (4) public art; (5) pedestrian access and walkways; (6) bicycle access, including bicycle storage facilities and installing equipment for transporting bicycles on mass transportation vehicles; (7) transit connections to parks within the recipient's transit service area; (8) signage; and (9) enhanced access for persons with disabilities to mass transportation.

It is the responsibility of the MPO to determine how the one percent will be allotted to transit projects. The one percent minimum requirement does not preclude more than one percent being expended in an urbanized area for transit enhancements. However, items that are only eligible as enhancements—in particular, operating costs for historic facilities—may be assisted only within the one percent funding level.

The recipient must submit a report to the appropriate FTA regional office listing the projects or elements of projects carried out with those funds during the previous fiscal year and the amount awarded. The report must be submitted with the Federal fiscal year's final quarterly progress report in TEAM-Web. The report should include the following elements: (a) Grantee name, (b) urbanized area name and number, (c) FTA project number, (d) transit enhancement category, (e) brief description of enhancement and progress towards project implementation, (f) activity line item code from the approved budget, and (g) amount awarded by FTA for the enhancement.

E. Fiscal Year 2004 Operating Assistance

In general, FY 2004 funding for operating assistance is available only to urbanized areas with populations under 200,000. For these areas, there is no limitation on the amount of the State apportionment that may be used for operating assistance, and the Federal/local share ratio is 50/50. The Consolidated Appropriations Act, 2004 provides an exception to the restriction on operating assistance in areas over 200,000 in population for transit providers that provide mass transportation service exclusively to elderly persons and persons with disabilities within the urbanized area. The language in Section 176 of the *General Provisions-Federal Transit Administration* in the Consolidated Appropriations Act, 2004 stipulates that the number of vehicles operated by the eligible transit providers must be 25 or fewer vehicles and that operating assistance to all entities shall not exceed $10,000,000. The areas eligible under the criteria included in TEA–21 prior to this amendment have already been identified and notified.

The Surface Transportation Extension Act of 2003 also continues the provisions of Pub. L. 107–232, which allow transit systems in urbanized areas that, for the first time, exceeded 200,000 population according to the 2000 Census to use section 5307 funds for operating assistance. A list of the eligible 2000 Census urbanized areas (with populations 200,000 or greater) that may use FY 2004 funds for operating assistance is provided in Table 15. The table also shows the maximum amount of the area's FY 2004 apportionment that may be used for operating assistance and the amount of an area's apportionment currently available for obligation as operating assistance. The use of the urbanized area funds for operating assistance by these areas is restricted to projects carried out within the geographical or service area boundary of the affected 1990 census small (less than 200,000 population) urbanized area.

In addition, the Surface Transportation Extension Act of 2003 adds a provision that allows operating assistance, in an urbanized area at least 200,000, for a 2000 Census urbanized area if a portion of the area was not designated as an urbanized area as determined under the 1990 Federal decennial census and received assistance under section 5311 in FY 2002. The provision further stipulates that this portion of the urbanized area shall receive an amount of funds made available under section 5307 that is not less than the amount the portion of the area received under section 5311 in FY 2002. Affected areas are not identified in Table 15. A grant applicant for an area eligible to receive operating assistance under this provision that wants to make use of this provision must so state in the grant application. The application must identify the previously nonurbanized portion of the urbanized area that qualifies (*i.e.*, that portion of the area that was not designated as urbanized under the 1990 census and received assistance under section 5311). Contact the appropriate FTA regional office for additional information or guidance if you intend to make use of this provision.

F. Designated Transportation Management Areas

All 2000 Census urbanized areas having a population of at least 200,000 have been designated as Transportation Management Areas (TMAs), in accordance with 49 U.S.C. 5305. In addition, the Santa Barbara, CA urbanized area, which did not meet the population threshold requirement for TMA status with respect to 2000 Census, retained its previously granted TMA status based on Gubernatorial request. These TMA designations were formally made in the FTA Notices at 67 FR 45173 *et seq.* (July 8, 2002) and 67 FR 62285 *et seq.* (October 4, 2002).

Guidance for setting the boundaries of TMAs is contained in the joint transportation planning regulations codified at 23 CFR part 450 and 49 CFR part 613. In some cases, the TMA planning boundaries, which have been established by the MPO for the designated TMA, also include one or more urbanized areas less than 200,000 in population. Where this situation exists, the discretion of the Governor to allocate Urbanized Area Formula program "Governor's Apportionment" funds for urbanized areas with less than 200,000 in population is restricted, *i.e.*, the Governor only has discretion to allocate Governor's Apportionment funds attributable to areas that are outside of designated TMA planning boundaries.

If any additional small urbanized areas within the planning boundaries of a TMA are identified, notification should be made in writing to the Associate Administrator for Program Management, Federal Transit Administration, 400 Seventh Street, SW., Washington, DC 20590, no later than July 1 of each year. FTA has updated and provided below the list of urbanized areas with population less than 200,000 included within the planning boundaries of designated TMAs. .

Designated TMA	Small urbanized area included in TMA boundary
Albany, NY	Saratoga Springs, NY.
Houston, TX	Galveston, TX; Lake Jackson-Angleton, TX; Texas City, TX; The Woodlands, TX.
Jacksonville, FL	St. Augustine, FL.
Orlando, FL	Kissimmee, FL.
Palm Bay-Melbourne, FL	Titusville, FL.
Philadelphia, PA-NJ-DE-MD	Pottstown, PA.
Pittsburgh, PA	Monessen, PA; Weirton, WV—Steubenville, OH-PA (PA portion); Uniontown-Connellsville, PA.
Seattle, WA	Bremerton, WA.
Washington, DC-VA-MD	Frederick, MD.

G. Urbanized Area Formula Funds Used for Highway Purposes

Urbanized Area Formula funds apportioned to a TMA can be transferred to FHWA and made available for highway projects if the following three conditions are met: (1) Such use must be approved by the MPO in writing after appropriate notice and opportunity for comment and appeal are provided to affected transit providers; (2) in the determination of the Secretary, such funds are not needed for investments required by the Americans with Disabilities Act of 1990 (ADA); and (3) the MPO determines that local transit needs are being addressed.

Urbanized Area Formula funds that are designated for highway projects will be transferred to and administered by FHWA. The MPO should notify FTA of its intent to use FTA funds for highway purposes, as prescribed in section VIII.A., below.

VI. Nonurbanized Area Formula Program and Rural Transit Assistance Program

A. Nonurbanized Area Formula Program

The Consolidated Appropriations Act, 2004 provides $239,188,058 to the Nonurbanized Area Formula Program (49 U.S.C. 5311) after across-the-board .59 percent rescission. The FY 2004 Nonurbanized Area Formula apportionments to the States total $238,501,062 and are displayed in Table 5. Of the $239,188,058 appropriated, $1,195,940 was reserved for oversight. The funds apportioned include $508,944 in prior year funds available for reapportionment. Table 5 also shows the amount of a State's apportionment that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

The Nonurbanized Area Formula Program provides capital, operating and administrative assistance for areas under 50,000 in population. Each State must spend no less than 15 percent of its FY 2004 Nonurbanized Area Formula

apportionment for the development and support of intercity bus transportation, unless the Governor certifies to the Secretary that the intercity bus service needs of the State are being adequately met.

B. Rural Transit Assistance Program

The Consolidated Appropriations Act, 2004 provides $5,219,025 to the Rural Transit Assistance Program (RTAP) (49 U.S.C. 5311(b)(2)) after the across-the-board .59 percent rescission. The FY 2004 RTAP allocations to the States total $5,219,104 and are displayed in Table 5. This amount includes $79 in prior year funds available for reapportionment. Table 5 also shows the amount of a State's allocation that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

The funds are allocated to the States to undertake research, training, technical assistance, and other support services to meet the needs of transit operators in nonurbanized areas. These funds are to be used in conjunction with a State's administration of the Nonurbanized Area Formula Program.

FTA also supports RTAP activities at the national level within the National Planning and Research Program (NPRP). The National RTAP activities support the States in their provision of training and technical assistance. Congress did not designate any funds for the National RTAP among the NPRP allocations in the Conference Report accompanying the Consolidated Appropriations Act, 2004. FTA will, however, consider the National RTAP among projects to be funded from the limited available NPRP funds.

VII. Elderly and Persons With Disabilities Program

The Consolidated Appropriations Act, 2004 provides $90,117,950 to the Elderly and Persons with Disabilities Program (49 U.S.C. 5310) after the across-the-board .59 percent rescission. The FY 2004 Elderly and Persons with Disabilities Program apportionments to the States total $90,361,027 and are displayed in Table 6. The funds apportioned include $243,077 in prior year funds available for reapportionment. Also displayed in Table 6 is the amount of a State's apportionment currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

The formula for apportioning these funds uses 2000 Census population data for persons aged 65 and over and for persons with disabilities. The funds provide capital assistance for transportation for elderly persons and persons with disabilities. Eligible capital expenses may include, at the option of the recipient, the acquisition of transportation services by a contract, lease, or other arrangement.

While the assistance is intended primarily for private non-profit organizations, public bodies that coordinate services for the elderly and persons with disabilities, or any public body that certifies to the State that there are no non-profit organizations in the area that are readily available to carry out the service, may receive these funds.

These funds may be transferred by the Governor to supplement Urbanized Area Formula or Nonurbanized Area Formula capital funds during the last 90 days of the fiscal year.

VIII. FHWA Surface Transportation Program and Congestion Mitigation and Air Quality Funds Used for Transit Purposes

A. Transfer Process

The process for transferring flexible formula funds between FTA and FHWA programs is described below. For information on the transfer of FHWA funds to FTA planning programs contact the FTA/FHWA staff identified in section IV.F, above.

Transfer from FHWA to FTA. FHWA funds designated for use in transit capital projects must be derived from the metropolitan and statewide planning and programming process, and must be included in an approved Statewide Transportation Improvement Program (STIP) before the funds can be transferred. By letter the State DOT requests the FHWA Division Office to transfer highway funds for a transit project. The letter should specify the project, amount to be transferred, apportionment year, State, Federal aid apportionment category (*i.e.*, Surface Transportation Program (STP), Congestion Mitigation and Air Quality (CMAQ), Interstate Substitute, or congressional earmark), and should include a description of the project as contained in the STIP.

The FHWA Division Office confirms that the apportionment amount is available for transfer and concurs in the transfer by letter to the State DOT and FTA. The FHWA Office of Budget and Finance then transfers obligation authority and an equal amount of cash to FTA. All FHWA CMAQ, STP, and congressional earmarked funds for transit projects in the Appropriations Act or Conference Report will be transferred to one of the three FTA formula programs (*i.e.* Urbanized Area Formula (section 5307), Nonurbanized Area Formula (section 5311) or Elderly and Persons with Disabilities (section 5310).

The FTA grantee's application for the project must specify which program the funds will be used for and the application should be prepared in accordance with the requirements and procedures governing that program. Upon review and approval of the grantee's application, FTA obligates funds for the project.

Transferred funds are treated as FTA formula funds, but are assigned a distinct identifying code for tracking purposes. The funds may be used for any capital purpose eligible under the FTA formula program to which they are transferred and, in the case of CMAQ, for certain operating costs. FTA and FHWA have issued guidance on project eligibility under the CMAQ program in a Notice at 65 FR 9040 *et seq.* (February 23, 2000). In accordance with 23 U.S.C. 104(k), all FTA requirements except local share are applicable to transferred funds; FHWA local share requirements apply to funds transferred from FHWA to FTA. Transferred funds should be combined with regular FTA funds in a single annual grant application.

In the event that transferred funds are not obligated for the intended purpose within the period of availability of the program to which they were transferred, they become available to the Governor for any eligible transit project.

Transfers from FTA to FHWA. The Metropolitan Planning Organization (MPO) submits a written request to the FTA Regional Office for a transfer of FTA section 5307 formula funds (apportioned to an urbanized area 200,000 and over in population) to FHWA based on approved use of the funds for highway purposes, as contained in the Governor's approved State Transportation Improvement Program. The MPO must certify that: (1) The funds are not needed for capital investments required by the Americans with Disabilities Act; (2) notice and opportunity for comment and appeal has been provided to affected transit providers; and (3) local funds used for non-Federal match are eligible to provide assistance for either highway or transit projects. The FTA Regional Administrator reviews and concurs in the request, then forwards the approval to FTA Headquarters, where a reduction equal to the dollar amount being transferred to FHWA is made to the grantee's urbanized area formula apportionment.

For information regarding these procedures, please contact Kristen D. Clarke, FTA Budget Office, at (202) 366–

1686; or James V. Lunetta, FHWA Finance Division, at (202) 366–2845.

B. Matching Share for FHWA Transfers

The provisions of Title 23 U.S.C. regarding the non-Federal share apply to Title 23 funds used for transit projects. Thus, FHWA funds transferred to FTA retain the same matching share that the funds would have if used for highway purposes and administered by FHWA.

There are three instances in which a Federal share higher than 80 percent would be permitted. First, in States with large areas of Indian and certain public domain lands and national forests, parks and monuments, the local share for highway projects is determined by a sliding scale rate, calculated based on the percentage of public lands within that State. This sliding scale, which permits a greater Federal share, but not to exceed 95 percent, is applicable to transfers used to fund transit projects in these public land States. FHWA develops the sliding scale matching ratios for the increased Federal share.

Secondly, commuter carpooling and vanpooling projects and transit safety projects using FHWA transfers administered by FTA may retain the same 100 percent Federal share that would be allowed for ride-sharing or safety projects administered by the FHWA.

The third instance includes the 100 percent Federal safety projects; however, these are subject to a nationwide 10 percent program limitation.

IX. Capital Investment Program (49 U.S.C. 5309)

A. Fixed Guideway Modernization

The formula for allocating the Fixed Guideway Modernization funds contains seven tiers. The apportionment of funding under the first four tiers is based on data used to apportion the funding in FY 1997. Funding under the last three tiers is apportioned based on the latest available data on route miles and revenue vehicle miles on segments at least seven years old, as reported to the NTD.

Table 7 displays the FY 2004 Fixed Guideway Modernization apportionments and the amount of an area's apportionment that is currently available for obligation, in accordance with the Consolidated Appropriations Act, 2004 and the Surface Transportation Extension Act of 2003. Fixed Guideway Modernization funds apportioned for this section must be used for capital projects to maintain, modernize, or improve fixed guideway systems.

Eligible urbanized areas (those with a population of at least 200,000) with fixed guideway systems that are at least seven years old are entitled to receive Fixed Guideway Modernization funds. A request for the start-up service dates for fixed guideways has been incorporated into the NTD reporting system to ensure that all eligible fixed guideway data is included in the calculation of the apportionments. A threshold level of more than one mile of fixed guideway is required to receive Fixed Guideway Modernization funds. Therefore, urbanized areas reporting one mile or less of fixed guideway mileage under the NTD are not included.

The Consolidated Appropriations Act, 2004 provides $1,199,387,615 to the Fixed Guideway Modernization after the across-the-board .59 percent rescission. An amount of $11,993,876 is reserved for oversight, leaving $1,187,393,739 available for apportionment to eligible urbanized areas. Of this amount, $642,390,071 is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

Table 13 contains information regarding the Fixed Guideway Modernization apportionment formula.

B. New Starts

The Consolidated Appropriations Act, 2004 provides $1,320,498,097 to New Starts after the across-the-board .59 percent rescission. This amount includes transfers of $4,514,482 from unobligated FY 2000 and FY 2001 JARC funds, in accordance with language in the Consolidated Appropriations Act, 2004 and accompanying Conference Report. Of the $1,320,498,097 available, $13,204,981 is reserved for oversight activities, leaving $1,307,293,116 for allocations to projects. In addition, Congress directed that funds be made available from projects in previous appropriations acts, which increases the total amount made available to $1,307,293,121. The reallocated funds are derived from unobligated balances for the following projects: Boston-South Boston Piers transitways project, $2; and Massachusetts North Shore corridor project, $3. The final allocation for each New Starts project is listed in Table 8. Also displayed in Table 8 is the amount of each New Starts project allocation that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003.

Prior year unobligated allocations for New Starts in the amount of $499,881,522 remain available for obligation in FY 2004. This amount includes $408,432,112 in fiscal years 2002 and 2003 unobligated allocations, and $91,449,410 for fiscal years 2000 and 2001 unobligated allocations that are extended in the FY 2004 Conference Report. These unobligated amounts are displayed in Table 8A.

Capital Investment Program funds for New Starts projects identified as having been extended in the FY 2004 Conference Report accompanying the Consolidated Appropriations Act, 2004 will lapse on September 30, 2004. A list of these extended projects and the amounts that remained unobligated as of September 30, 2003, is appended to Table 8A for reference.

C. Bus and Bus-Related

The Consolidated Appropriations Act, 2004 provides $623,499,520 for the purchase of buses, bus-related equipment and paratransit vehicles, and for the construction of bus-related facilities, after the across-the-board .59 percent rescission. This amount includes $20 million (adjusted for the .59 percent rescission) in FY 2004 funds transferred from the JARC program.

TEA–21 authorized a $100 million Clean Fuels Formula Program under 49 U.S.C. 5308 (described in section XII below). The program is authorized to be funded with $50 million from the Bus and Bus-Related category of the Capital Investment Program and $50 million from the Formula Program. However, the Consolidated Appropriations Act, 2004 directs FTA to transfer the formula portion to, and merge it with, funding provided for the Bus and Bus-Related category of the Capital Investment Program. The .59 percent across-the-board rescission has been applied to the $50 million. Thus, $673,204,520 of funds appropriated in FY 2004 is available for funding the Bus and Bus-Related category of the Capital Investment Program. In addition, Congress directed that funds made available for bus and bus facilities include $2,188,112 reallocated from projects in previous appropriations acts, which increases the total amount made available to $675,392,632. The reallocated funds are derived from FY 2001 unobligated balances for the following projects: (MA) Woburn, buses and bus facilities, $247,579; (NJ) Elizabeth Ferry Project, $495,157; (NY) Greenport Sag Harbor, ferries and vans, $59,419; (NY) Westchester and Duchess counties, vans, $148,063; and (PA) Phoenixville, transit related improvements, $1,237,894.

After reserving $6,732,045 for oversight, the amount available for allocation under the Bus and Bus-Related category is $668,660,587. Table 9 displays the allocation of the FY 2004 Bus and Bus-Related funds by State and

project. Also displayed in Table 9 is the amount of each Bus and Bus-Related project allocation that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003. The FY 2004 Conference Report accompanying the Consolidated Appropriations Act, 2004 allocated all of the FY 2004 Bus and Bus-Related funds to specified States or localities for bus and bus-related projects. FTA will fund all designations that comply with the statutory requirements for the program.

Prior year unobligated balances for Bus and Bus-Related allocations in the amount of $645,560,480 remain available for obligation in FY 2004. This includes $624,654,956 in fiscal years 2002 and 2003 unobligated allocations, and $20,905,524 for fiscal years 1998, 1999, 2000, and 2001 unobligated allocations extended in the FY 2004 Conference Report. These unobligated amounts are displayed in Table 9A.

Capital Investment Program funds for Bus and Bus-Related projects identified as having been extended in the Conference Report accompanying the Consolidated Appropriations Act, 2004 will lapse on September 30, 2004. A list of the extended projects and the amounts that remains unobligated as of September 30, 2003, is appended to Table 9A for reference.

In addition, the FY 2004 Conference Report provides clarifications for Bus and Bus-Related projects as follows

(1) San Dieguito Transportation Cooperative, California—Amounts made available from fiscal year 2002 for the San Dieguito Transportation Cooperative, California, shall instead be distributed to the North County Transit District, California, for initial design and planning for a new intermodal center.

(2) Cambria County, Pennsylvania—Amounts made available from fiscal year 2003 for the Cambria County operations and maintenance facility, Pennsylvania, shall be distributed to the Johnstown Inclined Plane visitor's center, Pennsylvania.

(3) Somerset County, Pennsylvania—Amounts made available from fiscal year 2002 for the Somerset County Transportation System buses, Pennsylvania, shall be distributed to Somerset County Accessible Raised Roof Vans ($90,000) and to Somerset County bus and bus facilities ($146,000), Pennsylvania.

(4) Community Medical Centers, California—Amounts made available from fiscal year 2001 for the Community Medical Centers Intermodal Facility, Fresno, California, shall be available for the City of Fresno for the same project. The availability of funds is extended for one year.

(5) Illinois statewide buses—The conference committee expects IDOT to provide at least half the FY 2004 funds made available for downtown Illinois replacement of buses in Bloomington, Champaign-Urbana, Decatur, Madison County, Peoria, Quincy, RIDES, River Valley, Rockford, Rock Island, South Central Illinois MTD, and Springfield. Further the conferees expect IDOT to provide appropriate funds for bus facilities in Bloomington, Galesburg, Rock Island, and Metro Link's bus maintenance facility in St. Clair County.

(6) Civil Rights Trail Trolleys—Amounts made available in fiscal year 2001 for the Montgomery Civil Rights Trail Trolleys shall instead be distributed to the City of Montgomery's Rosa Parks bus project. The availability of funds is extended for one year.

(7) Vermont buses—Amounts made available in fiscal year 2001 for Central Vermont Transit Authority Wheels Transportation Services shall be distributed to the Vermont Agency of Transportation. The availability of funds is extended for one year.

(8) Reno, Nevada, bus projects—Amounts made available for Bus Rapid Transit, South Virginia Street, Reno ($1,950,000) for fiscal year 2003 and Reno Suburban transit coaches ($500,000 in fiscal year 2002) shall be made available for Reno/Sparks intermodal transportation terminals, as proposed by the Senate.

(9) Falls Church Bus Rapid Transit terminus, Virginia—Funds made available for Falls Church Bus Rapid Transit terminus, Virginia, for fiscal year 2001 shall be made available to the City of Falls Church to purchase three 30-foot buses to provide shuttle service from temporary parking lots during the construction of a parking garage at the West Falls Church Metrorail station. Once the garage is completed, the buses will be used to provide feeder service to the West Falls Church Metrorail station. The availability of funds is extended for one year.

(10) Eastchester, Metro North Facilities, New York—Amounts made available in fiscal year 2001 for Eastchester, Metro North Facilities, New York shall instead be distributed to the Bronx Zoo Intermodal Transportation Facility, New York. The availability of funds is extended for one year.

(11) Westbrook, Intermodal Facility, Maine—Amounts made available in fiscal year 2003 for Westbrook, Intermodal Facility, Maine shall instead be distributed to State of Maine, Statewide Buses.

(12) Section 175 of the Consolidated Appropriations Act, 2004 allows the Memphis-Shelby International Airport intermodal facility to be eligible under "Federal Transit Administration, bus and bus facilities."

X. Job Access and Reverse Commute Program

The Consolidated Appropriations Act, 2004 provides $105 million for the Job Access and Reverse Commute (JARC) Program, reduced to $104,380,500 by the .59 percent rescission. JARC project allocations designated in the accompanying Conference Report are included in this notice as Table 11. The amounts designated in the report have been adjusted to reflect the rescission, and the $298,230 set aside for technical assistance and evaluation of the program. Because TEA–21 requires that JARC project selections be made through a national competition based on statutorily specified criteria, FTA cannot honor the designations in report language without further statutory direction, such as that provided in legislation enacted subsequent to the Appropriations Act in FY 2002 and FY 2003. The Consolidated Appropriations Act, 2004 includes language at Section 547, directing FTA to honor the JARC designations in the report. FTA will not conduct a solicitation for applications for projects to be competitively selected in FY 2004, as no additional funds are available.

The JARC program, established under TEA–21, provides funding for the provision of transportation services designed to increase access to jobs and employment-related activities. Job Access projects are those that transport welfare recipients and low-income individuals, including economically disadvantaged persons with disabilities, in urban, suburban, or rural areas to and from jobs and activities related to their employment. Reverse Commute projects provide transportation services for the general public from urban, suburban, and rural areas to suburban employment opportunities. A total of up to $10,000,000 from the appropriation may be used for Reverse Commute Projects.

Prior year unobligated balances for JARC allocations in the amount of $107,012,264 remain available for obligation in FY 2004. These balances include congressional allocations from fiscal years 2002 and 2003 totaling $103,012,302, along with FY 2002 competitive allocations totaling $3,999,962, which are available through the end of FY 2004. These unobligated amounts are displayed in Table 11A. Congress transferred $4,514,482 from unobligated JARC projects

Congressionally designated in the conference reports accompanying the fiscal year 2000 and 2001 Appropriations Acts to the New Starts program. Projects reallocated included all fiscal year 2000 and 2001 JARC Congressional allocations for which FTA had not received an application as of November 7, 2003.

XI. Over-the-Road Bus Accessibility Program

The Consolidated Appropriations Act, 2004 provides $6,908,995 for the Over-the-Road Bus Accessibility (OTRB) Program after the across-the-board .59 percent rescission. Of this amount, $5,219,025 is allocable to providers of intercity fixed-route service, and $1,689,970 to other providers of over-the-road bus services, including local fixed-route service, commuter service, and charter and tour service. The total amount of $3,698,147 is currently available for obligation in accordance with the Surface Transportation Extension Act of 2003. This includes $2,792,101 for intercity fixed-route service and $906,046 for other over-the-road bus services.

The OTRB program authorizes FTA to make grants to operators of over-the-road buses to help finance the incremental capital and training costs of complying with the DOT over-the-road bus accessibility final rule, published on September 28, 1998 (63 FR 51670). Funds will be provided at 90 percent Federal share. FTA conducts a national solicitation of applications and grantees are selected on a competitive basis.

A **Federal Register** Notice providing program guidance and application procedures for FY 2004 was published in the **Federal Register** November 24, 2003. Applications were due February 2, 2004.

XII. Clean Fuels Formula Program

TEA–21 established the Clean Fuels Formula Grant Program under section 5308 of Title 49 U.S.C. to assist non-attainment and maintenance areas in achieving or maintaining attainment status and to support markets for emerging clean fuel technologies. No funds were provided for this program in the Consolidated Appropriations Act, 2004. For further information contact Nancy Grubb, FTA Office of Resource Management and State Programs, at (202) 366–2053.

XIII. National Planning and Research Program

The Consolidated Appropriations Act, 2004 provides $35,290,550 for the National Planning and Research Program after the across-the-board .59 percent rescission. Of this amount $25,685,159 is allocated for specific activities after applicable reductions for the Small Business Innovation Research program. The project allocations are listed in Table 10, along with the amount that is currently available for obligation, in accordance with the Surface Transportation Extension Act of 2003. For additional information contact Bruce Robinson, Office of Research, Demonstration and Innovation, at (202) 366–4209.

XIV. Unit Values of Data for Urbanized Area Formula Program, Nonurbanized Area Formula Program, and Fixed Guideway Modernization

The dollar unit values of data derived from the computations of the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, and the Capital Investment Program—Fixed Guideway Modernization apportionments are displayed in Table 14 of this notice. To replicate an area's apportionment, multiply its population, population density, and data from the NTD by the appropriate unit value.

XV. Period of Availability of Funds

The funds apportioned in this notice under the Metropolitan Planning Program and the Statewide Planning and Research Program, the Urbanized Area Formula Program, and Fixed Guideway Modernization Program will remain available to be obligated by FTA to recipients for three fiscal years following FY 2004. Any of these apportioned funds that remain unobligated at the close of business on September 30, 2007, will revert to FTA for reapportionment under the respective program.

Funds apportioned to nonurbanized areas under the Nonurbanized Area Formula Program, including RTAP funds, will remain available for two fiscal years following FY 2004. Any such funds that remain unobligated at the close of business on September 30, 2006, will revert to FTA for reapportionment among the States under the Nonurbanized Area Formula Program. Funds allocated to States under the Elderly and Persons with Disabilities Program in this notice must be obligated by September 30, 2004. Any such funds that remain unobligated as of that date will revert to FTA for reapportionment among the States under the Elderly and Persons with Disabilities Program. The Consolidated Appropriations Act, 2004 includes a provision requiring that FY 2004 New Starts and Bus and Bus-Related funds not obligated for their original purpose as of September 30, 2006, shall be made available for other projects under 49 U.S.C. 5309.

Funds for JARC projects competitively selected by FTA remain available for two fiscal years following the fiscal year of selection. Any such funds that remain unobligated after that time will revert to FTA for reallocation under the JARC program. There were no competitive JARC selections by FTA in FY 2003 and none are anticipated in FY 2004. JARC projects selected by FTA in FY 2002 will revert to FTA for reallocation after September 30, 2004. Congressional allocations of JARC projects remain available to the designated entity unless reallocated by Congress. Congress reallocated unobligated Congressional allocations for JARC projects from fiscal years 2000 and 2001 in the Consolidated Appropriations Act, 2004.

Capital Investment Program funds for New Starts and Bus and Bus-Related projects identified as having been extended in the FY 2004 Conference Report accompanying the Consolidated Appropriations Act, 2004 will lapse September 30, 2004.

XVI. Automatic Pre-Award Authority To Incur Project Costs

This information incorporates and elaborates on guidance previously provided in the FTA FY 2002 and FY 2003 Apportionments and Allocations Notice found at *http://www.fta.dot.gov/library/legal/federalregister/2002/fr1202a.pdf* and *http://www.fta.dot.gov/library/legal/federalregister/2003/fr31203.pdf*.

A. Policy

FTA provides blanket or automatic pre-award authority to cover certain program areas described below. This pre-award authority allows grantees to incur project costs prior to grant approval and retain their eligibility for subsequent reimbursement after grant approval. The grantee assumes all risk and is responsible for ensuring that all conditions are met to retain eligibility. This automatic pre-award spending authority permits a grantee to incur costs on an eligible transit capital or planning project without prejudice to possible future Federal participation in the cost of the project or projects. Prior to exercising pre-award authority, grantees must comply with the conditions and Federal requirements outlined in paragraphs B and C immediately below. Failure to do so will render an otherwise eligible project ineligible for FTA financial assistance. In addition, grantees are strongly encouraged to consult with the appropriate FTA regional office if there is any question regarding the eligibility

of the project for future FTA funds or the applicability of the conditions and Federal requirements.

Pre-award authority was extended in the June 24, 1998 **Federal Register** Notice on TEA–21 to all formula funds and flexible funds that will be apportioned during the authorization period of TEA–21, 1998–2003. In the March 12, 2003 **Federal Register** Notice of FY 2003 Apportionments and Allocations, FTA extended pre-award authority to grantees for project costs to be reimbursed by formula funds and flexible funds to be appropriated in FY 2004. In this notice, FTA is extending this pre-award authority for formula funds and flexible funds that will be appropriated in FY 2005. Pre-award authority for operating and planning projects under the formula grant programs is not limited to the authorization period. Pre-award authority also applies to Capital Investment Bus and Bus-Related allocations identified in this notice. For such section 5309 Capital Investment Bus and Bus-Related projects, the date that costs may be incurred is the date that the appropriation bill in which they are contained is enacted. In this notice, FTA is also extending comparable pre-award authority to those surface transportation projects commonly referred to as section 330 projects administered by FTA, for which amounts were provided in the Department of Transportation and Related Agencies Appropriations Acts (DOT Appropriations Act) in fiscal years 2002 and 2003.

Blanket pre-award authority does not apply to Capital New Starts funds, or to Capital Investment Bus and Bus-Related projects not specified in this or previous notices. Specific instances of pre-award authority for Capital New Starts projects are described in paragraph D below. Before an applicant may incur costs for Bus and Bus-Related Capital projects not listed in this notice or previous notices, it must first obtain a written Letter of No Prejudice (LONP) from FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA regional office, as described in section XVII below.

In using pre-award authority for FY 2004 or FY 2005 formula funds, grantees are cautioned that reauthorization may result in changes in program structure, administrative requirements, or funding availability. As with all pre-award authority, activities must be conducted in compliance with Federal requirements in order to retain eligibility for future reimbursement.

B. Conditions

The conditions under which pre-award authority may be utilized are specified below:

(1) The pre-award authority is not a legal or implied commitment that the project(s) will be approved for FTA assistance or that FTA will obligate Federal funds. Furthermore, it is not a legal or implied commitment that all items undertaken by the applicant will be eligible for inclusion in the project(s).

(2) All FTA statutory, procedural, and contractual requirements must be met.

(3) No action will be taken by the grantee that prejudices the legal and administrative findings that the Federal Transit Administrator must make in order to approve a project.

(4) Local funds expended by the grantee pursuant to and after the date of the pre-award authority will be eligible for credit toward local match or reimbursement if FTA later makes a grant for the project(s) or project amendment(s).

(5) The Federal amount of any future FTA assistance awarded to the grantee for the project will be determined on the basis of the overall scope of activities and the prevailing statutory provisions with respect to the Federal/local match ratio at the time the funds are obligated.

(6) For funds to which the pre-award authority applies, the authority expires with the lapsing of the fiscal year funds.

(7) When a grant for the project is subsequently awarded, the Financial Status Report, in TEAM-Web, must indicate the use of pre-award authority.

C. Environmental, Planning, and Other Federal Requirements

FTA emphasizes that all of the Federal grant requirements must be met for the project to remain eligible for Federal funding. Compliance with the National Environmental Policy Act (NEPA) and other environmental laws or executive orders (*e.g.*, protection of parklands, wetlands, and historic properties) must be completed *before* State or local funds are spent on implementing activities such as final design, construction, and acquisition for a project that is expected to be subsequently funded with FTA funds. Depending on which class the project is included under in FTA environmental regulations, 23 CFR part 771, the grantee may not advance the project beyond planning and preliminary engineering before FTA has issued either a categorical exclusion, 23 CFR part 771.117(d), a finding of no significant impact (FONSI), or an environmental record of decision (ROD). The conformity requirements of the Clean Air Act, 40 CFR part 93, also must be fully met before the project may be advanced into implementation under pre-award authority with non-Federal funds.

Similarly, the requirement that a project be included in a locally adopted metropolitan transportation improvement program and federally approved statewide transportation improvement program must be followed before the project may be advanced with non-Federal funds under pre-award authority. For planning projects, the project must be included in a locally approved Planning Work Program that has been coordinated with the State. In addition, Federal procurement procedures, as well as the whole range of Federal requirements, must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this increased administrative flexibility requires a grantee to make certain that no Federal requirements are circumvented through the use of pre-award authority. If a grantee has questions or concerns regarding the environmental requirements, or any other Federal requirements that must be met before incurring costs, it should contact the appropriate regional office.

D. Pre-Award Authority for New Starts Projects

The pre-award authorities related to New Starts projects that were provided in the FY 2003 Apportionments and Allocations Notice published in the **Federal Register** on March 12, 2003, (68 FR 1106 *et seq.*) remain in effect. The FY 2003 Notice may be found on the FTA Web site at *http://www.fta.dot.gov/library/legal/federalregister/2003/fr31203.pdf*. The referenced FY 2003 Notice includes a complete description of the conditions that apply to each of the pre-award authorities listed in the chart below:

Pre-award authority to incur cost for:	Preaward authority is effective upon:
NEPA Compliance	Inclusion of Project in the STIP.
Preliminary Engineerinig (PE)	FTA's Approval of Entry into PE.

Pre-award authority to incur cost for:	Preaward authority is effective upon:
Acquisition of Real Prooperty	FTA's Complection of the NEPA Process.
Final Design	FTA's Approval of Entry into Final Design.
Construction	Full Funding Grant Agreement.

XVII. Letter of No Prejudice (LONP) Policy

A. Policy

LONP authority allows an applicant to incur costs on a project utilizing non-Federal resources, with the understanding that the costs incurred subsequent to the issuance of the LONP may be reimbursable as eligible expenses or eligible for credit toward the local match should FTA approve the project at a later date. LONPs are applicable to projects and project activities not covered by automatic pre-award authority. The majority of LONPs will be for Section 5309 New Starts funds not covered under a full funding grant agreement or for Section 5309 Bus and Bus-Related funds not yet appropriated by Congress. At the end of an authorization period, LONPs may be issued for formula funds beyond the life of the current authorization or FTA's extension of automatic pre-award authority.

B. Conditions and Federal Requirements

The conditions for pre-award authority specified in Part XVI, B, above apply to all LONPs. The Environmental, Planning and Other Federal Requirements described in Part XVI, C, also apply to all LONPs. Because project implementation activities may not be initiated prior to NEPA completion, FTA will normally not issue an LONP for such activities until the NEPA process has been completed with a ROD, FONSI, or Categorical Exclusion determination.

C. Request for LONP

Before an applicant may incur costs for a project not covered by automatic pre-award authority, it must first submit a written request for an LONP to the appropriate regional office and obtain written approval.

XVIII. Program Guidance

The FTA Web site at *http://www.fta.dot.gov* is a source of program guidance and current information of interest to FTA grantees, including this apportionment notice. The Web site is currently being redesigned to provide a more customer-focused source of information. Grantees should check the FTA Web site frequently to keep up to date on new postings.

The following FTA program Circulars are posted on the Web site: C9030.1C, Urbanized Area Formula Program: Grant Application Instructions, dated October 1, 1998; C9040.1E, Nonurbanized Area Formula Program Guidance and Grant Application Instructions, dated October 1, 1998; C9070.1E, The Elderly and Persons with Disabilities Program Guidance and Application Instructions, dated October 1, 1998; C9300.1A, Capital Program: Grant Application Instructions, dated October 1, 1998; 4220.1E, Third Party Contracting Requirements, dated June 19, 2003; C5010.1C, Grant Management Guidelines, dated October 1, 1998; C8100.1B, Program Guidance and Application Instructions for Metropolitan Planning Program Grants, dated October 25, 1996; C8200.1, Program Guidance and Application Instructions for State Planning and Research Program Grants, dated December 27, 2001; and C5200.1A, Full Funding Grant Agreement Guidance, dated December 5, 2002. The FY 2004 Annual List of Certifications and Assurances is also posted on the FTA Web site. Other documents on the FTA Web site of particular interest to public transit providers and users include the annual Statistical Summaries of FTA Grant Assistance Programs and the National Transit Database Profiles. The DOT final rule on "Participation by Disadvantaged Business Enterprises in Department of Transportation Financial Assistance Programs," which was effective July 16, 2003, can be found on the Department's Web site at *http://osdbuweb.dot.gov/business/dbe/Docs/03–14989.pdf.*

XIX. FTA Fiscal Year 2004 Annual List of Certifications and Assurances

On January 15, 2004, FTA published in the **Federal Register** the list and accompanying text of all Certifications and Assurances required of recipients of FTA assistance in FY 2004. *See*, 69 FR 2454 *et seq*. The full text of the FY 2004 Certifications and Assurances is also accessible both on FTA's Internet Web site at *http://www.fta.dot.gov/library/legal/federalregister/2004/2004_CERTS.doc* and on TEAM-Web. In compliance with 49 U.S.C. 5323(n), which requires a simultaneous publication of a list of the Certifications and Assurances and FTA's annual notice of Apportionments, recipients are directed to the January 15, 2004, notice at 69 FR 2454 *et seq*. for the list and text of FTA's Certifications and Assurances and to FTA's Web sites displaying those Certifications and Assurances. Any questions regarding this document may be addressed to the appropriate FTA regional office.

As in previous years, the grant applicant should certify electronically. Under certain circumstances the applicant may enter its Personal Identification Number (PIN) in lieu of an electronic signature provided by its attorney, provided the applicant has on file the current affirmation of its attorney in writing dated this Federal fiscal year. The applicant is advised to contact the appropriate FTA regional office for electronic procedure information.

XX. Grant Application Procedures

Grantees must provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number for inclusion in all applications for a Federal grant or cooperative agreement submitted on or after October 1, 2003. The Office of Management and Budget (OMB) published this requirement in the **Federal Register** on June 27, 2003 at 68 FR 38402 *et seq*. On August 4, 2003, FTA issued a Dear Colleague letter including instructions on how to obtain a DUNS number, which can be accessed at *http://www.fta.dot.gov/office/public/2003/c0314.html*. The DUNS number should be entered into the grantee profile in TEAM. Additional information about this and other Federal grant streamlining initiatives mandated by the Federal Financial Assistance Management Improvement Act of 1999 (Pub. L. 106–107) can be accessed on OMB's Web site at *http://www.whitehouse.gov/omb/grants/reform.html*.

All applications for FTA funds should be submitted to the appropriate FTA regional office. FTA utilizes TEAM-Web, an Internet accessible electronic grant application system, and all applications should be filed electronically. FTA has provided exceptions to the requirement for electronic filing of applications for certain new, non-traditional grantees in the Job Access and Reverse Commute and Over-the-Road Bus Accessibility programs, as well as to a few grantees

that have not successfully connected to or accessed TEAM-Web.

In FY 2004 FTA is committed to reducing the average days required to process a grant to 36, while continuing to process at least 80 percent of grants within 60 days of receipt of a completed application by the appropriate Regional Office. In FY 2003, FTA achieved this goal with 83 percent of grants obligated within 60 days of submission of a completed application and an average processing time of 39 days. In order for an application to be considered complete, it must meet the following requirements: all projects must be contained in an approved STIP (when required), all environmental findings must be made by FTA, an adequate project description must be included, the local share must be secured, any flexible funds included in the budget must be secured, all required civil rights submissions must be current, and certifications and assurances must be properly submitted. Once an application is complete, the FTA Regional Office will assign a project number and, when required, submit the application to the Department of Labor (DOL) for a certification under section 5333(b). During FY 2004, any grantees applying for funds available under an extension of TEA–21 before the full year's apportionment becomes available, are encouraged to include contingency items for the remainder of the funds, so that the entire project can be certified by DOL at the time of the initial application. The FTA circulars contain more information regarding application contents. State applicants for section 5311funds are reminded that they must certify to DOL that all subrecipients have agreed to the standard labor protection warranty for section 5311 and provide DOL with specified related information for each grant.

This notice and all program guidance circulars may be accessed via the FTA Web site. Copies of circulars are available from FTA regional offices, as well.

Issued on: February 4, 2004.

Jennifer L. Dorn,

Administrator.

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FEDERAL TRANSIT ADMINISTRATION

TABLE 1

(Appropriation amounts include a 59 percent reduction directed by Section 168 of Division H of the Consolidated Appropriations Act, 2004, Pub. L. 108-199)

FY 2004 APPROPRIATIONS, APPORTIONMENTS, AND AVAILABLE FUNDING FOR GRANT PROGRAMS

SOURCE OF FUNDS	APPROPRIATION & APPORTIONMENT	AVAILABLE FUNDING
TRANSIT PLANNING AND RESEARCH PROGRAMS		
Section 5303 Metropolitan Planning Program	$60,029,325	$32,220,852
Reapportioned Funds Added	1,426,868	1,426,868
Total Apportioned	$61,456,193	$33,647,720
Section 5313(b) State Planning and Research Program	$12,539,975	$6,730,855
Reapportioned Funds Added	719,074	719,074
Total Apportioned	$13,259,049	$7,449,929
Section 5311(b)(2) Rural Transit Assistance Program (RTAP)	$5,219,025	$2,891,651
Reapportioned Funds Added	79	79
Total Apportioned	$5,219,104	$2,891,730
Section 5314 National Planning and Research Program	$35,290,550	$17,634,111
FORMULA PROGRAMS	$3,766,644,900 a/	$2,006,513,324 a/
Alaska Railroad (Section 5307)	4,821,335	2,580,695
Less Oversight (one-half percent)	(24,107)	(12,903)
Total Available	4,797,228	2,567,792
Section 5308 Clean Fuels Formula Program	0 a/	0 a/
Over-the-Road Bus Accessibility Program	6,908,995	3,698,147
Section 5307 Urbanized Area Formula Program		
91.23% of Total Available for Sections 5307, 5311, and 5310	$3,425,608,562	$1,824,813,918
Less Oversight (one-half percent)	(17,128,043)	(9,124,070)
Reapportioned Funds Added	3,039,008	3,039,008
Total Apportioned	$3,411,519,527	$1,818,728,856
Section 5311 Nonurbanized Area Formula Program		
6.37% of Total Available for Sections 5307, 5311, and 5310	$239,188,058	$127,414,936
Less Oversight (one-half percent)	(1,195,940)	(637,075)
Reapportioned Funds Added	508,944	508,944
Total Apportioned	$238,501,062	$127,286,805
Section 5310 Elderly and Persons with Disabilities Formula Program		
2.4% of Total Available for Sections 5307, 5311, and 5310	$90,117,950	$48,005,628
Reapportioned Funds Added	243,077	243,077
Total Apportioned	$90,361,027	$48,248,705
CAPITAL INVESTMENT PROGRAM	$3,193,090,232	$1,720,402,574
Section 5309 Fixed Guideway Modernization	$1,199,387,615	$648,878,860
Less Oversight (one percent)	(11,993,876)	(6,488,789)
Total Apportioned	$1,187,393,739	$642,390,071
Section 5309 New Starts	$1,320,498,097 b/	$676,712,542 b/
Less Oversight (one percent)	(13,204,981)	(6,767,125)
Reallocated Funds Added	5	5
Total Allocated	$1,307,293,121	$669,945,422
Section 5309 Bus and Bus-Related	$673,204,520 c/	$394,811,172 c/
Less Oversight (one percent)	(6,732,045)	(3,948,112)
Reallocated Funds Added	2,188,112 d/	2,188,112 d/
Total Allocated	$668,660,587	$393,051,172
JOB ACCESS AND REVERSE COMMUTE PROGRAM (Section 3037, TEA-21)	$104,380,500	$55,489,667
TOTAL APPROPRIATION (Above Grant Programs)	**$7,177,194,507**	**$3,841,883,034**
TOTAL APPORTIONMENT/ALLOCATION (Above Grant Programs)	**$7,135,040,682**	**$3,823,030,127**

a/ The Consolidated Appropriations Act, 2004 transfers funds appropriated for the Cleans Fuels Formula Program to the Section 5309 Bus and Bus-Related category

b/ Includes $4,514,482 in FY 2000 and FY 2001 funds transferred from the Job Access and Reverse Commute Program.

c/ Includes funds transferred from the Clean Fuels Program and the Job Access and Reverse Commute Program in the Consolidated Appropriations Act, 2004 (Pub. L. 108-199).

d/ FY 2004 Conference Report supplements Bus funds with reallocated funds made available from projects included in previous Appropriations Acts.

FEDERAL TRANSIT ADMINISTRATION

TABLE 2

FY 2004 SECTION 5303 METROPOLITAN PLANNING PROGRAM
AND SECTION 5313(b) STATE PLANNING AND RESEARCH PROGRAM APPORTIONMENTS

STATE	SECTION 5303 APPORTIONMENT	SECTION 5313(b) APPORTIONMENT	AVAILABLE SECTION 5303 APPORTIONMENT	AVAILABLE SECTION 5313(b) APPORTIONMENT
Alabama	$465,199	$125,457	$254,700	$70,491
Alaska	245,825	66,295	134,591	37,250
Arizona	1,229,061	252,578	672,920	141,917
Arkansas	245,825	66,295	134,591	37,250
California	9,668,139	1,940,124	5,293,378	1,090,101
Colorado	921,026	207,649	504,269	116,673
Connecticut	682,662	184,094	373,762	103,438
Delaware	245,825	66,295	134,591	37,250
District of Columbia	245,825	66,295	134,591	37,250
Florida	4,016,192	870,551	2,198,895	489,141
Georgia	1,584,057	323,796	867,283	181,933
Hawaii	245,825	66,295	134,591	37,250
Idaho	245,825	66,295	134,591	37,250
Illinois	3,408,148	629,317	1,865,986	353,598
Indiana	925,878	220,443	506,925	123,861
Iowa	267,153	72,047	146,268	40,481
Kansas	312,366	78,060	171,023	43,860
Kentucky	389,858	101,257	213,450	56,894
Louisiana	609,068	163,873	333,469	92,076
Maine	245,825	66,295	134,591	37,250
Maryland	1,377,570	277,738	754,230	156,054
Massachusetts	1,809,959	364,189	990,966	204,629
Michigan	2,021,821	425,163	1,106,962	238,888
Minnesota	862,830	175,256	472,406	98,472
Mississippi	245,825	66,295	134,591	37,250
Missouri	910,075	199,743	498,273	112,231
Montana	245,825	66,295	134,591	37,250
Nebraska	245,825	66,295	134,591	37,250
Nevada	449,932	108,337	246,341	60,872
New Hampshire	245,825	66,295	134,591	37,250
New Jersey	2,850,946	501,115	1,560,914	281,564
New Mexico	245,825	66,295	134,591	37,250
New York	5,433,989	1,002,038	2,975,149	563,020
North Carolina	901,270	243,059	493,452	136,569
North Dakota	245,825	66,295	134,591	37,250
Ohio	1,955,748	472,517	1,070,786	265,495
Oklahoma	355,545	95,885	194,663	53,875
Oregon	546,935	127,714	299,451	71,759
Pennsylvania	2,524,886	530,664	1,382,394	298,167
Puerto Rico	1,019,766	224,693	558,330	126,249
Rhode Island	254,006	66,295	139,070	37,250
South Carolina	449,050	121,102	245,858	68,044
South Dakota	245,825	66,295	134,591	37,250
Tennessee	710,478	191,605	388,992	107,658
Texas	4,511,344	956,232	2,469,994	537,283
Utah	418,917	112,976	229,360	63,478
Vermont	245,825	66,295	134,591	37,250
Virginia	1,394,669	304,613	763,592	171,154
Washington	1,310,059	278,148	717,267	156,284
West Virginia	245,825	66,295	134,591	37,250
Wisconsin	728,566	183,706	398,895	103,220
Wyoming	245,825	66,295	134,591	37,250
TOTAL	**$61,456,193**	**$13,259,049**	**$33,647,720**	**$7,449,929**

FEDERAL HIGHWAY ADMINISTRATION

TABLE 3

FY 2004 METROPOLITAN PLANNING PROGRAM (PL) AVAILABLE APPORTIONMENTS

STATE	AVAILABLE APPORTIONMENT
Alabama	$964,141
Alaska	500,000
Arizona	1,941,070
Arkansas	500,000
California	14,909,876
Colorado	1,595,790
Connecticut	1,414,765
Delaware	500,000
District of Columbia	500,000
Florida	6,690,204
Georgia	2,488,378
Hawaii	500,000
Idaho	500,000
Illinois	4,836,316
Indiana	1,694,110
Iowa	553,683
Kansas	599,895
Kentucky	778,164
Louisiana	1,259,365
Maine	500,000
Maryland	2,135,735
Massachusetts	2,798,803
Michigan	3,267,386
Minnesota	1,346,846
Mississippi	500,000
Missouri	1,535,032
Montana	500,000
Nebraska	500,000
Nevada	832,573
New Hampshire	500,000
New Jersey	3,851,080
New Mexico	500,000
New York	7,700,688
North Carolina	1,867,914
North Dakota	500,000
Ohio	3,631,304
Oklahoma	736,879
Oregon	981,483
Pennsylvania	4,078,155
Rhode Island	500,000
South Carolina	930,672
South Dakota	500,000
Tennessee	1,472,490
Texas	7,348,669
Utah	868,220
Vermont	500,000
Virginia	2,340,959
Washington	2,137,572
West Virginia	500,000
Wisconsin	1,411,783
Wyoming	500,000
TOTAL	**$100,000,000**

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	ONE PERCENT TRANSIT ENHANCEMENT	APPORTIONMENT	AVAILABLE ONE PERCENT TRANSIT ENHANCEMENT	AVAILABLE APPORTIONMENT
OVER 1,000,000 IN POPULATION	$24,977,943	$2,497,794,566	$13,316,093	$1,331,609,269
200,000-1,000,000 IN POPULATION	5,862,158	586,216,201	3,125,195	312,520,069
50,000-200,000 IN POPULATION	0	327,508,760	0	174,599,518
NATIONAL TOTAL	$30,840,101	$3,411,519,527	$16,441,288	$1,818,728,856
Amounts Apportioned to Urbanized Areas 1,000,000 and Over in Population:				
Atlanta, GA	$539,570	$53,956,958	$287,652	$28,765,210
Baltimore, MD	363,771	36,377,097	193,931	19,393,140
Boston, MA--NH--RI	969,602	96,960,241	516,909	51,690,863
Chicago, IL--IN	2,061,992	206,199,235	1,099,277	109,927,701
Cincinnati, OH--KY--IN	164,726	16,472,576	87,818	8,781,761
Cleveland, OH	242,230	24,222,979	129,136	12,913,609
Columbus, OH	103,099	10,309,896	54,964	5,496,350
Dallas--Fort Worth--Arlington, TX	528,374	52,837,426	281,684	28,168,372
Denver--Aurora, CO	337,821	33,782,121	180,097	18,009,722
Detroit, MI	358,710	35,871,006	191,233	19,123,336
Houston, TX	563,171	56,317,082	300,234	30,023,425
Indianapolis, IN	95,237	9,523,671	50,772	5,077,203
Kansas City, MO--KS	113,196	11,319,594	60,346	6,034,634
Las Vegas, NV	189,567	18,956,657	101,061	10,106,059
Los Angeles--Long Beach--Santa Ana, CA	2,247,375	224,737,462	1,198,107	119,810,690
Miami, FL	779,292	77,929,192	415,451	41,545,144
Milwaukee, WI	192,390	19,239,020	102,566	10,256,591
Minneapolis--St. Paul, MN	390,175	39,017,542	208,008	20,800,798
New Orleans, LA	153,573	15,357,307	81,872	8,187,195
New York--Newark, NY--NJ--CT	6,729,760	672,976,004	3,587,729	358,772,929
Orlando, FL	156,923	15,692,302	83,658	8,365,786
Philadelphia, PA--NJ--DE--MD	1,132,554	113,255,430	603,781	60,378,057
Phoenix--Mesa, AZ	323,399	32,339,948	172,409	17,240,879
Pittsburgh, PA	323,809	32,380,871	172,627	17,262,696
Portland, OR--WA	307,691	30,769,103	164,034	16,403,440
Providence, RI--MA	183,144	18,314,441	97,637	9,763,685
Riverside--San Bernardino, CA	215,742	21,574,245	115,015	11,501,532
Sacramento, CA	160,695	16,069,533	85,669	8,566,893
San Antonio, TX	205,438	20,543,786	109,522	10,952,180
San Diego, CA	468,844	46,884,404	249,947	24,994,733
San Francisco--Oakland, CA	1,162,813	116,281,286	619,912	61,991,182
San Jose, CA	370,860	37,085,993	197,711	19,771,063
San Juan, PR	313,477	31,347,743	167,119	16,711,921
Seattle, WA	744,768	74,476,846	397,047	39,704,650
St. Louis, MO--IL	271,698	27,169,797	144,846	14,484,599
Tampa--St. Petersburg, FL	178,826	17,882,598	95,335	9,533,464
Virginia Beach, VA	145,080	14,508,026	77,344	7,734,432
Washington, DC--VA--MD	1,188,551	118,855,148	633,633	63,363,345
TOTAL	**$24,977,943**	**$2,497,794,566**	**$13,316,093**	**$1,331,609,269**

Note: The amount listed for transit enhancement is included in the apportionment amount for the urbanized area.

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	ONE PERCENT TRANSIT ENHANCEMENT	APPORTIONMENT	AVAILABLE ONE PERCENT TRANSIT ENHANCEMENT	AVAILABLE APPORTIONMENT
Amounts Apportioned to Urbanized Areas 200,000 to 1,000,000 in population				
Aguadilla--Isabela--San Sebastian, PR	$12,237	$1,223,678	$6,524	$652,360
Akron, OH	62,596	6,259,587	33,371	3,337,074
Albany, NY	69,524	6,952,397	37,064	3,706,420
Albuquerque, NM	66,326	6,632,594	35,359	3,535,929
Allentown--Bethlehem, PA--NJ	60,002	6,000,239	31,988	3,198,812
Anchorage, AK	32,188	3,218,842	17,160	1,716,010
Ann Arbor, MI	41,068	4,106,806	21,894	2,189,396
Antioch, CA	46,018	4,601,783	24,533	2,453,275
Asheville, NC	13,196	1,319,640	7,035	703,518
Atlantic City, NJ	67,792	6,779,233	36,141	3,614,104
Augusta-Richmond County, GA--SC	18,609	1,860,902	9,921	992,073
Austin, TX	156,061	15,606,146	83,199	8,319,855
Bakersfield, CA	51,072	5,107,242	27,227	2,722,742
Barnstable Town, MA	31,992	3,199,170	17,055	1,705,522
Baton Rouge, LA	41,504	4,150,405	22,126	2,212,639
Birmingham, AL	47,059	4,705,932	25,088	2,508,798
Boise City, ID	21,385	2,138,519	11,401	1,140,074
Bonita Springs--Naples, FL	10,605	1,060,500	5,654	565,368
Bridgeport--Stamford, CT--NY	160,305	16,030,494	85,461	8,546,081
Buffalo, NY	114,035	11,403,465	60,793	6,079,347
Canton, OH	28,022	2,802,247	14,939	1,493,917
Cape Coral, FL	32,916	3,291,557	17,548	1,754,775
Charleston--North Charleston, SC	36,535	3,653,463	19,477	1,947,712
Charlotte, NC--SC	97,243	9,724,277	51,841	5,184,148
Chattanooga, TN--GA	25,820	2,581,967	13,765	1,376,483
Colorado Springs, CO	47,089	4,708,893	25,104	2,510,377
Columbia, SC	30,985	3,098,455	16,518	1,651,830
Columbus, GA--AL	17,401	1,740,136	9,277	927,691
Concord, CA	191,519	19,151,899	102,101	10,210,146
Corpus Christi, TX	40,255	4,025,455	21,460	2,146,026
Davenport, IA--IL	34,267	3,426,676	18,268	1,826,809
Dayton, OH	134,488	13,448,774	71,697	7,169,730
Daytona Beach--Port Orange, FL	35,212	3,521,155	18,772	1,877,177
Denton--Lewisville, TX	18,488	1,848,831	9,856	985,638
Des Moines, IA	46,148	4,614,848	24,602	2,460,240
Durham, NC	47,409	4,740,914	25,274	2,527,448
El Paso, TX--NM	92,161	9,216,062	49,132	4,913,212
Eugene, OR	38,868	3,886,795	20,721	2,072,105
Evansville, IN--KY	17,394	1,739,423	9,273	927,311
Fayetteville, NC	19,920	1,991,994	10,620	1,061,960
Flint, MI	53,198	5,319,760	28,360	2,836,039
Fort Collins, CO	17,582	1,758,249	9,373	937,347
Fort Wayne, IN	23,194	2,319,382	12,365	1,236,495
Fresno, CA	69,061	6,906,069	36,817	3,681,722
Grand Rapids, MI	60,843	6,084,327	32,436	3,243,640
Greensboro, NC	25,285	2,528,499	13,480	1,347,978
Greenville, SC	16,805	1,680,497	8,959	895,896
Gulfport--Biloxi, MS	16,279	1,627,879	8,678	867,845

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	ONE PERCENT TRANSIT ENHANCEMENT	APPORTIONMENT	AVAILABLE ONE PERCENT TRANSIT ENHANCEMENT	AVAILABLE APPORTIONMENT
Harrisburg, PA	43,079	4,307,925	22,966	2,296,615
Hartford, CT	121,074	12,107,440	64,546	6,454,646
Honolulu, HI	246,313	24,631,302	131,313	13,131,292
Huntsville, AL	14,261	1,426,114	7,603	760,281
Indio--Cathedral City--Palm Springs, CA	27,449	2,744,904	14,633	1,463,347
Jackson, MS	20,494	2,049,446	10,926	1,092,588
Jacksonville, FL	122,749	12,274,855	65,439	6,543,897
Knoxville, TN	32,671	3,267,112	17,417	1,741,743
Lancaster, PA	30,273	3,027,310	16,139	1,613,901
Lancaster--Palmdale, CA	60,538	6,053,757	32,273	3,227,343
Lansing, MI	41,907	4,190,673	22,341	2,234,106
Lexington-Fayette, KY	30,155	3,015,525	16,076	1,607,619
Lincoln, NE	23,123	2,312,321	12,327	1,232,731
Little Rock, AR	32,572	3,257,167	17,364	1,736,441
Louisville, KY--IN	105,242	10,524,221	56,106	5,610,810
Lubbock, TX	22,380	2,238,000	11,931	1,193,109
Madison, WI	58,592	5,859,205	31,236	3,123,624
McAllen, TX	26,236	2,623,640	13,987	1,398,699
Memphis, TN--MS--AR	110,760	11,076,012	59,048	5,904,777
Mission Viejo, CA	77,289	7,728,924	41,204	4,120,398
Mobile, AL	23,329	2,332,944	12,437	1,243,725
Modesto, CA	33,622	3,382,181	17,924	1,792,426
Nashville-Davidson, TN	62,718	6,271,816	33,436	3,343,593
New Haven, CT	143,597	14,359,665	78,553	7,655,338
Ogden--Layton, UT	47,402	4,740,190	25,271	2,527,061
Oklahoma City, OK	64,694	6,469,410	34,489	3,448,933
Omaha, NE--IA	60,521	6,052,122	32,265	3,226,471
Oxnard, CA	63,149	6,314,895	33,666	3,366,559
Palm Bay--Melbourne, FL	41,931	4,193,130	22,354	2,235,416
Pensacola, FL--AL	24,598	2,459,781	13,113	1,311,344
Peoria, IL	23,872	2,387,242	12,727	1,272,672
Port St. Lucie, FL	17,659	1,765,914	9,414	941,434
Poughkeepsie--Newburgh, NY	32,204	3,220,389	17,168	1,716,835
Provo--Orem, UT	40,600	4,060,015	21,645	2,164,451
Raleigh, NC	45,593	4,559,296	24,306	2,430,625
Reading, PA	23,197	2,319,723	12,367	1,236,677
Reno, NV	43,306	4,330,597	23,087	2,308,702
Richmond, VA	85,083	8,508,312	45,359	4,535,900
Rochester, NY	76,002	7,600,193	40,518	4,051,769
Rockford, IL	21,633	2,163,283	11,533	1,153,277
Round Lake Beach--McHenry--Grayslake, IL--WI	35,780	3,577,960	19,075	1,907,461
Salem, OR	27,934	2,793,398	14,892	1,489,199
Salt Lake City, UT	183,451	18,345,130	97,800	9,780,046
Santa Rosa, CA	29,646	2,964,610	15,805	1,580,475
Sarasota--Bradenton, FL	54,335	5,433,497	28,967	2,896,673
Savannah, GA	26,565	2,656,479	14,162	1,416,206
Scranton, PA	33,615	3,361,523	17,921	1,792,075
Shreveport, LA	27,368	2,736,827	14,590	1,459,041
South Bend, IN--MI	34,350	3,435,040	18,313	1,831,268
Spokane, WA--ID	59,479	5,947,903	31,709	3,170,911
Springfield, MA--CT	81,643	8,164,328	43,525	4,352,518
Springfield, MO	17,571	1,757,091	9,367	936,730

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	ONE PERCENT TRANSIT ENHANCEMENT	APPORTIONMENT	AVAILABLE ONE PERCENT TRANSIT ENHANCEMENT	AVAILABLE APPORTIONMENT
Stockton, CA	72,576	7,257,571	38,691	3,869,113
Syracuse, NY	46,320	4,631,991	24,694	2,469,379
Tallahassee, FL	20,959	2,095,927	11,174	1,117,368
Temecula--Murrieta, CA	14,710	1,471,032	7,842	784,228
Thousand Oaks, CA	23,659	2,365,881	12,613	1,261,284
Toledo, OH--MI	54,439	5,443,891	29,022	2,902,215
Trenton, NJ	45,132	4,513,234	24,061	2,406,068
Tucson, AZ	89,910	8,991,046	47,933	4,793,252
Tulsa, OK	58,961	5,896,120	31,433	3,143,304
Victorville--Hesperia--Apple Valley, CA	18,534	1,853,434	9,881	988,092
Wichita, KS	42,105	4,210,514	22,447	2,244,684
Winston-Salem, NC	22,871	2,287,103	12,193	1,219,287
Worcester, MA--CT	53,210	5,320,977	28,367	2,836,687
Youngstown, OH--PA	27,207	2,720,686	14,504	1,450,436
TOTAL	**$5,862,158**	**$586,216,201**	**$3,125,195**	**$312,520,069**

Note: The amount listed for transit enhancement is included in the apportionment amount for the urbanized area.

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Amounts Apportioned to State Governors for Urbanized Areas 50,000 to 200,000 in Population		
ALABAMA	$6,538,715	$3,485,881
Anniston, AL	599,830	319,778
Auburn, AL	561,078	299,119
Decatur, AL	536,775	286,162
Dothan, AL	507,886	270,761
Florence, AL	641,595	342,043
Gadsden, AL	498,535	265,776
Montgomery, AL	2,092,226	1,115,395
Tuscaloosa, AL	1,100,790	586,847
ALASKA	$443,175	$236,263
Fairbanks, AK	443,175	236,263
ARIZONA	$3,076,034	$1,639,878
Avondale, AZ	777,394	414,440
Flagstaff, AZ	570,538	304,162
Prescott, AZ	592,381	315,807
Yuma, AZ--CA	1,135,721	605,469
ARKANSAS	$4,413,910	$2,353,118
Fayetteville--Springdale, AR	1,647,275	878,186
Fort Smith, AR--OK	1,091,673	581,986
Hot Springs, AR	433,140	230,913
Jonesboro, AR	454,905	242,516
Pine Bluff, AR	569,262	303,482
Texarkana, TX--Texarkana, AR	217,655	116,035
CALIFORNIA	$45,205,607	$24,099,741
Atascadero--El Paso de Robles (Paso Robles), CA	550,705	293,588
Camarillo, CA	825,618	440,149
Chico, CA	1,080,532	576,046
Davis, CA	1,200,531	640,020
El Centro, CA	733,256	390,909
Fairfield, CA	1,898,936	1,012,350
Gilroy--Morgan Hill, CA	947,646	505,203
Hanford, CA	876,607	467,332
Hemet, CA	1,496,737	797,931
Livermore, CA	1,119,868	597,017
Lodi, CA	1,236,948	659,434
Lompoc, CA	433,934	231,336
Madera, CA	704,595	375,630
Manteca, CA	783,384	417,633
Merced, CA	1,489,738	794,200
Napa, CA	1,145,300	610,575
Petaluma, CA	836,121	445,748
Porterville, CA	778,207	414,873
Redding, CA	977,956	521,362
Salinas, CA	2,852,431	1,520,671
San Luis Obispo, CA	797,231	425,015
Santa Barbara, CA	2,756,159	1,469,347
Santa Clarita, CA	2,328,569	1,241,393
Santa Cruz, CA	2,035,736	1,085,279
Santa Maria, CA	1,721,562	917,789
Seaside--Monterey--Marina, CA	1,697,589	905,008
Simi Valley, CA	1,835,584	978,576
Tracy, CA	1,038,319	553,542
Turlock, CA	1,057,539	563,789

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Vacaville, CA	1,334,831	711,617
Vallejo, CA	2,821,937	1,504,414
Visalia, CA	1,598,291	852,071
Watsonville, CA	968,423	516,280
Yuba City, CA	1,236,132	659,000
Yuma, AZ--CA	8,655	4,614
COLORADO	$6,760,726	$3,604,238
Boulder, CO	1,616,629	861,847
Grand Junction, CO	896,749	478,070
Greeley, CO	1,193,932	636,502
Lafayette--Louisville, CO	631,603	336,717
Longmont, CO	1,011,977	539,499
Pueblo, CO	1,409,836	751,603
CONNECTICUT	$14,399,987	$7,676,835
Danbury, CT--NY	6,074,747	3,238,533
Norwich--New London, CT	1,570,599	837,308
Waterbury, CT	6,754,641	3,600,994
DELAWARE	$624,206	$332,772
Dover, DE	605,654	322,882
Salisbury, MD--DE	18,552	9,890
FLORIDA	$17,807,805	$9,493,592
Brooksville, FL	876,526	467,288
Deltona, FL	1,434,939	764,986
Fort Walton Beach, FL	1,456,250	776,348
Gainesville, FL	1,722,458	918,266
Kissimmee, FL	1,878,670	1,001,545
Lady Lake, FL	407,345	217,161
Lakeland, FL	1,940,006	1,034,245
Leesburg--Eustis, FL	875,532	466,758
North Port--Punta Gorda, FL	1,098,378	585,561
Ocala, FL	907,332	483,712
Panama City, FL	1,164,212	620,658
St. Augustine, FL	505,149	269,302
Titusville, FL	518,172	276,245
Vero Beach--Sebastian, FL	1,122,163	598,241
Winter Haven, FL	1,425,094	759,738
Zephyrhills, FL	475,579	253,538
GEORGIA	$7,104,592	$3,787,556
Albany, GA	876,379	467,210
Athens-Clarke County, GA	946,339	504,506
Brunswick, GA	440,298	234,729
Dalton, GA	470,000	250,563
Gainesville, GA	704,205	375,421
Hinesville, GA	516,449	275,326
Macon, GA	1,323,483	705,567
Rome, GA	531,766	283,492
Valdosta, GA	540,139	287,956
Warner Robins, GA	755,534	402,786

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
HAWAII	$1,755,356	$935,805
Kailua (Honolulu County)--Kaneohe, HI	1,755,356	935,805
IDAHO	$3,533,870	$1,883,956
Coeur d'Alene, ID	751,420	400,593
Idaho Falls, ID	741,498	395,303
Lewiston, ID--WA	319,223	170,182
Nampa, ID	1,042,036	555,524
Pocatello, ID	679,693	362,354
ILLINOIS	$8,717,262	$4,647,295
Alton, IL	823,268	438,896
Beloit, WI--IL	127,829	68,148
Bloomington--Normal, IL	1,501,485	800,463
Champaign, IL	1,654,079	881,813
Danville, IL	527,045	280,975
Decatur, IL	1,006,792	536,735
DeKalb, IL	759,716	405,015
Dubuque, IA--IL	25,886	13,800
Kankakee, IL	754,272	402,113
Springfield, IL	1,536,890	819,337
INDIANA	$8,314,702	$4,432,683
Anderson, IN	912,310	486,365
Bloomington, IN	1,020,695	544,147
Columbus, IN	526,802	280,845
Elkhart, IN--MI	1,273,063	678,688
Kokomo, IN	644,022	343,337
Lafayette, IN	1,437,785	766,503
Michigan City, IN--MI	698,644	372,457
Muncie, IN	991,156	528,399
Terre Haute, IN	810,225	431,942
IOWA	$6,390,477	$3,406,853
Ames, IA	702,808	374,677
Cedar Rapids, IA	1,907,561	1,016,948
Dubuque, IA--IL	696,028	371,062
Iowa City, IA	993,988	529,909
Sioux City, IA--NE--SD	922,351	491,718
Waterloo, IA	1,167,741	622,539
KANSAS	$2,702,007	$1,440,478
Lawrence, KS	1,166,003	621,612
St. Joseph, MO--KS	9,495	5,062
Topeka, KS	1,526,509	813,804
KENTUCKY	$2,577,879	$1,374,303
Bowling Green, KY	558,755	297,880
Clarksville, TN--KY	244,201	130,187
Huntington, WV--KY--OH	500,526	266,837
Owensboro, KY	676,336	360,564
Radcliff--Elizabethtown, KY	598,061	318,835
LOUISIANA	$7,101,087	$3,785,689
Alexandria, LA	699,354	372,836
Houma, LA	1,218,982	649,856
Lafayette, LA	1,625,601	866,631
Lake Charles, LA	1,221,641	651,274
Mandeville--Covington, LA	561,543	299,366
Monroe, LA	1,045,630	557,440
Slidell, LA	728,336	388,286

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
MAINE	$3,046,639	$1,624,207
Bangor, ME	553,126	294,879
Dover--Rochester, NH--ME	58,026	30,935
Lewiston, ME	598,463	319,049
Portland, ME	1,761,767	939,223
Portsmouth, NH--ME	75,257	40,121
MARYLAND	$5,976,323	$3,186,061
Aberdeen--Havre de Grace--Bel Air, MD	1,724,343	919,271
Cumberland, MD-WV-PA	477,973	254,814
Frederick, MD	1,114,772	594,301
Hagerstown, MD--WV--PA	865,332	461,321
Salisbury, MD--DE	516,832	275,530
St. Charles, MD	719,953	383,817
Westminster, MD	557,118	297,007
MASSACHUSETTS	$3,339,753	$1,780,468
Leominster--Fitchburg, MA	1,142,978	609,337
Nashua, NH--MA	225	120
New Bedford, MA	1,696,493	904,424
Pittsfield, MA	500,057	266,587
MICHIGAN	$10,948,727	$5,836,921
Battle Creek, MI	747,140	398,311
Bay City, MI	760,747	405,565
Benton Harbor--St. Joseph, MI	552,348	294,464
Elkhart, IN--MI	16,673	8,889
Holland, MI	958,014	510,731
Jackson, MI	868,421	462,968
Kalamazoo, MI	1,873,258	998,660
Michigan City, IN--MI	4,453	2,374
Monroe, MI	536,919	286,239
Muskegon, MI	1,463,310	780,111
Port Huron, MI	818,836	436,533
Saginaw, MI	1,467,498	782,344
South Lyon--Howell--Brighton, MI	881,110	469,732
MINNESOTA	$3,580,024	$1,908,561
Duluth, MN--WI	898,587	479,049
Fargo, ND--MN	447,803	238,730
Grand Forks, ND--MN	95,770	51,056
La Crosse, WI--MN	54,504	29,057
Rochester, MN	1,035,920	552,264
St. Cloud, MN	1,047,440	558,405
MISSISSIPPI	$1,103,147	$588,103
Hattiesburg, MS	585,200	311,978
Pascagoula, MS	517,947	276,125
MISSOURI	$3,605,824	$1,922,316
Columbia, MO	1,029,489	548,835
Jefferson City, MO	487,340	259,808
Joplin, MO	625,390	333,404
Lee's Summit, MO	651,809	347,489
St. Joseph, MO--KS	811,796	432,780
MONTANA	$2,568,467	$1,369,286
Billings, MT	1,118,648	596,367
Great Falls, MT	726,863	387,501
Missoula, MT	722,956	385,418

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
N. MARIANA ISLANDS	$672,596	$358,570
Saipan, MP	672,596	358,570
NEBRASKA	$180,026	$95,974
Sioux City, IA--NE--SD	180,026	95,974
NEVADA	$631,628	$336,730
Carson City, NV	631,628	336,730
NEW HAMPSHIRE	$4,334,932	$2,311,013
Dover--Rochester, NH--ME	641,869	342,189
Manchester, NH	1,535,283	818,481
Nashua, NH--MA	1,801,080	960,181
Portsmouth, NH--ME	356,700	190,162
NEW JERSEY	$2,089,730	$1,114,065
Hightstown, NJ	807,591	430,538
Vineland, NJ	812,743	433,285
Wildwood--North Wildwood--Cape May, NJ	469,396	250,242
NEW MEXICO	$2,270,689	$1,210,537
Farmington, NM	459,513	244,973
Las Cruces, NM	1,005,197	535,885
Santa Fe, NM	805,979	429,679
NEW YORK	$6,234,420	$3,323,657
Binghamton, NY--PA	1,691,034	901,514
Danbury, CT--NY	39,482	21,048
Elmira, NY	704,214	375,426
Glens Falls, NY	556,755	296,814
Ithaca, NY	541,559	288,713
Kingston, NY	510,525	272,168
Middletown, NY	503,265	268,298
Saratoga Springs, NY	461,428	245,994
Utica, NY	1,226,158	653,682
NORTH CAROLINA	$10,002,546	$5,332,500
Burlington, NC	867,092	462,259
Concord, NC	999,368	532,777
Gastonia, NC	1,201,251	640,404
Goldsboro, NC	512,559	273,253
Greenville, NC	865,825	461,584
Hickory, NC	1,446,570	771,187
High Point, NC	1,206,685	643,301
Jacksonville, NC	887,348	473,058
Rocky Mount, NC	576,404	307,289
Wilmington, NC	1,439,444	767,388
NORTH DAKOTA	$3,040,342	$1,620,850
Bismarck, ND	840,011	447,822
Fargo, ND--MN	1,487,689	793,108
Grand Forks, ND--MN	712,642	379,920
OHIO	$8,095,234	$4,315,684
Huntington, WV--KY--OH	332,098	177,046
Lima, OH	709,539	378,265
Lorain--Elyria, OH	2,167,939	1,155,759
Mansfield, OH	757,737	403,960
Middletown, OH	995,137	530,522
Newark, OH	740,694	394,875
Parkersburg, WV--OH	234,693	125,118
Sandusky, OH	503,335	268,335

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Springfield, OH	965,130	514,524
Weirton, WV--Steubenville, OH--PA	399,899	213,192
Wheeling, WV--OH	289,033	154,088
OKLAHOMA	$2,001,543	$1,067,051
Fort Smith, AR--OK	20,513	10,936
Lawton, OK	863,571	460,382
Norman, OK	1,117,459	595,733
OREGON	$2,620,730	$1,397,147
Bend, OR	548,298	292,305
Corvallis, OR	621,072	331,102
Longview, WA--OR	14,635	7,802
Medford, OR	1,436,725	765,938
PENNSYLVANIA	$10,500,620	$5,598,026
Altoona, PA	921,066	491,033
Binghamton, NY--PA	33,109	17,651
Cumberland, MD-WV-PA	122	65
Erie, PA	2,316,875	1,235,158
Hagerstown, MD--WV--PA	11,215	5,979
Hazleton, PA	522,158	278,370
Johnstown, PA	765,418	408,055
Lebanon, PA	700,662	373,533
Monessen, PA	533,511	284,422
Pottstown, PA	654,275	348,803
State College, PA	1,010,555	538,741
Uniontown--Connellsville, PA	515,055	274,583
Weirton, WV--Steubenville, OH--PA	2,424	1,292
Williamsport, PA	652,004	347,592
York, PA	1,862,171	992,749
PUERTO RICO	$10,256,699	$5,467,990
Arecibo, PR	1,397,071	744,798
Fajardo, PR	798,294	425,582
Florida--Barceloneta--Bajadero, PR	621,577	331,372
Guayama, PR	811,817	432,791
Juana Diaz, PR	545,334	290,725
Mayaguez, PR	1,263,499	673,589
Ponce, PR	2,780,303	1,482,218
San German--Cabo Rojo--Sabana Grande, PR	977,678	521,214
Yauco, PR	1,061,126	565,701
RHODE ISLAND	0	0
SOUTH CAROLINA	$5,231,300	$2,788,880
Anderson, SC	567,172	302,367
Florence, SC	551,490	294,007
Mauldin--Simpsonville, SC	703,056	374,809
Myrtle Beach, SC	1,054,202	562,010
Rock Hill, SC	586,172	312,497
Spartanburg, SC	1,180,355	629,264
Sumter, SC	588,853	313,926
SOUTH DAKOTA	$2,336,117	$1,245,417
Rapid City, SD	745,734	397,561
Sioux City, IA--NE--SD	30,053	16,022
Sioux Falls, SD	1,560,330	831,834
TENNESSEE	$5,688,024	$3,032,365
Bristol, TN--Bristol, VA	308,326	164,373
Clarksville, TN--KY	904,550	482,228

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Cleveland, TN	496,808	264,856
Jackson, TN	637,273	339,739
Johnson City, TN	853,252	454,881
Kingsport, TN--VA	745,395	397,380
Morristown, TN	463,008	246,836
Murfreesboro, TN	1,279,412	682,072
TEXAS	$30,160,283	$16,078,868
Abilene, TX	1,210,369	645,265
Amarillo, TX	2,108,381	1,124,007
Beaumont, TX	1,375,777	733,446
Brownsville, TX	2,156,201	1,149,501
College Station--Bryan, TX	1,654,547	882,062
Galveston, TX	949,903	506,406
Harlingen, TX	1,141,541	608,572
Killeen, TX	2,064,591	1,100,662
Lake Jackson--Angleton, TX	814,584	434,266
Laredo, TX	2,860,024	1,524,719
Longview, TX	736,257	392,509
McKinney, TX	581,710	310,117
Midland, TX	1,106,426	589,851
Odessa, TX	1,212,651	646,481
Port Arthur, TX	1,372,156	731,515
San Angelo, TX	919,624	490,265
Sherman, TX	562,313	299,777
Temple, TX	715,985	381,702
Texarkana, TX--Texarkana, AR	407,162	217,064
Texas City, TX	935,864	498,922
The Woodlands, TX	986,269	525,794
Tyler, TX	1,017,160	542,262
Victoria, TX	525,298	280,044
Waco, TX	1,710,361	911,817
Wichita Falls, TX	1,035,129	551,842
UTAH	$1,451,741	$773,944
Logan, UT	807,967	430,739
St. George, UT	643,774	343,205
VERMONT	$1,038,637	$553,712
Burlington, VT	1,038,637	553,712
VIRGINIA	$7,041,958	$3,754,168
Blacksburg, VA	635,667	338,883
Bristol, TN--Bristol, VA	181,418	96,716
Charlottesville, VA	904,362	482,128
Danville, VA	482,472	257,213
Fredericksburg, VA	901,071	480,374
Harrisonburg, VA	556,371	296,609
Kingsport, TN--VA	14,064	7,498
Lynchburg, VA	873,900	465,889
Roanoke, VA	1,977,168	1,054,056
Winchester, VA	515,465	274,802
WASHINGTON	$9,881,675	$5,268,061
Bellingham, WA	981,437	523,218
Bremerton, WA	1,670,330	890,476
Kennewick--Richland, WA	1,561,859	832,649
Lewiston, ID--WA	186,515	99,434
Longview, WA--OR	668,666	356,475
Marysville, WA	1,082,250	576,963
Mount Vernon, WA	492,104	262,348
Olympia--Lacey, WA	1,364,391	727,376

FEDERAL TRANSIT ADMINISTRATION

TABLE 4

FY 2004 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Wenatchee, WA	601,743	320,798
Yakima, WA	1,272,380	678,324
WEST VIRGINIA	$4,925,078	$2,625,629
Charleston, WV	1,760,180	938,377
Cumberland, MD-WV-PA	20,295	10,820
Hagerstown, MD--WV--PA	266,189	141,909
Huntington, WV--KY--OH	898,282	478,887
Morgantown, WV	542,640	289,289
Parkersburg, WV--OH	607,572	323,905
Weirton, WV--Steubenville, OH--PA	276,209	147,251
Wheeling, WV--OH	553,711	295,191
WISCONSIN	$13,811,177	$7,362,931
Appleton, WI	2,280,441	1,215,735
Beloit, WI--IL	477,090	254,343
Duluth, MN--WI	292,606	155,992
Eau Claire, WI	873,290	465,563
Fond du Lac, WI	593,633	316,474
Green Bay, WI	2,132,977	1,137,120
Janesville, WI	746,506	397,973
Kenosha, WI	1,366,528	728,515
La Crosse, WI--MN	957,303	510,352
Oshkosh, WI	883,505	471,009
Racine, WI	1,661,947	886,007
Sheboygan, WI	850,618	453,476
Wausau, WI	694,733	370,372
WYOMING	$1,374,734	$732,890
Casper, WY	646,386	344,597
Cheyenne, WY	728,348	388,293
TOTAL	**$327,508,760**	**$174,599,518**

FEDERAL TRANSIT ADMINISTRATION

TABLE 5

FY 2004 SECTION 5311 NONURBANIZED AREA FORMULA APPORTIONMENTS, AND SECTION 5311(b)(2) RURAL TRANSIT ASSISTANCE PROGRAM (RTAP) APPORTIONMENTS

STATE	SECTION 5311 APPORTIONMENT	SECTION 5311(b)(2) APPORTIONMENT	AVAILABLE SECTION 5311 APPORTIONMENT	AVAILABLE SECTION 5311(b)(2) APPORTIONMENT
Alabama	$6,667,593	$117,113	$3,558,461	$65,006
Alaska	929,305	72,263	495,965	39,828
American Samoa	152,438	11,191	81,355	6,169
Arizona	3,252,704	90,423	1,735,952	50,022
Arkansas	4,823,046	102,697	2,574,035	56,912
California	10,249,275	145,107	5,469,986	80,721
Colorado	2,895,675	87,632	1,545,407	48,455
Connecticut	1,482,228	76,585	791,057	42,254
Delaware	672,024	70,252	358,656	38,699
Florida	6,684,574	117,246	3,567,523	65,080
Georgia	8,451,488	131,056	4,510,516	72,833
Guam	411,900	13,219	219,829	7,307
Hawaii	999,450	72,812	533,402	40,135
Idaho	1,836,315	79,352	980,032	43,807
Illinois	7,135,696	120,772	3,808,285	67,060
Indiana	7,103,057	120,517	3,790,865	66,916
Iowa	4,820,069	102,673	2,572,446	56,899
Kansas	3,939,493	95,791	2,102,488	53,035
Kentucky	6,585,421	116,471	3,514,606	64,645
Louisiana	5,144,225	105,207	2,745,447	58,322
Maine	2,556,919	84,985	1,364,615	46,969
Maryland	2,658,175	85,776	1,418,654	47,413
Massachusetts	1,899,702	79,848	1,013,861	44,085
Michigan	8,939,821	134,873	4,771,137	74,976
Minnesota	5,874,251	110,913	3,135,058	61,525
Mississippi	5,759,841	110,018	3,073,998	61,023
Missouri	6,664,068	117,086	3,556,579	64,990
Montana	1,777,392	78,892	948,585	43,549
N. Mariana Islands	20,025	10,157	10,687	5,588
Nebraska	2,411,059	83,845	1,286,770	46,329
Nevada	856,628	71,695	457,178	39,509
New Hampshire	1,819,852	79,224	971,246	43,735
New Jersey	1,757,590	78,737	938,017	43,462
New Mexico	2,545,560	84,896	1,358,553	46,919
New York	9,237,750	137,201	4,930,140	76,283
North Carolina	11,410,542	154,184	6,089,748	85,816
North Dakota	1,094,647	73,556	584,208	40,553
Ohio	10,754,410	149,056	5,739,574	82,938
Oklahoma	5,233,770	105,907	2,793,236	58,714
Oregon	3,845,539	95,056	2,052,345	52,623
Pennsylvania	10,829,460	149,642	5,779,628	83,267
Puerto Rico	883,159	71,903	471,337	39,625
Rhode Island	319,824	67,500	170,689	37,153
South Carolina	5,689,227	109,467	3,036,311	60,713
South Dakota	1,490,721	76,651	795,590	42,291
Tennessee	7,249,420	121,661	3,868,979	67,559
Texas	16,113,490	190,941	8,599,687	106,451
Utah	1,290,708	75,088	688,845	41,413
Vermont	1,339,595	75,470	714,935	41,628
Virgin Islands	288,991	12,259	154,233	6,768
Virginia	6,293,279	114,188	3,358,691	63,363
Washington	4,231,465	98,073	2,258,311	54,317
West Virginia	3,441,140	91,896	1,836,519	50,849
Wisconsin	6,708,274	117,431	3,580,172	65,184
Wyoming	978,792	72,650	522,376	40,045
TOTAL	**$238,501,062**	**$5,219,104**	**$127,286,805**	**$2,891,730**

FEDERAL TRANSIT ADMINISTRATION

TABLE 6

FY 2004 SECTION 5310 ELDERLY AND PERSONS WITH DISABILITIES APPORTIONMENTS

STATE	APPORTIONMENT	AVAILABLE APPORTIONMENT
Alabama	$1,577,848	$845,217
Alaska	239,902	181,960
American Samoa	60,053	54,984
Arizona	1,647,527	879,759
Arkansas	1,026,721	572,008
California	9,456,317	4,750,789
Colorado	1,156,406	636,296
Connecticut	1,125,150	620,802
Delaware	352,200	237,629
District of Columbia	308,401	215,917
Florida	6,044,201	3,059,310
Georgia	2,288,079	1,197,298
Guam	157,115	140,920
Hawaii	474,925	298,467
Idaho	454,617	288,400
Illinois	3,514,414	1,805,225
Indiana	1,865,436	987,782
Iowa	977,883	547,797
Kansas	880,015	499,282
Kentucky	1,457,184	785,400
Louisiana	1,450,921	782,295
Maine	531,663	326,594
Maryland	1,540,533	826,718
Massachusetts	2,034,741	1,071,711
Michigan	2,929,051	1,515,045
Minnesota	1,361,686	738,059
Mississippi	1,029,560	573,415
Missouri	1,783,015	946,924
Montana	383,581	253,186
N. Mariana Islands	60,959	55,433
Nebraska	594,868	357,926
Nevada	719,862	419,889
New Hampshire	456,694	289,430
New Jersey	2,579,198	1,341,613
New Mexico	653,360	386,923
New York	6,070,348	3,072,272
North Carolina	2,555,231	1,329,732
North Dakota	310,078	216,748
Ohio	3,419,683	1,758,265
Oklahoma	1,204,626	660,200
Oregon	1,119,039	617,772
Pennsylvania	4,030,787	2,061,206
Puerto Rico	1,395,270	754,708
Rhode Island	461,827	291,974
South Carolina	1,378,880	746,583
South Dakota	338,559	230,867
Tennessee	1,908,598	1,009,178
Texas	5,625,331	2,851,665
Utah	590,694	355,857
Vermont	293,836	208,697
Virgin Islands	150,682	137,731
Virginia	2,011,109	1,059,996
Washington	1,715,373	913,392
West Virginia	782,034	450,710
Wisconsin	1,569,358	841,008
Wyoming	255,598	189,741
TOTAL	**$90,361,027**	**$48,248,705**

FEDERAL TRANSIT ADMINISTRATION
TABLE 7

FY 2004 SECTION 5309 FIXED GUIDEWAY MODERNIZATION APPORTIONMENTS

STATE	AREA	APPORTIONMENT	AVAILABLE APPORTIONMENT
AK	Anchorage, AK - Alaska Railroad	$2,039,405	$1,103,335
AZ	Phoenix--Mesa, AZ	2,300,373	1,244,521
CA	Concord, CA	7,497,530	4,056,227
CA	Lancaster--Palmdale, CA	1,816,912	982,965
CA	Los Angeles--Long Beach--Santa Ana, CA	33,716,101	18,240,696
CA	Mission Viejo, CA	1,244,800	673,447
CA	Oxnard, CA	1,054,392	570,435
CA	Riverside--San Bernardino, CA	3,504,777	1,896,114
CA	Sacramento, CA	3,116,717	1,686,171
CA	San Diego, CA	13,193,789	7,137,952
CA	San Francisco--Oakland, CA	66,233,207	35,832,726
CA	San Jose, CA	12,981,956	7,023,348
CA	Thousand Oaks, CA	578,794	313,133
CO	Denver--Aurora, CO	3,041,909	1,645,698
CT	Hartford, CT	1,568,213	848,417
CT	Southwestern Connecticut	39,099,565	21,153,196
DC	Washington, DC--VA--MD	63,862,240	34,550,013
FL	Jacksonville, FL	106,587	57,665
FL	Miami, FL	17,521,309	9,479,176
FL	Tampa--St. Petersburg, FL	118,403	64,057
GA	Atlanta, GA	26,718,394	14,454,877
HI	Honolulu, HI	1,118,490	605,113
IL	Chicago, IL--IN	139,271,688	75,347,163
IL	Round Lake Beach--McHenry--Grayslake, IL-WI	2,090,455	1,130,954
IN	South Bend, IN--MI	703,817	380,771
LA	New Orleans, LA	2,843,412	1,538,310
MA	Boston, MA-NH-RI	70,481,969	38,131,342
MA	Worcester, MA--CT	920,125	497,795
MD	Baltimore Commuter Rail	18,648,081	10,088,770
MD	Baltimore, MD	9,180,255	4,966,596
MI	Detroit, MI	591,335	319,917
MN	Minneapolis--St. Paul, MN	5,993,572	3,242,573
MO	Kansas City, MO--KS	29,842	16,145
MO	St. Louis, MO--IL	4,191,569	2,267,674
NJ	Atlantic City, NJ	1,509,365	816,579
NJ	Northeastern New Jersey	85,710,342	46,370,021
NJ	Trenton, NJ	1,377,322	745,143
NY	Buffalo, NY	1,292,578	699,296
NY	New York	363,875,535	196,859,746
OH	Cleveland, OH	12,773,513	6,910,579
OH	Dayton, OH	4,884,526	2,642,570
OR	Portland, OR--WA	4,181,173	2,262,050
PA	Harrisburg, PA	722,617	390,942
PA	Philadelphia, PA-NJ-DE-MD	19,671,814	10,642,618
PA	Philadelphia/Southern New Jersey	74,243,371	40,166,293
PA	Pittsburgh, PA	20,436,444	11,056,289
PR	San Juan, PR	2,252,934	1,218,857
RI	Providence, RI--MA	2,713,999	1,468,297
TN	Chattanooga, TN--GA	83,841	45,358
TN	Memphis, TN--MS--AR	200,995	108,740
TX	Dallas--Fort Worth--Arlington, TX	3,135,228	1,696,185
TX	Houston, TX	6,847,000	3,704,285
VA	Virginia Beach, VA	1,235,828	668,593
WA	Seattle, WA	22,120,743	11,967,510
WI	Madison, WI	744,588	402,828
	TOTAL	**$1,187,393,739**	**$642,390,071**

FEDERAL TRANSIT ADMINISTRATION

TABLE 8

FY 2004 SECTION 5309 NEW STARTS ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	ALLOCATION	AVAILABLE ALLOCATION
AK/HI	Hawaii and Alaska Ferry Boats	10,133,105	5,192,897
AL	Birmingham Transit Corridor, Alabama	3,444,626	1,765,272
AR	Little Rock, Arkansas, River Rail Streetcar Project	2,952,537	1,513,093
AZ	Phoenix, Arizona, Central Phoenix/East Valley Light Rail Transit Project	12,794,325	6,556,684
CA	BART San Francisco Airport (SFO), California, Extension Project	98,417,890	50,435,960
CA	Phase II, LA to Pasadena Metro Gold Line Light Rail Project	3,936,715	2,017,452
CA	San Diego, California, Mission Valley East Light Rail Transit Extension	63,971,625	32,783,362
CA	San Diego, California, Oceanside - Escondido Rail Project	47,240,585	24,209,256
CA	San Francisco, California, Muni Third Street Light Rail Project	8,857,610	4,539,248
CA	San Jose, California, Silicon Valley Rapid Transit Corridor	1,968,358	1,008,734
CO	Denver, Colorado, Southeast Corridor LRT (T-REX)	78,734,308	40,348,750
CT	Stamford, Connecticut, Urban Transitway & Intermodal Transportation Center Improvements	3,936,715	2,017,452
DC	Washington, DC/VA Dulles Corridor Rapid Transit Project	19,683,577	10,087,199
DE	Wilmington, Delaware, Train Station Improvements	1,476,268	756,554
FL	Fort Lauderdale, Florida, Tri-Rail Commuter Project	18,118,733	9,285,268
GA	Atlanta, Georgia, Northwest Corridor BRT	2,115,407	1,084,090
IL	Chicago, Illinois, Metra Commuter Rail Expansions and Extensions	51,177,300	26,226,692
IL	Chicago, Illinois Transit Authority, Douglas Branch Reconstruction	83,655,202	42,870,545
IL	Chicago, Illinois, Ravenswood Reconstruction	9,841,789	5,043,607
IN	South Shore Commuter Rail Service Capacity Enhancement, Indiana	984,179	504,374
LA	New Orleans, Louisiana, Canal Street Streetcar Project	22,922,877	11,747,233
MA	Boston, Massachusetts, Silver Line Phase III	1,968,358	1,008,734
MD	Baltimore, Maryland, Central Light Rail Double Track Project	39,367,154	20,174,382
MD	Washington, DC/MD, Largo Extension	63,971,625	32,783,362
ME	Maine Marine Highway	1,525,477	781,772
ME	Yarmouth to Auburn Line, Maine	984,179	504,374
MN	Minneapolis, Minnesota, Hiawatha Corridor Light Rail Transit (LRT)	73,793,730	37,816,866
MN	Minneapolis, Minnesota, Northstar Corridor Rail Project	5,659,028	2,900,080
NC	Charlotte, North Carolina, South Corridor Light Rail Project	11,810,146	6,052,325
NC	Raleigh, North Carolina, Tnangle Transit Regional Rail Project	5,412,984	2,773,991
NC	Western North Carolina Rail Passenger Service	984,179	504,374
NJ	Newark-Elizabeth, New Jersey, Rail Link (NERL) MOS-1	22,209,000	11,381,395
NJ	Northern, New Jersey Hudson - Bergen Light Rail MOS-2	98,417,885	50,435,933
NV	Las Vegas, Nevada, Resort Corridor Fixed Guideway, MOS	19,683,577	10,087,199
NY	Eastside Access Project, New York, Phase I	73,813,414	37,826,954
NY	New York, Second Avenue Subway	1,968,358	1,008,734
OH	Cleveland, Ohio, Euclid Corridor Transportation Project	10,825,967	5,547,966
OK	Northern Oklahoma Regional Multimodal Transportation System	2,952,537	1,513,093
OR	Portland, Oregon, Interstate MAX Light Rail Extension	76,273,861	39,087,852
OR	Wilsonville to Beaverton, Oregon, Commuter Rail	3,198,581	1,639,182
PA	Philadelphia, Pennsylvania, Schuylkill Valley Metro	13,778,504	7,061,044
PA	Pittsburgh, Pennsylvania, North Shore Connector	9,841,789	5,043,607
PA	Pittsburgh, Pennsylvania, Stage II Light Rail Transit Reconstruction	31,733,314	16,262,291
PA	Scranton, Pennsylvania, New York City Rail Service	2,460,447	1,260,913
PR	Tren Urbano Rapid Transit System, San Juan, Puerto Rico	19,683,577	10,087,199
RI	Integrated Intermodal Project, Rhode Island	2,952,537	1,513,093
TN	Memphis, Tennessee, Medical Center Rail Extension	9,101,281 a/	4,664,121
TX	Dallas, Texas, North Central Light Rail Extension	29,684,097	15,212,135
TX	Houston Advanced Metro Transit Plan, Texas	7,873,431	4,034,889
UT	Regional Commuter Rail (Weber County to Salt Lake City), Utah	8,857,610	4,539,248
UT	Salt Lake City, Utah, Medical Center LRT Extension	30,178,231	15,465,363
VA	VRE Parking Improvements, Virginia	2,952,537	1,513,093
WA	Seattle, Washington, South Transit Central Link Initial Segment	73,813,414	37,826,954
WI	Kenosha-Racine-Milwaukee Commuter Rail Extension, Wisconsin	3,198,581	1,639,182
	TOTAL ALLOCATION	**$1,307,293,121**	**$669,945,422**

a/ SEC. 174 of the Consolidated Appropriations Act, 2004 provides that to the extent that funds provided by the Congress for the Memphis Medical Center light rail extension project through the Section 5309 new fixed guideway systems program remain available upon the closeout of the project, Federal Transit Administration is directed to permit the Memphis Area Transit Authority to use all of those funds for planning, engineering, design, construction or acquisition projects pertaining to the Memphis Regional Rail Plan. Such funds shall remain available until expended.

FEDERAL TRANSIT ADMINISTRATION

TABLE 8A

PRIOR YEAR UNOBLIGATED SECTION 5309 NEW START ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	FY 2002 UNOBLIGATED ALLOCATIONS	FY 2003 UNOBLIGATED ALLOCATIONS	TOTAL UNOBLIGATED ALLOCATIONS	
AK/HI	Alaska/Hawaii Ferry Project	$10,193,175	$10,126,964	$20,320,139	a/
AK	Wasilla Alternative Route Project	2,475,033	0	2,475,033	
AL	Birmingham- Transit Corridor Project	1,980,026	1,967,165	3,947,191	
AR	Little Rock River Rail Streetcar Project	0	1,672,090	1,672,090	
AZ	Phoenix-Central Phoenix/East Valley Corridor Project	9,900,131	11,802,989	21,703,120	
CA	Orange County Centerline Light Rail Project	0	1,475,374	1,475,374	
CA	San Diego- Mid-Coast Corridor Project	990,013	0	990,013	
CA	Stockton-Altamont Commuter Rail Project	1,762,326	983,582	2,745,908	
CT	Bridgeport Intermodal Transportation Center	0	2,458,956	2,458,956	
CT	Metro North Rolling Stock	0	3,934,330	3,934,330	
CT	Stamford Urban Transitway Project	4,950,065	9,835,824	14,785,889	
DE	Wilmington-Downtown Transit Connector Project (Commuter Rail Improvements)	0	4,953,216	4,953,216	
DE	Wilmington Train Station Improvements	0	1,967,165	1,967,165	
FL	Fort Lauderdale Tri-County Commuter Rail Upgrades	0	28,769,785	28,769,785	
HI	Honolulu bus Rapid Transit Project	11,880,157	0	11,880,157	
IA	Des Moines DSM Bus Feasibility Project	148,502	0	148,502	
IA	Iowa Matrolink Light Rail Feasibility Project	297,004	0	297,004	
IA	Sioux City Light Rail Project	1,683,022	0	1,683,022	
IN	Indianapolis-Northeast Downtown Corridor Project	2,475,033	0	2,475,033	
KS	Johnson County, Kansas - Kansas City, Missouri-I-35 Commuter Rail Project	1,485,020	0	1,485,020	
LA	New Orleans Canal Street Cer Line Project	0	21,638,813	21,638,813	
LA	New Orleans Desire Corridor Streetcar Project	1,188,016	0	1,188,016	
MA	Boston-North Shore Corridor Project	0	332,451	332,451	
MA	Boston-South Boston Piers Transitway Project	0	669,820	669,820	
MA/NH	Lowell, MA - Neshua, NH Commuter Rail Project	2,970,039	2,950,747	5,920,786	
MD	MARC Commuter Rail Improvements Project	11,880,157	11,557,093	23,437,250	
MN	Minneapolis Rice, Northstar Corridor Commuter Rail Project	9,900,131	4,917,912	14,818,043	
NC	Charlotte-North-South Corridor Transitway Project	3,003,883	10,819,406	13,823,289	
NC	Raleigh-Durham-Chapel Hill-Triangle Transit Project	5,190,704	8,852,242	14,042,946	
NM	Albuquerque Light Rail Project	990,013	0	990,013	
NV	Las Vegas Resort Corridor Fixed Guideway Project	0	6,885,077	6,885,077	
OH	Cleveland-Euclid Corridor Improvement Project	0	400,000	400,000	
OR	Washington County Wilsonville to Beaverton Commuter Rail Project	0	2,458,956	2,458,956	
PA	Philadelphia-Reading SEPTA Schuylkill Valley Metro Project	8,910,118	8,852,242	17,762,360	
PA	Pittsburgh-North Shore- Central Business District Corridor Project	0	6,909,666	6,909,666	
PA	Scranton to New York City, New York Passenger Rail Service	0	1,967,165	1,967,165	
PR	San Juan Tren Urbano Project	0	39,343,296	39,343,296	
TX	Houston-Advanced Transit Program	0	7,894,406	7,894,406	
UT	Ogden to Provo Commuter Rail Corridor Project	0	1,645,592	1,645,592	
VA	Dulles Corridor Project	24,750,327	26,064,934	50,815,261	
VA	Virginia Railway Express	0	1,967,165	1,967,165	
VT	Burlington-Middlebury Commuter Rail Project	0	1,475,374	1,475,374	
VT	Vermont Transportation Authority Rolling Stock	0	491,791	491,791	
WA	Puget Sound RTA Sounder Commuter Rail Project	9,900,131	29,507,472	39,407,603	
WI	Kenosha-Racine-Milwaukee Commuter Rail Project	1,980,026	0	1,980,026	
	TOTAL UNOBLIGATED ALLOCATION	**$130,883,052**	**$277,549,060**	**$408,432,112**	

Fiscal Years 2000 and 2001 Allocations Extended in FY 2004 Conference Report (House Rpt. 108-401)

AL	Birmingham Transit Corridor	$4,953,216	
CA	Hollister/Gilroy Branch Line Rail Extension Project	990,644	
CA	Los Angeles-San Diego LOSSAN Corridor Project	2,971,930	
CO	Roaring Fork, Colorado Valley Project	1,971,723	b/
DC/VA	Dulles, Virginia Corridor Project	58,932,526	
DE	Wilmington, Delaware Commuter Rail Project	4,953,216	c/
IN	Indianapolis, Indiana Northeast-Downtown Corridor Project	2,753,009	
MA	Lowell, Massachusetts-Neshua, New Hampshire Commuter Rail Project	1,195,286	
NM	Albuquerque Mess Transit Project	3,821,637	
PA	Philadelphia, Pennsylvania SEPTA Cross County Metro Project	1,981,286	
VT	Burlington-Bennington (ABRB), Vermont Commuter Rail Project	1,981,286	
WI	Kenosha-Racine-Milwaukee, Wisconsin Rail Extension Project	4,943,651	
	Total Extended Allocations	**$91,449,410**	d/

a/ SEC. 163 of the Consolidated Appropriations Act, 2004 provides that funds made available for Alaska or Hawaii ferry boats or ferry terminal facilities pursuant to 49 U.S.C. 5309(m)(2)(B) may be used to construct new vessels and facilities, or to improve existing vessels and facilities, including both the passenger and vehicle-related elements of such vessels and facilities, and for repair facilities: Provided, That not more than $3,000,000 of the funds made available pursuant to 49 U.S.C. 5309(m)(2)(B) may be used by the State of Hawaii to initiate and operate a passenger ferryboat services demonstration project to test the viability of different intra-island and inter-island ferry boat routes and technology: Provided further, That notwithstanding 49 U.S.C. 5302(a)(7), funds made available for Alaska or Hawaii ferry boats may be used to acquire passenger ferry boats and to provide passenger ferry transportation services within areas of the State of Hawaii under the control or use of the National Park Service

b/ SEC. 164 of the Consolidated Appropriations Act, 2004 provides that notwithstanding any other provision of law, funds made available to the Colorado Roaring Fork Transportation Authority under 'Federal Transit Administration, Capital investment grants' in Public Laws 106-69 and 106-346 shall be available for expenditure on park and ride lots in Carbondale and Glenwood Springs, Colorado as part of the Roaring Fork Valley Bus Rapid Transit project.

c/ FY 2003 DOT Appropriations made these FY 2001 funds available for commuter rail improvements. Funds now available until September 30, 2005.

d/ Period of availability for funds extended in the Conference Report accompanying the Consolidated Appropriations Act, 2004 is one additional year, and they will lapse September 30, 2004. Projects extended in the FY 2004 Conference Report whose funds were obligated as of September 30, 2003 are not listed.

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
AK	Alaska Mobility Coalition Bus Replacement	$491,130	$288,695
AK	Anchorage Ship Creek Intermodal Facility, Alaska	1,964,520	1,154,782
AK	Arctic Wintar Gamas busas and bus facilities, Alaska	1,473,390	866,086
AK	Coffman-Cova Inner Island Farry/Bus Tarminal, Alaska	1,473,390	866,086
AK	Girdwood Transportation Centar, Alaska	982,260	577,391
AK	Port McKenzia Intarmodal Facility, Alaska	982,260	577,391
AK	Port of Anchorage Intarmodal Facility, Alaska	2,946,779	1,732,172
AK	Sawmill Craak Intarmodal Facility, Alaska	1,964,520	1,154,782
AL	Alabama A&M Univarsity Transit Loop, Alabama	1,473,390	866,086
AL	Alabama Area Agancias on Aging Sanior Van Raplacamant	982,260	577,391
AL	Alabama Stata Docks Intarmodal Facility	9,331,468	5,485,211
AL	Birmingham Downtown Intermodal Facility phasa II, Alabama	3,437,909	2,020,867
AL	Cummings Rasaarch Park Commarcial Cantar Intarmodal Facility, Alabama	1,964,520	1,154,782
AL	Huntsville Airport Phase III Intarmodal Facility, Alabama	3,437,909	2,020,867
AL	Jasper Bus Raplacement, Alabama	39,290	23,095
AL	Mobila Watarfront Tarminal and Maritima Canter of the Gulf, Alabama	4,420,169	2,598,258
AL	Northwast Shoals Community Collega Transportation Modarnization, Alabama	442,017	259,826
AL	Oranga Baach Sanior Activity Center busas, Alabama	98,226	57,739
AL	Troy Stata Univarsity Bus Shuttla Program, Troy, Alabama	1,473,390	866,086
AR	Arkansas Statawida busas and bus facilitias	4,665,734	2,742,606
AR	Fort Smith Transit Facility Arkansas	736,695	433,043
AR	Southaast Arkansas Araa Agancias on Aging busas and bus facilitias, Arkansas	314,323	184,765
AZ	Altarnativa Fuel Raplacamant Busas for Sun Tran, Arizona	491,130	288,695
AZ	Coconino County buses and bus facilitias, Arizona	1,375,164	808,347
AZ	Masa Operating Facility, Arizona	1,964,520	1,154,782
AZ	Phoanix/Glandala West Vallay Operating Facility, Arizona	4,911,299	2,886,953
AZ	Phoanix/Regional Haavy Maintanance Facility, Arizona	982,260	577,391
AZ	Ronstadt Transit Canter Modifications, Arizona	2,946,779	1,732,172
AZ	Tampe Downtown Transit Cantar, Arizona	491,130	288,695
AZ	Tampe/Scottsdala East Vallay Facilitias, Arizona	3,929,039	2,309,562
AZ	Tucson Altarnativa Fual Raplacamant Buses, Arizona	3,536,135	2,078,606
CA	AC Transit Expansion Busas, California	982,260	577,391
CA	Access Enhancamants to Sierra Madra Villa Gold Lina Station, California	589,356	346,434
CA	Alameda Point Arail Transit Project, California	491,130	288,695
CA	Anaheim Rasort Transit (ART), California	491,130	288,695
CA	Antalope Vallay Transit Authority Operations and Maintenance Facility, California	1,227,825	721,738
CA	Baldwin Park Downtown/Matrolink Parking Improvements, California	245,565	144,348
CA	Burbank Empira Araa Transit Canter, California	736,695	433,043
CA	Calaxico Transit Systam, California	294,678	173,217
CA	Cerone Operating Complax Improvaments, California	491,130	288,695
CA	Carritos Circulator Buses, California	294,678	173,217
CA	Claramont Intarmodal Transit Villaga Expansion Project, California	1,227,825	721,738
CA	Collegian Busway Improvaments, California	196,452	115,478
CA	Corona Transit Cantar, California	687,582	404,174
CA	Davis Intarmodal Facility, California	196,452	115,478
CA	Eastarn Contra Costa County Park and Rida Lots, California	589,356	346,434
CA	Ed Roberts Campus transit center, California	392,904	230,956
CA	El Garces Intermodal Station, Needlas, California	1,866,294	1,097,042
CA	Escondido Bus Maintanance Facility, California	491,130	288,695
CA	Eureka Intermodal Dapot, California	245,565	144,348
CA	Foothill Transit Transit Oriented Naighborhood Program, California	2,455,649	1,443,476
CA	Frasno FAX Buses, Equipment, and Facilitias, California	1,178,712	692,869
CA	Golden Empira Transit Traffic Signal Priority, California	245,565	144,348
CA	Hamet Transit Center/Bus Facility, California	306,465	180,146
CA	Interstata 15 Managed Lanas BRT Capital Purchase, California	982,260	577,391
CA	Long Baach Transit buses and bus facilitias, California	982,260	577,391
CA	Los Angalas County Circulator Buses, California	392,904	230,956
CA	Los Angalas MTA buses, California	3,929,039	2,309,562
CA	Mammoth Lakas Bus Purchase, California	785,808	461,913
CA	Modasto Bus Facility, California	982,260	577,391
CA	Montaray-Salinas Transit Buses, California	1,473,390	866,086
CA	Omnitrans - Paratransit Vahicias, California	294,878	173,217
CA	Oranga County Transit Center Improvamants, California	319,234	187,652

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
CA	Orange County Bus Rapid Transit, California	2,210,085	1,299,129
CA	Orange County Fare Collection System, California	982,260	577,391
CA	Orange County Inter-County Express Bus Service, California	1,080,486	635,130
CA	Palmdale Intermodal Facility Parking Lot Expansion, California	294,678	173,217
CA	Palo Alto Intermodal Transit Center, California	736,695	433,043
CA	Redondo Beach Catalina Transit Terminal, California	785,808	461,913
CA	Raseda Boulavard Bus Rapid Transit Project Capital Improvement, California	245,565	144,348
CA	Riverside Transit Agency, Autometic Traveler Information System (ATIS), California	73,669	43,304
CA	Riverside Transit Agency, Bus Rapid Transit Investment, California	491,130	288,695
CA	Riverside Transit Agency, Transit Center, California	982,260	577,391
CA	Rosevilla Multitransit Center, California	491,130	288,695
CA	Sacramento Regional Bus Expansion, Enhancement, and Coordination Program, City of Auburn, California	98,226	57,739
CA	Sacramento Regional Bus Expansion, Enhancement, and Coordination Program, City of Lincoln, California	491,130	288,695
CA	Sacramento Regional Transit District, Bus Maintanance Facility, California	491,130	288,695
CA	San Fernando Local Transit System, California	294,678	173,217
CA	San Francisco Muni buses and bus facilities, California	3,929,039	2,309,562
CA	San Joaquin RTD buses and bus facilities, California	245,565	144,348
CA	San Mateo County Transit District Zero-Emission buses, California	884,034	519,652
CA	Sante Barbara Metropolitan Transit District Electric Bus Investment, California	294,678	173,217
CA	Santa Clara Valley Transportation Authority Zero-Emission Buses, California	294,678	173,217
CA	Sonoma County Transit CNG Buses, California	491,130	288,695
CA	South San Fernando Valley Park and Ride facility expansion, California	294,678	173,217
CA	Spring Valley Multi-Modal Center, California	589,356	346,434
CA	SunLine Transit Agency Clean Fuels Mall Facility and Hydrogen Infrastructure Expansion, California	442,017	259,826
CA	Temecula Transit Canter, California	785,808	461,913
CA	Transit First Implementation, Chula Vista, California	392,904	230,956
CA	Truckee Replacement Buses, California	73,669	43,304
CA	Ventura County CNG Fueling Station and Facility Pevement Replacement, California	392,904	230,956
CA	Visalia Bus Operations and Maintenance Facility, California	982,260	577,391
CO	Colorado Transit Coalition buses and bus facilities, Colorado	13,751,621	8,083,459
CT	Bridgeport Intermodal Transport Canter, Connecticut	3,929,039	2,309,562
CT	Connecticut Statewide buses and bus facilities	2,946,779	1,732,172
CT	East Haddam Mobility Improvement Project, Connecticut	2,946,779	1,732,172
CT	Greater New Haven Transit District Fuel Cell and Electric Bus Funding, Connecticut	1,473,390	866,086
CT	Hartford Downtown Circulator, Connecticut	1,350,607	793,912
CT	Pulse Point Joint Development and Safety Improvements, Norwalk, Connecticut	491,130	288,695
DC	WMATA Bus Fleet, Washington, DC	736,695	433,043
DE	Delaware Statewide bus and bus facilities	982,260	577,391
DE	University of Delaware Fual Cell Bus Project, Delawere	1,718,955	1,010,434
FL	Citrus County Enhancement Project for the Transportation Disadvanteged, Florida	122,782	72,174
FL	Flagler Senior Services Transit Coaches, Florida	122,782	72,174
FL	Florida International University/University of Miami University Transportation Center, Florida	392,904	230,956
FL	Fort Lauderdale Tri-County Transit Authority fare collection system, Florida	785,808	461,913
FL	HART Bus Purchase, Florida	491,130	288,695
FL	Jacksonville Transportation Authority, Bus and Bus Facilities, Florida	982,260	577,391
FL	Key West bus and bus facilities, Florida	1,080,486	635,130
FL	Lakaland Area Mass Transit District Citrus Connection, Florida	540,243	317,565
FL	Lee County LeeTran Bus Replacement, Florida	196,452	115,478
FL	Levy County Improvement Project for the Transportation Disadvantaged, Florida	196,452	115,478
FL	Miami Dade County System Enhancements, Florida	982,260	577,391
FL	Miami-Dade County buses, Florida	982,260	577,391
FL	North Florida and West Coast Bus Procurement, Florida	3,929,039	2,309,562
FL	NW 7th Avenue Transit HUB Improvements, Florida	982,260	577,391
FL	Palm Beech County and Broward County Regional Buses, Florida	982,260	577,391
FL	Palm Beach Gardens Mass Transit Bus Shelters, Florida	19,645	11,548
FL	Putnam County Transit Coaches for Ride Solutions, Florida	1,178,712	692,869
FL	St. Augustine Intermodal Transportetion and Parking Facility, Florida	540,243	317,565
FL	St. Johns County Council on Aging Administrative Facility, Florida	196,452	115,478
FL	St. Johns County Council on Aging Passenger Amenities, Florida	39,290	23,095
FL	St. Johns County Council on Aging Transit Coaches, Florida	343,791	202,087
FL	TalTran buses and bus facilities, Florida	687,582	404,174
FL	TalTran Intermodal Facility, Florida	491,130	288,695
FL	VOTRAN Public Transit System Buses, Florida	736,695	433,043

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
FL	West Palm Beach Trolley Buses, Florida	785,808	461,913
FL	Winter HavenTransit Terminal, Florida	343,791	202,087
GA	Athens Clarke County Park Ride Project, Georgie	2,701,214	1,587,824
GA	Chatham Area Transit Authority buses and bus facilities, Georgia	5,893,559	3,464,344
GA	City of Macon Alternative Fuel Vehicle Purchase, Georgia	294,678	173,217
GA	Dekalb County BRT Improvements, Georgia	1,473,390	866,086
GA	Georgia Statewide buses and bus facilities, Albany & Rome	982,260	577,391
GA	GRTA buses and bus facilities, Georgia	4,911,299	2,886,953
GA	Hamilton Clean Fuels Bus Facility, Georgia	982,260	577,391
GA	Leesburg Train Depot Renovation and Restoration, Georgia	294,678	173,217
GA	Macon and Athens Multimodal Station, Georgia	1,571,616	923,825
GA	Macon Multi-Modal Terminal Station, Georgie	1,473,390	866,086
GA	MARTA Automated Fare Collection/Smart Card System, Georgia	3,929,039	2,309,562
GA	MARTA Buses, Georgia	5,893,559	3,464,344
GA	Regional Transit Project for Quitman, Clay, Randolph and Stewart Counties, Georgia	491,130	288,695
GA	Terminal Station Multi-Modal Roof Rehabilitation, Georgia	332,004	195,158
HI	Hawaii Statewide Rural Bus Program	3,929,039	2,309,562
HI	Honolulu Bus and Paratransit Replacement Program, Hawaii	9,822,598	5,773,906
HI	Honolulu Middle Street Intermodal Center, Hawaii	2,946,779	1,732,172
IA	Ames Maintenance Facility improvement, Iowa	982,260	577,391
IA	Coralville Intermodal Facility, Iowa	491,130	288,695
IA	Iowa Statewide buses and bus facilities	6,482,915	3,810,778
IA	UNI Multimodal Project, Iowa	3,437,909	2,020,867
ID	Idaho Transit Coalition buses and bus facilities	3,929,039	2,309,562
IL	Illinois Statewide buses and bus facilities	6,875,819	4,041,735
IL	Lincoln Park Museum Trolleys, Illinois	589,356	346,434
IL	Normal Multimodal Transportation Center and public facilities, Illinois	736,695	433,043
IL	Peoria Bus Purchase, Illinois	294,678	173,217
IL	Rock Island County Mass Transit District (Metrolink) transit facility, Illinois	491,130	288,695
IL	Springfield Bus Purchase, Illinois	294,678	173,217
IN	Bloomington Transit, Bloomington, Indiana	707,227	415,721
IN	Cherry Street Multi-Modal Facility, Terre Haute, Indiana	1,866,294	1,097,042
IN	Fort Weyne Citilink Bus Purchase, Indiana	392,904	230,956
IN	Indiana University Bloomington, Indiana	785,808	461,913
IN	Indianapolis Downtown Transit Center, Indiana	3,437,909	2,020,867
IN	Muncia Transit System, Indiana	687,582	404,174
IN	South Bend TRANSPO Bus Facilities, Indiana	982,260	577,391
KS	City of Wichita Transit Authority System Upgrades, Kansas	245,565	144,348
KS	Johnson County Nolte Transit Center, Kansas	245,565	144,348
KS	Johnson County Transit Equipment and Transit Coach Improvement, Kansas	98,226	57,739
KS	Kansas City Area Transit Authority buses and bus facilities, Kansas	1,669,842	981,564
KS	Kansas Statewide buses and bus facilities	2,946,779	1,732,172
KS	KCATA buses and bus facilities, Kansas	2,946,779	1,732,172
KS	Topeka Transit buses and bus facilities, Kansas	491,130	288,695
KS	Unified Government of Kansas City bus replacement, Kansas	343,791	202,087
KY	Audubon Area Community Services, Kentucky	98,226	57,739
KY	Danville Hub-Gilcher Transit Facility / Parking Structure, Kentucky	1,718,955	1,010,434
KY	Daviess County Parking Garage and Intra-County Transit Facility, Kentucky	1,964,520	1,154,782
KY	Fulton County Transit Authority, Kentucky	147,339	86,609
KY	Henderson Area Rapid Transit Authority, Kentucky	14,734	8,661
KY	Kentucky Transportation Cabinet/Community Action Groups	392,904	230,956
KY	Paducah Area Transit Authority, Kentucky	39,290	23,095
KY	Perry County Intermodal Facility, Kentucky	1,964,520	1,154,782
KY	Red Cross Wheels, Kentucky	78,581	46,191
KY	Senior Services of Northern Kentucky buses and bus facilities, Kentucky	245,565	144,348
KY	Southern and Eastern Kentucky buses and bus facilities	1,522,503	894,956
KY	Transit Authority of Northern Kentucky Bus Replacement, Kentucky	1,964,520	1,154,782
KY	Transit Authority of River City buses and bus facilities, Kentucky	2,455,649	1,443,478
KY	Transportation Authority of the River City (TARC) bus/trolley replacement, Kentucky	2,455,849	1,443,476
KY	Transportation Authority of the River City (TARC) expansion facility, Kentucky	785,808	461,913
KY	Western Kentucky University Bus Shuttle System, Kentucky	2,455,649	1,443,476
LA	Greater Ouachita Port and Intermodal Facility, Louisiana	1,227,825	721,738
LA	Intermodal Transit Facility for ULM, Louisiana	982,260	577,391

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
LA	Louisiana Statewide buses and bus facilities	5,402,429	3,175,649
LA	Shreveport Intermodal Bus Facility, Louisiana	687,582	404,174
LA	St. Bernard Parish Intermodal Facilities, Louisiana	491,130	288,695
LA	St. Tammany Park and Ride, Louisiana	392,904	230,956
MA	Berkshire Regional Transit Authority (BRTA) Buses and Fare Boxes, Massachusetts	751,429	441,704
MA	Brockton Intermodal Transportation Centre, Massachusetts	982,260	577,391
MA	Bus Replacement, Brockton Area Transit Authority, Massachusetts	1,964,520	1,154,782
MA	Franklin Regional Transit Authority (FRTA) Bus, Massachusetts	147,339	86,609
MA	Lowell Regional Transit Authority Gallagher Intermodal Transportation Center, Massachusetts	982,260	577,391
MA	Montachusett Area Regional Transit (MART) buses and bus facilities, Massachusetts	1,964,520	1,154,782
MA	Newton Rapid Transit Handicap Access Improvements, Massachusetts	294,678	173,217
MA	Pioneer Valley Transit Authority (PVTA) buses, Massachusetts	2,455,649	1,443,476
MA	Pittsfield Intermodal Transportation Center, Massachusetts	604,090	355,095
MA	Springfield Union Station Intermodal facility redevelopment, Massachusetts	4,420,169	2,598,258
MD	Baltimore Center Plaza, Maryland	589,356	346,434
MD	Maryland Statewide buses and bus facility	7,366,948	4,330,430
MD	Southern Maryland Commuter Bus Initiative	4,420,169	2,598,258
MD	WMATA Buses, Maryland	589,356	346,434
ME	Cranberry Isles Intermodal Transportation Facility, Maine	245,565	144,348
ME	Curtis Ferry, Maine	736,695	433,043
ME	Maine Statewide buses and bus facilities	1,227,825	721,738
ME	Portland Bayside Parking Garage / Intermodal Facility, Maine	245,565	144,348
MI	Allegan County Transportation Services, Michigan	982,260	577,391
MI	Ann Arbor Fuel Cell Bus Project, Michigan	1,964,520	1,154,782
MI	Ann Arbor Transit Authority Transit Center, Michigan	736,695	433,043
MI	Barry County Transit replacement maintenance equipment, Michigan	19,645	11,548
MI	Bay Area Metropolitan Transportation Authority New and Replacement Buses, Michigan	245,565	144,348
MI	Bay Area Transportation Authority Downtown Transfer Center Construction and Bus Purchase, Grand Traverse County, Michigan	982,260	577,391
MI	Belding bus replacement and communication equipment, Michigan	39,290	23,095
MI	Berrien County Public Transportation, Michigan	78,581	46,191
MI	Cadillac/Wexford Transit Authority buses, Michigan	73,669	43,304
MI	Cadillac/Wexford Transit Authority Intermodal Facility, Michigan	589,356	346,434
MI	Capital Metro Hybrid Electric Buses, Texas	491,130	288,695
MI	CATA, Lansing, Michigan	982,260	577,391
MI	Clare County Transit Corporation Replacement Buses, Michigan	98,226	57,739
MI	Clinton Transit Bus Purchase, Michigan	39,290	23,095
MI	County Connection L.L.C., Midland County, Michigan	73,669	43,304
MI	Detroit Bus Replacement, Michigan	2,455,649	1,443,476
MI	Detroit Downtown Transit Center, Michigan	6,875,819	4,041,735
MI	Detroit Timed Transfer Center Phase II, Michigan	982,260	577,391
MI	Flint buses and bus facilities, Michigan	2,455,649	1,443,476
MI	Grand Rapids Metropolitan Area multimodal surface transportation center, Michigan	1,522,503	894,956
MI	Harbor Transit Bus Replacement, Michigan	196,452	115,478
MI	Holland Macatawa Area Express (MAX), Michigan	589,356	346,434
MI	Intelligent Transportation System for ITP The Rapid, Michigan	589,356	346,434
MI	Isabella County Transportation Commission Vehicle Replacement, Michigan	245,565	144,348
MI	Kalamazoo County Human Services Care-A-Van, Michigan	73,669	43,304
MI	Lake Erie Transit Bus Storage Facility and Maintenance Facility Expansion, Michigan	982,260	577,391
MI	Lansing Fixed Route Bus Replacement, ADA Para transit Small Bus Replacement, Maintanance, Administration and Storage Facility Renovation and Expansion, CATA/MSU Bus Way, Rural Small Bus Replacement, Michigan	1,473,390	866,086
MI	LETS Bus Replacement, Michigan	88,403	51,965
MI	Ludinton Mass Transportation Authority Bus Facility, Michigan	245,565	144,348
MI	Manistee County Transportation, Inc. Replacement Buses, Michigan	29,468	17,322
MI	Marquette County, Phase II - Transit Administrative, Operations, Maintenance & Storage Facility, Michigan	982,260	577,391
MI	Mecosta Osceola County Area Transit Vehicle Replacement, Michigan	196,452	115,478
MI	Michigan Statewide buses and bus facilities	982,260	577,391
MI	Northern Michigan buses and bus facilities	491,130	288,695
MI	Sanilac County bus facility, Michigan	98,226	57,739
MI	Shiawassee Transportation Center and replacement buses, Michigan	39,290	23,095
MI	St. Joseph County Transit, Michigan	34,379	20,209
MI	Suburban Mobility Authority for Regional Transportation (SMART) buses and bus facilities, Michigan	4,420,169	2,598,258
MI	VanBuren Public Transit, Michigan	17,881	10,393

FEDERAL TRANSIT ADMINISTRATION

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FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
MN	Metro Transit buses and bus facilities, Minnesota	4,321,943	2,540,519
MN	Minnesota District 8 Transit Vehicles and Transit Bus Facilities	785,808	461,913
MN	Minnesota Transit buses and bus facilities, Minnesota	1,642,338	965,397
MN	Northwest Corridor Busway, Minnesota	2,946,779	1,732,172
MN	Southern Minnesota Transit Facilities	29,468	17,322
MN	Southern Minnesota Transit Vehicles	368,347	218,521
MN	St. Cloud Buses, Minnesota	98,226	57,739
MN	Union Depot Multi-modal Transportation Hub, Minnesota	736,695	433,043
MO	City of Columbia Transit Replacement, Missouri	98,226	57,739
MO	Clinton Transit Office, Missouri	245,565	144,348
MO	Jefferson City Transit System, Missouri	294,678	173,217
MO	Missouri Bus & Paratransit Vehicles- Rolling Stock	785,808	461,913
MO	Missouri Statewide buses and bus facilities	7,858,078	4,619,125
MO	OATS buses and bus facilities, Missouri	1,473,390	866,086
MO	Oats Transportation Service of Southwest Missouri	68,758	40,417
MO	Rey County Transportation vehicle replacement, Missouri	78,581	46,191
MO	Southeast Missouri Bus Service Capital Improvements	1,473,390	866,086
MO	Southwest Missouri State University Transfer Facility, Missouri	2,455,649	1,443,476
MO	St. Louis Downtown Shuttle/Trolley Equipment, Missouri	245,565	144,348
MO	St. Louis METRO buses and bus facilities, Missouri	1,227,825	721,738
MS	Coast Transit Authority, Mississippi	491,130	288,695
MS	Harrison County multi-model facilities and shuttle service, Mississippi	982,260	577,391
MS	Hattiesburg Intermodal Facility, Mississippi	2,946,779	1,732,172
MS	Intermodal Facility, JIA, Mississippi	1,964,520	1,154,782
MS	JATRAN vehicles for disabled and alderly, Mississippi	245,565	144,348
MT	Billings Downtown Bus Transfer Facility, Montana	1,473,390	866,086
MT	Great Falls Transit Authority Bus Replacement and Facility Improvement, Montana	294,678	173,217
MT	Helene Transit Facility, Montene	491,130	288,695
MT	Liberty County COA Bus Fecility, Montena	49,113	28,870
MT	Mountain Line Bus Replacement and Facility Improvements, Montena	196,452	115,478
NC	Ashaville Transit System Fleet Replacement, North Carolina	294,678	173,217
NC	Chepel Hill Bus Maintenance Facility, North Carolina	982,260	577,391
NC	Charlotte Area Transit System Transit Maintenance and Operations Center, North Ceroline	4,911,299	2,886,953
NC	Durham Multimodal Transportation Fecility, North Carolina	1,473,390	866,086
NC	High Point Project Terminals, North Carolina	785,808	461,913
NC	Intermodal Transportation Hub Project, North Cerolina	147,339	86,609
NC	North Carolina Statewide buses and bus facilities	6,139,124	3,608,692
NC	Piedmont Authority for Regional Transportation (PART) multimodal transportation center, North Carolina	1,080,486	635,130
NC	Winston-Salem Union Station, North Carolina	1,276,938	750,608
ND	North Dekota Statewide buses and bus facilities	2,946,779	1,732,172
ND	Small Urban and Rural Transit Center, North Dakote	392,904	230,956
NE	Kearney RYDE Transit, Nebraska	982,260	577,391
NE	Metro Area Transit (MAT) buses and bus facilities, Omaha, Nebraska	1,964,520	1,154,782
NE	Nebraska Statewide Rural Automatic Vehicle Locating & Comms System	736,695	433,043
NH	New Hampshire Statewide buses and bus fecilities	4,420,169	2,598,258
NJ	Harrison Intermodel Project, New Jersey	736,695	433,043
NJ	Howard Boulevard Intermodal Park & Ride, New Jersey	2,160,972	1,270,260
NJ	Hunterdon County Intermodel Stations and Park & Rides, New Jersey	392,904	230,956
NJ	Montclair State University Campus and Community Bus System, New Jersey	687,582	404,174
NJ	Morris County Intermodal Facilities and Park & Rides, New Jersey	2,946,779	1,732,172
NJ	Newark Penn Station Intermodal Improvements, New Jersey	2,946,779	1,732,172
NJ	Old Bridge Intermodal Stations and Park & Rides, New Jersey	491,130	288,695
NJ	South Amboy Regional Intermodal Transportation Initiative, New Jersey	982,260	577,391
NJ	Tranton Intermodal Station, New Jersey	736,695	433,043
NM	Farmington buses and bus facilities, New Mexico	98,226	57,739
NM	Las Cruces buses and bus facilities, New Mexico	368,347	216,521
NM	West Side Transit Facility Albuquerque Transit Department, New Mexico	1,964,520	1,154,782
NV	Bus Rapid Transit Project, Virginia Street, Reno, Navade	982,260	577,391
NV	Construction of new Intermodal Terminals in Downtown Reno and Sparks, Nevada	5,893,559	3,464,344
NV	Nevada Rural Transit Vehicles and Facilities	491,130	288,695
NV	RTC Central City Intermodal Transportation Terminal, Las Vegas, Nevada	491,130	288,695
NV	Sparks and Reno Bus and Bus Facilities, Nevada	147,339	86,609
NY	Capital District Transportation Authority (CDTA), Rensselaer Intermodal Station, New York	245,565	144,348

FEDERAL TRANSIT ADMINISTRATION

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FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
NY	Central New York Regional Transportation Authority	2,259,198	1,327,999
NY	Fort Edward Intermodal Station Interior Rastoration/Rehabilitation Project, New York	294,678	173,217
NY	Jacobi Transportation Facility, New York	785,808	461,913
NY	Jamaica Intermodal Facilities, Queens, New York	392,904	230,956
NY	Livingston County Transportation Canter, New York	392,904	230,956
NY	Main Street project for downtown Buffalo, New York	638,469	375,304
NY	Monigomery Buses, New York	39,290	23,095
NY	MTA/Long Island Bus clean fuel celt bus purchase, New York	982,260	577,391
NY	Myrtle Avenue Business Improvement District's Myrtle/Wyckoff/Palmatto Transit Hub Enhancement, New York	491,130	288,695
NY	Nassau County, Hub Enhancements, New York	1,178,712	692,869
NY	Niegra Frontier Transportation Authority Matro busas and bus facilitias, New York	1,571,616	923,825
NY	Onaont Bus Raplacement, New York	196,452	115,478
NY	Oranga County Bus Replacement, New York	1,227,825	721,738
NY	Over the Road Bus Accessibility, Intarcity Bus Accessibility Consortium, New York	2,946,779	1,732,172
NY	Rochaster Centrat Bus Tarminal, New York	5,402,429	3,175,649
NY	Roma Intermodal Station Rastoration, New York	1,227,825	721,738
NY	Smithtown Sanior Citizen Center Bus Raplacement, New York	196,452	115,478
NY	St. George Farry Terminal Reconstruction, New York	2,210,085	1,299,129
NY	Suffolk County Transit Buses, New York	1,866,294	1,097,042
NY	Tompkins County Bus Facilities, New York	392,904	230,956
NY	Ulstar County Area Transit Busas, New York	39,290	23,095
NY	Union Station Renovations, Utica, New York	736,695	433,043
NY	Villaga of Plaasantville, Handicapped Ramp, New York	47,148	27,714
NY	Village of Pleasantville, Memorial Plaza, New York	196,452	115,478
NY	Westchester County Bee Line Bus Replacement, Naw York	2,701,214	1,587,824
NY	Wastern Gateway Transportation Center Intermodal Facility, Schanectady, New York	392,904	230,956
NY	Whitahall Intar-Modal Terminal of the Statan Island Ferry Reconstruction, New York	785,808	461,913
NY	Wyandanch Intarmodal Transit Facility, New York	392,905	230,957
OH	Central Ohio Transit Authority Facility	442,017	259,826
OH	East Side Transit Centar, Clavaland, Ohio	982,260	577,391
OH	Graater Deyton Regionel Transit Authority, Ohio	736,695	433,043
OH	Kant State University Intarmodal Facility, Ohio	368,347	216,521
OH	Lorain Port Authority Lighthouse Shuttla and Black Rivar Watar Taxi Project, Ohio	196,452	115,478
OH	Ohio Statewide buses and bus facilities	4,911,299	2,886,953
OH	The Banks Intermodal Facility, Cincinnati, Ohio	3,437,909	2,020,867
OH	Wright Stop Plaza, Dayton, Ohio	1,473,390	866,086
OH	Zanesville Bus System Improvements, Ohio	19,645	11,548
OK	Central Oklahoma Transportation and Parking Authority	1,787,713	1,050,851
OK	Kibios Area Transit System (KATS) maintanance facility and vehicles, Oklahoma	638,469	375,304
OK	Multi-Modal Transportation Facility and Transit System at Oklahoma State University, Oklahoma	2,210,085	1,299,129
OK	Norman buses and bus facilities, Oklahoma	2,946,779	1,732,172
OK	Northern Oklahoma Regional Multimodal Transportation System	2,455,649	1,443,476
OK	Oklahoma City Buses, Oklahoma	2,210,085	1,299,129
OK	Oklahoma Department of Transportation Transit Programs Division	6,139,124	3,608,692
OK	Tulsa Transit Bus Replacement Program, Oklahome	4,420,169	2,598,258
OK	Tulsa Transit Paratransit Buses, Oklahoma	736,695	433,043
OR	City of Canby Transit Centar, Oregon	147,339	86,609
OR	City of Corvallis Bus Raplacement, Oragon	245,565	144,348
OR	Lane Transit District, BRT Phase II, Coburg Road Phase III, Oregon	1,964,520	1,154,782
OR	Lincoln County Transportation, Bus Garage Facility, Oregon	196,452	115,478
OR	Salem Araa Transit, Bus Replacement, Oregon	589,356	346,434
OR	South Clackamas Transit, Molalla, Oregon	98,226	57,739
OR	Springfield Stetion, Oregon	3,929,039	2,309,562
OR	Tillamook County Transit, Maintenance Facility, Oregon	196,452	115,478
OR	Tri-Met Regionel Bus Raplacement, Oregon	638,469	375,304
OR	Wilsonvilla Park and Ride, Oregon	294,678	173,217
PA	Adams County Transit Authority (ACTA) buses and bus facilities, Pennsylvania	19,645	11,548
PA	Allentown Intermodal Facility, Pennsylvania	2,455,649	1,443,476
PA	AMTRAN Buses and Transit System Improvements, Pennsylvanie	196,452	115,478
PA	Area Transit Authority buses and bus equipment, Pennsylvenia	2,455,649	1,443,476
PA	BARTA Fixed Route Bus and Paratransit Vehicle Replacement, Pennsylvania	2,553,875	1,501,215
PA	BARTA Transit Facilities, Pennsylvenia	638,469	375,304
PA	Beaver County Transit Authority replacement busas and equipment, Pennsylvania	245,565	144,348

FEDERAL TRANSIT ADMINISTRATION

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FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
PA	Butler Multi-Modal Transit Center, Pennsylvania	982,260	577,391
PA	Cambria County Transit buses and facilities, Pennsylvania	884,034	519,652
PA	Capital Area Transit Buses, Pennsylvania	1,571,616	923,825
PA	Centre Area Transit Authority, Advanced Public Transportation Systems Initiative, Pennsylvania	589,356	346,434
PA	Church Street Transportation Center, Williamsport, Lycoming County, Pennsylvania	245,565	144,348
PA	City Bus, Williamsport Bureau of Transportation, Lycoming County, Pennsylvania	982,260	577,391
PA	Endless Mountain Transportation Authority, Bradford County, Pennsylvania	9,823	5,774
PA	Erie Metropolitan Transit Authority Bus Acquisition, Pennsylvania	98,226	57,739
PA	Fayette County Intermodal Transit Facility, Pennsylvania	392,904	230,956
PA	Harrisburg CorridorONE, Pennsylvania	1,964,520	1,154,782
PA	Harrisburg Intermodal Airport Multi-Modal Transportation Facility, Pennsylvania	982,260	577,391
PA	Hazleton Intermodal Public Transit Center, Pennsylvania	1,718,955	1,010,434
PA	Indiana County Transit Authority/Bus Facility Expansion and Renovation, Pennsylvania	392,904	230,956
PA	Lebanon County Transit Authority, buses and bus related facilities, Pennsylvania	442,017	259,826
PA	Mid County Transit Authority Kittanning, Pennsylvania	392,904	230,956
PA	Mid Mon Valley Transit Authority, Charleroi, Pennsylvania	589,356	346,434
PA	New Castle Transit Authority replacement buses, Pennsylvania	98,226	57,739
PA	Paoli Transportation Center, Pennsylvania	491,130	288,695
PA	Pittsburgh Water Taxi, Pennsylvania	982,260	577,391
PA	Port Authority of Allegheny County Buses, Pennsylvania	2,701,214	1,587,824
PA	Port Authority of Allegheny County Clean Fuel Buses, Pennsylvania	2,239,552	1,316,450
PA	Schlow Library Bus Depot, State College, Pennsylvania	785,808	461,913
PA	Schuylkill Transportation System, buses and bus facilities, Pennsylvania	982,260	577,391
PA	SEPTA Bucks County Intermodal Facility Improvements, Pennsylvania	3,437,909	2,020,867
PA	SEPTA Hybrid Buses, Pennsylvania	785,808	461,913
PA	SEPTA Norristown Intermodal Facility, Pennsylvania	2,946,779	1,732,172
PA	Somerset County Transportation System Maintenance Facility, Pennsylvania	157,162	92,383
PA	Transit Authority of Warren County Intermodal Bus Facility, Pennsylvania	1,473,390	866,086
PA	Union County Union/Snyder Transportation Alliance (USTA), Pennsylvania	491,130	288,695
PA	Westmoreland County Transit Authority (WCTA) Bus Replacement, Pennsylvania	884,034	519,652
PA	York County Transit Authority (YCTA) buses and bus facilities, Pennsylvania	98,226	57,739
PR	Puerto Rico Metropolitan Bus Authority Replacement	491,130	288,695
RI	RIPTA Buses and Vans, Rhode Island	3,929,039	2,309,562
RI	RIPTA Facilities Upgrade, Rhode Island	392,904	230,956
SC	City of Greenville Multimodal Transportation Center Improvements, South Carolina	196,452	115,478
SC	Lowcountry Regional Transit Authority, South Carolina	294,678	173,217
SC	Medical University of South Carolina Intermodal Facility, South Carolina	3,929,039	2,309,562
SC	Myrtle Beach Regional Multimodal Transit Center, South Carolina	196,452	115,478
SC	North Charleston Regional Intermodal Transportation Center, South Carolina	1,227,825	721,738
SC	South Carolina Statewide Transit Facilities Construction Project	982,260	577,391
SC	South Carolina Statewide Transit Vehicles	3,929,039	2,309,562
SD	Cheyenne River Sioux Tribe public buses and bus facilities, South Dakota	2,210,085	1,299,129
SD	South Dakota Statewide buses and bus facilities	1,964,520	1,154,782
TN	Downtown Transit Center, Nashville, Tennessee	1,964,520	1,154,782
TN	Knoxville Electric Transit Intermodal Center, Tennessee	1,964,520	1,154,782
TN	Memphis International Airport Intermodal Facility, Tennessee	2,701,214	1,587,824
TN	Nashville replacement of aged buses, Tennessee	491,130	288,695
TN	Tennessee Statewide buses and bus facilities	6,384,689	3,753,039
TN	UCHRA Capital Improvements, Tennessee	589,356	346,434
TX	Austin Capital Metro buses and bus facilities, Texas	2,946,779	1,732,172
TX	Brazos County Bus Replacement Program, Texas	196,452	115,478
TX	CityLink van and technology replacement, Abilene, Texas	491,130	288,695
TX	Corpus Christi buses and bus facilities, Texas	1,964,520	1,154,782
TX	El Paso Sun Metro Bus Replacement, Texas	982,260	577,391
TX	Ft. Worth Transportation Authority Fleet Modernization and Bus Transfer Centers, Texas	1,473,390	866,086
TX	Galveston Maintenance Facility Renovations, Texas	785,808	461,913
TX	Grapevine Bus Purchase, Texas	157,162	92,383
TX	Hunt County Committee on Aging Transportation Facility, Texas	392,904	230,956
TX	Laredo Bus Facility, Texas	834,921	490,782
TX	Lubbock/Citibus Buses, Texas	1,473,390	866,086
TX	Nacogdoches Vehicle Replacement, Texas	785,808	461,913
TX	North Side Transfer Center Brownsville Urban System (BUS), Texas	343,791	202,087
TX	Public Transportation Management, Tyler/Longview, Texas	343,791	202,087

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

FY 2004 SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
TX	San Antonio VIA Metropolitan Transit buses and bus facilities, Texas	4,911,299	2,886,953
TX	South East Texas Transit Facility Improvements and Bus Replacements	245,565	144,348
TX	The District-Bryan Intermodal Transit Terminal/Parking Facility & Pedestrian Improvements, Texas	392,904	230,956
TX	The Woodlands Capital Costs, Texas	343,791	202,087
TX	The Woodlands Park and Ride Expansion, Texas	270,121	158,782
UT	UTA Transit ITS, Upgrades, Utah	245,565	144,348
UT	Utah Statewide buses and bus facilities	5,893,559	3,464,344
UT	Utah Statewide Intermodal Centers	3,929,039	2,309,562
VA	Alexandria After School Bus program, Virginia	73,669	43,304
VA	Clean Fleet Bus Purchase and Facilities, Virginia	982,260	577,391
VA	Danville Trolley Buses, Virginia	171,895	101,043
VA	Fairfax County, Richmond Highway Transit Improvements, Virginia	687,582	404,174
VA	Hampton Roads Transit Southside Bus Facility, Virginia	1,964,520	1,154,782
VA	Main Street Station Multimodal Transportation Center, Virginia	1,473,390	866,086
VA	Potomac and Rappahannock Transportation Commission, Virginia	491,130	288,695
VA	Richmond Highway Public Transportation Initiative, Virginia	2,946,779	1,732,172
VI	Virgin Islands Transit (VITRAN) Buses	491,130	288,695
VT	Brattleboro Multimodal, Vermont	1,964,520	1,154,782
VT	Burlington Transit Facilities, Vermont	2,455,649	1,443,476
VT	Vermont Alternative Fuel Station and Buses, Vermont	491,130	288,695
VT	Vermont, Bus Upgrades	785,808	461,913
WA	Clallam Transit Buses, Washington	245,565	144,348
WA	Clark County Transit, Bus Replacement Project, Washington	2,946,779	1,732,172
WA	Community Transit Bus and Van Replacement, Washington	982,260	577,391
WA	Edmonds Crossing Multimodal Transportation Terminal, Washington	1,964,520	1,154,782
WA	Everett Transit, Bus Replacement, Washington	982,260	577,391
WA	Grant Transit Authority, Bus Facility, Washington	491,130	288,695
WA	Grays Harbor Transportation Authority Capital Improvement, Washington	73,669	43,304
WA	Intercity Transit Bus Expansion and Replacement, Washington	982,260	577,391
WA	Jefferson Transit bus purchase, Washington	196,452	115,478
WA	Jefferson Transit Facilities, Washington	982,260	577,391
WA	King County Metro Clean Air Buses, Washington	4,911,299	2,886,953
WA	Kitsap Transit Bus Replacement, Washington	982,260	577,391
WA	Link Transit Vehicle Replacement, Wenatchee, Washington	785,808	461,913
WA	Mason County Transportation Authority Capital Improvements, Washington	196,452	115,478
WA	Metro Transit Turn Around at Taylor Landing Park, Washington	39,290	23,095
WA	Mukilteo Lane Park and Ride, Washington	982,260	577,391
WA	North Bend Park and Ride, Washington	589,356	346,434
WA	Pierce Transit Maintenance and Operations facility, Washington	982,260	577,391
WA	Snohomish County Community Transit Park and Ride Lot Expansion Program, Washington	1,964,520	1,154,782
WA	Sound Transit Regional Express Transit Hubs, Washington	1,964,520	1,154,782
WA	Washington State Small Bus System Program of Projects		
WA	Clallam Transit	670,500	394,132
WA	Columbia County Public Transportation (CCPT)	100,380	59,005
WA	Grays Harbor Transportation Authority	140,337	82,493
WA	Island Transit	1,066,172	626,716
WA	Jefferson Transit	405,419	238,313
WA	Mason County Transportation Authority	467,791	274,976
WA	Pullman Transit	85,762	50,413
WA	Twin Transit	105,253	61,870
WA	Valley Transit	689,991	405,590
WI	Wisconsin, Statewide buses and bus facilities	14,733,883	8,660,854
WV	West Virginia Statewide buses and bus facilities	3,929,039	2,309,562
WY	Wyoming Statewide buses and bus facilities	1,964,520	1,154,782
	TOTAL ALLOCATION	**$668,660,587**	**$393,051,172**

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
FY 2002 Unobligated Allocations		
AK	City of Wasilla bus facility	$594,017
AK	Fairbanks buses and bus facility	1,473,044
AK	Mat-su Community Transit buses and facilities	800,001
AK	Port MacKenzie buses and bus facilities	1,485,044
AL	Alabama State Dock intermodal passenger and freight terminal bus and bus related facilities	4,950,145
AL	Gadsden Transportation Services	247,507
AZ	City of Glendale buses	173,255
AZ	Phoenix Regional Public Transportation Authority buses and bus facilities	6,583,693
CA	Anaheim Resort transit project	495,015
CA	Belle Vista park and ride	247,507
CA	Boyle Heights bus facility	346,510
CA	City of Carpinteria electric-gasoline hybrid bus	495,015
CA	City of Monrovia natural gas vehicle fueling facility	267,308
CA	City of Sierra Madre bus replacement	148,504
CA	Contra Costa Connection buses	226,510
CA	Costa Mesa CNG facility	247,507
CA	County of Amador bus replacement	117,813
CA	County of Calaveras bus fleet replacement	103,953
CA	Imperial Valley CNG bus maintenance facility	247,507
CA	Livermore Amador Valley Transit Authority buses and facility	1,485,044
CA	Merced County Transit CNG buses	297,009
CA	Monterey-Salinas Transit facility	1,485,044
CA	North County Transit District, initial design and planning for new intermodal center	297,009 a/
CA	North Ukiah Transit Center	297,009
CA	Pasadena Area Rapid Transit System	396,012
CA	Sacramento Regional buses and bus facilities	990,029
CA	San Bernardino CNG/LNG buses	371,261
CA	Sierra Madre Villa & Chinatown intermodal transportation centers/Los Angeles County Metropolitan Transportation Authority bus and bus related facilities in LACMTA's service area	1,485,043
CA	Sunline Transit hydrogen refueling station	495,015
CA	Transportation Hub at the Village of Indian Hills	990,029
CT	Bridgeport intermodal corridor project	297,486
CT	East Haddam transportation vehicles and transit facilities	415,812
CT	Greater New Haven Transit District CNG vehicle project (ConnDOT)	990,029
CT	New Haven bus facility	495,015
FL	Broward County alternative vehicle mass transit buses and bus facilities	2,475,073
FL	Miami Beach development electrowave shuttle service	2,970,087
FL	Northeast Miami-Dade passenger center	371,261
FL	South Florida Regional Transit buses and bus facilities	1,737,197
FL	South Miami intermodal pedestrian access project	990,029
FL	TALTRAN intermodal center	594,017
GA	Chatham Area Transit buses and bus facilities	2,960,002
GA	Cobb County Community Transit bus facilities	990,029
GA	Georgia Regional Transit Authority express bus program	5,940,174
GA	Gwinnett County operations and maintenance facility	495,015
GA	Macon terminal intermodal station	885,044
ID	Statewide, bus and bus facilities	256,546
IL	Statewide buses and bus facilities	1,900,076
IN	Cherry Street Project multi-modal facility	1,287,038
IN	Indiana bus consortium, buses and bus facilities	1,669,902
IN	Indianapolis downtown transit facility	3,143,342
IN	West Lafayette Transit Project buses and bus facilities	1,732,551
KS	Statewide buses and bus facilities, Kansas	1,130,087
KS	Wichita Transit Authority buses	898,946
KY	Leslie County parking structure	1,980,058
KY	Transit Authority of River City buses and bus facilities	1,980,058

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
LA	Jefferson Parish bus and bus related facilities	1,185,644
LA	Lake Charles bus and bus related facilities	396,012
LA	Louisiana State University Health Sciences Center-Shreveport, intermodal parking facility	990,029
LA	Shreveport bus and bus related facilities	1,450,393
MA	Attleboro intermodal facilities	990,029
MA	Gallagher Intermodal Transportation bus hub and CNG trolleys	990,029
MA	Merrimack Valley Regional Transit Authority (Amesbury) buses and bus facilities	495,015
MA	MetroWest buses and bus facilities	495,015
MA	Salem/Beverly Intermodal Center	495,015
MA	Springfield Union Station intermodal facility	3,960,116
MD	Statewide buses and bus facilities	6,036,483
ME	Auburn intermodal facility and parking garage	247,507
ME	Statewide buses	2,970,087
MI	Blue Water Area Transportation Commission bus facilities	1,485,044
MI	Northern Oakland Transportation Authority	148,504
MN	Greater Minnesota Transit Authority bus, paratransit and transit hub (MNDOT)	136,520
MN	Metro transit buses and bus facilities (Twin Cities)	1,441,469
MN	Moorhead buses, bus facilities, and equipment	99,003
MN	Mower County Public Transit Initiative facility	495,015
MN	Rush Line Corridor buses and bus facilities	495,015
MO	Cab Care paratransit facility	495,015
MO	Kansas City bus rapid transit	2,315,073
MO	Missouri Pacific Depot	495,015
MS	Brookhaven multi-modal facility	990,029
MS	Hattiesburg intermodal facility	3,465,102
MT	Area VII agency on aging bus facility	544,516
MT	Billings Logan international airport bus terminal and facility	52,000
MT	Ravalli County Council on aging bus facility	145,970
MT	Statewide bus and bus facilities	599,109
NC	Statewide buses and bus facilities	2,444,888
NH	Granite State Clean Cities Coalition CNG buses and facilities	990,029
NH	Town of Ossipee multimodal vistor center	1,425,646
NJ	Bergen intermodal stations, park and ride and shuttle service	2,326,568
NJ	Middlesex County jitney transit buses	396,012
NJ	Trenton Rail Station rehabilitation	2,475,073
NM	Las Cruces intermodal transit facility	1,980,058
NM	Statewide buses and bus facilities	505,144
NM	Village of Taos Ski Valley bus and bus facilities	495,015
NM	West Side Transit facility and buses	3,429,709
NV	Reno Bus Rapid Transit high-capacity articulated buses	1,485,044
NV	Reno/Sparks intermodal transportation terminals	495,015 a/
NY	Binghamton intermodal terminal	1,980,058
NY	Pelham trolley	257,408
NY	Rochester buses and facilities	990,029
NY	Station Plaza commuter parking lot	495,015
NY	Sullivan County Coordinated Public Transportation Service bus facility	495,015
NY	Tompkins Consolidated Area transit center	617,778
OH	Alliance intermodal facility	990,029
OH	Butler County transit facility	990,029
OH	Dayton, Wright-Dunbar Transit Access Project	698,812
OH	Statewide buses and bus facilities, Ohio	50,270
OK	Oklahoma Department of Transportation transit program buses and bus facilities	990,028
OR	Clackamas County south corridor transit improvements	2,916,087
PA	Allentown intermodal transportation center	495,015
PA	Bucks County intermodal facility improvement	555,646

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
PA	Butler Township multi-modal transfer center	245,015
PA	Callowhill bus garage replacement	3,267,096
PA	County of Lackawanna Transit bus facility	495,015
PA	Doylestown Area Regional Transit buses	99,003
PA	Hershey intermodal transportation center	1,237,536
PA	LeHigh and Northampton Transportation Authority bus facility	495,015
PA	Monroe County Transit Authority park and ride	594,017
PA	Montgomery County intermodal facility	240,001
PA	Red Rose transit transfer center	495,015
PA	Somerset County accessible raised roof vans, and buses and bus facilities	247,507 a/
PA	Southeastern Pennsylvania Transportation Authority trackless trolleys	990,029
PA	Wilkes-Barre Intermodal facility	990,029
PA	York County bus replacement	990,029
SC	Statewide buses and bus facility	720,000
SD	Oglala Sioux Tribe buses and bus facilities	2,227,565
TN	Memphis International Airport intermodal facility	1,722,650
TN	Statewide buses and bus facilities	1,201,000
TX	Brazos Transit buses, intermodal facility, and parking facility	742,522
TX	El Paso buses	495,015
TX	Fort Worth 9th Street Transfer Station	1,584,046
TX	Sun Metro buses and bus facilities	495,015
UT	Utah Transit Authority and Park City Transit buses	66,827
VA	Greater Richmond Transit Downtown Center	990,029
VA	Hampton Roads regional buses	3,465,102
VI	Virgin Islands Transit (VITRAN) buses	495,015
VT	Vermont Public Transit alternative fuel/hybrid buses and facility	1,980,058
WA	Issaquah Highlands park and ride	1,980,058
WA	King County Transit Oriented Development Projects	990,029
WA	Snohomish county transit buses and bus facilities	1,980,058
WA	Spokane Transit Authority, buses and bus facilities	990,029
WI	Statewide buses, bus facilities, and equipment	720,000
WV	Morgantown Intermodal parking facility	1,980,058
WY	Southern Teton Area Rapid Transit bus facility	495,015
WY	Statewide buses and bus facilities	759,189
	Subtotal FY 2002 Unobligated Allocations	***$167,961,000***
FY 2003 Unobligated Allocations		
AK	Anchorage Int'l Airport Intermodal Facility	$1,967,357
AK	Anchorage ship creek intermodal facility (AK)	3,934,715
AK	Coffman-Cove Inner-island Ferry/Bus Terminal	1,967,357
AK	Fairbanks Intermodal Facility	245,920
AK	Fairbanks Rail/Bus Transfer	1,967,357
AK	Port MacKenzie Intermodal Facility	1,967,357
AK	Seward Buses & Bus Facility	196,736
AK	Skagway Municipal and Regional Transit	344,287
AK	Wasilla Intermodal Facility	885,311
AL	Alabama A&M University bus & bus facilities	491,839
AL	Alabama State Docks Intermodal Facility	7,869,429
AL	Alabama Statewide Replacement of Senior Center Vans	983,679
AL	Bevill State Community College Transit Project	295,104
AL	Cullman County Commission (CARTS)	147,552
AL	Hoover & Vestavia Hills Diesel Hybrid Electric Buses	983,679
AL	Huntsville Intermodal Center	2,951,036
AL	Jefferson Count Diesel Hybrid Electric Buses	737,759
AL	Maritime Center of the Gulf	3,934,715
AL	Troy State University Bus Shuttle Program	1,475,518
AR	Fort Smith Bus	737,759
AR	State of Arkansas Bus & Bus Facilities	4,426,554

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
AZ	City of Phoenix (RPTA) replacement buses	3,772,408
AZ	Coconino County Buses	983,679
AZ	RPTA Bus Facilities (Mesa, Scottsdale, Tempe, Phoenix)	4,131,450
AZ	Sun Tran Replacement Buses, including alternatively fueled	983,679
AZ	SunTran Bus Storage & Maintenance Facility	1,721,438
AZ	Tucson Intermodal Center (Union Pacific Depot)	3,934,715
CA	Anaheim Resort Transportation (ART) Project	491,839
CA	Chino, Transcenter, Omnitrans	324,614
CA	City of Salinas - Intermodal Transportation Center	1,229,598
CA	City of Sierra Madre Buses and Natural Gas Vehicle Fueling Station	295,104
CA	East County Bus Maintenance Facility	1,573,886
CA	El Garces Intermodal Station	1,524,702
CA	Fairfield/Suisun Transit Alternative Fueled Buses	491,839
CA	Folsom Railroad Block Project	983,679
CA	Foothill Transit - Bus Purchase	1,475,518
CA	Fresno Area Express (FAX) Bus Expansion	590,207
CA	Golden Empire Transit District	737,759
CA	Los Angeles to Pasadena Construction Authority Bus Program	2,951,036
CA	Modesto, Bus Maintenance Facility	1,672,254
CA	Monterey-Salinas Transit Bus Facility & Buses	875,785
CA	Municipal Transit Operators Coalition - Bus and Bus Facilities	1,721,438
CA	Omnitrans, City of Yucaipa - the Yucaipa Transit Advancement Project	934,495
CA	Palmdale intermodal facility	983,679
CA	Redondo Beach, Bus Transfer Station	491,839
CA	Riverside Transit Agency (RTA) Transit Centers - Corona, Riverside	983,679
CA	Roseville Multitransit Center	1,475,518
CA	Sacramento Hydrogen Bus Technology (University of California at Davis)	590,207
CA	San Diego Bus Rapid Transit	491,839
CA	San Fernando Valley East and Ventura Boulevard, Park and ride facilities	491,839
CA	Solano Transportation Authority - Fairfield/Vacaville Intermodal Station	491,839
CA	South Pasadena Circulator Bus	147,552
CA	Sun Line Transit Hydrogen Refueling Station	1,229,598
CO	Colorado Transit Coalition - Statewide Bus and Bus Facilities	2,094,491
CT	Bridgeport High Speed Ferry Terminal Project	983,679
CT	Connecticut State-wide Buses	983,679
CT	Hartford Downtown Circulator	1,475,518
CT	Hartford-New Britain Busway Project	7,377,590
CT	Hollyhock Station/Intermodal Transportation Center, Norwich	2,606,748
CT	New Haven, Bus Maintenance Facility	983,679
CT	New Haven, Fuel Cell and Electric Bus Project	983,679
CT	West Haven Intermodal	983,679
DC	Georgetown University Fuel Cell Transit Bus Program	4,770,841
DC	WMATA - Buses in D.C., Maryland, and Virginia	1,967,357
DE	Delaware Transit Corporation	2,951,036
FL	Broward County Buses and Bus Facility	196,736
FL	Collier Area Transit, Transit Facility	737,759
FL	DeLand Intermodal Center (VOTRAN)	1,551,438
FL	East Central Florida Transit Coalition Bus and Facilities	4,757,070
FL	Ft. Lauderdale, Transit Shuttle Vehicles	1,475,518
FL	Gainesville, Multimodal Transportation Center	923,679
FL	Hillsborough Area Regional Transit (HART)	72,000
FL	Jacksonville Transit Authority (JTA) - Buses	1,229,598
FL	Key West Buses and Bus Facilities	983,679
FL	Lakeland, Citrus Connection	491,839
FL	Lee County, Bus Facility	737,759
FL	LYNX buses, bus facilities, and passenger amenities	737,759
FL	Miami Beach Intermodal Transit Center	1,475,518
FL	Tallahassee (TALTRAN) Intermodal Center	491,839
FL	West Coast Florida Bus Coalition	2,596,912
FL	West Palm Beach, Trolley Buses	1,229,598
GA	Atlanta, Multimodal Terminal	1,967,357
GA	Chatham Area Transit	2,655,932
GA	Georgia Regional Transportation Authority - Regional Express Bus and Facilities	4,363,598
GA	Georgia Statewide Bus Replacement Program	1,475,518

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
GA	Gwinnett County Operations & Maintenance Facility	1,475,518
GA	Macon Intermodal Center	1,967,357
GA	MARTA buses, clean fuel buses and facilities	459,197
HI	BRT Systems, Appurtenances & Facilities	7,869,429
HI	Bus Transit Centers - Waianae, Mililani, Wahiawa	737,759
HI	Hawaii Statewide Bus and Bus Facilities	4,918,393
HI	Maui County Buses	1,082,046
IA	Cedar Falls Multimodal Facility	1,082,046
IA	State of Iowa, Buses, Facilities, Equipment	560,000
ID	Idaho Transit Coalition Bus and Bus Facilities	2,111,202
IL	Illinois Statewide Buses and Facilities	8,782,443
IL	Normal Multi-modal Facility	737,759
IN	Cherry Street Multimodal Facility	491,839
IN	Fort Wayne Public Transportation Corporation (Fort Wayne Citilink)	590,207
IN	Indianapolis Downtown Transit Facility	4,426,554
IN	Wabash Landing Transit Bus and Bus Facility	245,920
KS	City of Wichita, Mini-Transfer Station	393,471
KS	Johnson County Transit Programs	491,839
KS	Kansas City Area Transportation Authority (KCATA)	245,920
KS	Kansas, Buses and Bus Facilities	2,951,036
KS	Lawrence Transit System Transfer Center	491,839
KS	Topeka Transit Buses	1,475,518
KS	Wichita Transit Authority	1,180,414
KY	Fulton County Transit Authority R V Cutaways	177,062
KY	Henderson County Facility	491,839
KY	KY Statewide, Bus and Bus Facilities	6,417,590
KY	KY Transportation Cabinet - Community Action groups	1,401,742
KY	Laurel County intermodal facility	4,918,393
KY	Paducah Area Transit Authority Buses	472,166
KY	Pennyrile Allied Community Services Transit Facility	365,928
KY	Transit Authority of Northern Kentucky (TANK)	1,475,518
KY	Transit Authority of River City	1,967,357
LA	LA Public Transit Association, Buses and Bus Facilities	7,977,635
LA	LSU Health Sciences Center Shreveport Intermodal Facility	245,920
MA	Attleboro Intermodal Mixed-Use Garage Facility	737,759
MA	Cape Ann Transit Authority, buses and trolleys	147,552
MA	Cape Cod Intermodal Facilities (Cape & Island Transit Ctrs)	295,104
MA	Cities of Beverly and Salem, Intermodal Facility Improvements	245,920
MA	CTS Northern Tier Buses - MA	295,104
MA	Essex County, City of Lynn, MA, buses and senior citizen vans	137,715
MA	Essex County, City of Peabody, MA, buses	47,217
MA	Essex County, Town of Danvers, MA, buses and senior citizen vans	64,923
MA	Lowell-Gallagher Intermodal Facility	983,679
MA	Merrimack Valley Regional Transit Authority (MVRTA), facility improvements	245,920
MA	Northern Tier Intermodal Center - Athol	295,104
MA	Springfield Union Station Intermodal Redevelopment Project	5,902,072
MA	Worcester Regional Transit Authority (WRTA) Maintenance Facility	196,736
MD	Maryland Statewide Bus and Bus Facilities	7,869,429
MD	Montgomery County FDA Transit Center	245,920
ME	Maine Statewide Bus & Bus Facility	983,679
ME	Oceangateway Development Project	491,839
ME	State of Maine, statewide buses	983,679 a/
MI	Ann Arbor Transportation Authority Bus & Bus Facilities	245,920
MI	Blue Water Area Transportation	983,679
MI	Kalamazoo Metro Transit - Transfer Center	2,852,668
MI	Michigan Statewide Bus and Facilities	983,679
MN	Dakota County, Cedar Avenue Project	983,679
MN	Duluth Transit Authority Bus and Bus Facilities	491,839
MN	Greater Minnesota Transit Authority Bus & Bus Facilities	1,967,357
MN	La Crescent - Public Transfer Hub	59,021
MN	Metro Transit	11,395,917
MN	Metropolitan Light Rail Transit Joint Powers Board - Rush Line Corridor	491,839
MN	Minneapolis downtown circulator	1,967,357
MN	Minneapolis, 63rd Ave N. Park and Ride	983,679

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	
MN	Northwest Corridor Busway	2,459,197	
MN	Rochester - Bus Purchase	498,725	
MN	St. Cloud Metropolitan Transit Commission Facilities	491,839	
MN	STEELE - Bus Purchase	47,217	
MO	Houston buses	98,368	
MO	Kansas City KCATA Buses	196,736	
MO	Missouri Bus & Bus Facilities - Dunklin County, City of Houston, Southeast Missouri Transportation Service, Scott County, SE Missouri State University	245,920	
MO	Missouri Statewide Bus and Bus Facility Projects	2,772,000	
MO	Southeast Missouri Trans. Services Bus and Bus Facilities	491,839	
MO	Southwest Missouri State University Intermodal Transfer Facility	2,951,036	
MS	Brookhaven, Multi-modal Center	1,967,357	
MS	Harrison County multi-modal facilities and shuttle service	491,839	
MS	Hattiesburg Intermodal Facility	737,759	
MT	Billings bus and bus facilities	983,679	
MT	District IX - Bozeman Galavan	245,920	
MT	Mountain Line Buses Missoula	491,839	
NC	North Carolina Bus and Bus Facilities	7,434,289	
NC	Piedmont Authority for Regional Transportation (PART) - Bus Purchase	983,679	
NC	Triangle Transit Authority (TTA) Maintenance Facility	344,288	
ND	North Dakota Statewide Capital Transit	2,380,419	
NE	Metro Area Transit - Intermodal Facility	983,679	
NE	Metro Area Transit South Omaha/Stockyard Center	737,759	
NE	Nebraska Statewide	737,759	
NH	New Hampshire Statewide Bus Acquisition	737,759	
NJ	Bergen County Intermodal Facilities and Park-n-Ride	2,213,277	
NJ	Central New Jersey Raritan Valley Line Park-n-Ride	983,679	
NJ	Gloucester Co Sr. Buses	196,736	
NJ	Harrison New Jersey PATH Station Rehabilitation	245,920	
NJ	Montclair Community Wide Bus System	983,679	
NJ	Morris County, Intermodal Park-n-Rides Facilities	1,475,518	
NJ	Newark Penn Station Intermodal Access Enhancements	1,967,357	
NJ	Route 80 Howard Boulevard NJ Transit Park and Ride	491,839	
NJ	Trenton Station Intermodal	6,393,911	
NM	Espanola ADA van & Compressed Gas Equipment	73,776	
NM	Rio Rancho Buses and Facilities	245,920	
NM	Santa Fe Bus Facility Renovation	196,736	
NV	Bus Rapid Transit on South Virginia Street - Reno	460,013	b/
NV	Bus Rapid Transit Project Las Vegas Blvd	4,918,393	
NV	Las Vegas Downtown Transportation Center	2,213,277	
NV	Regional Transportation Commission (RTC) BRT - North Las Vegas CIVIS Bus Stops	319,696	
NV	Reno/Sparks intrmodal transportation terminals	1,950,000	a/
NY	Albany, NY - Capital District Transportation Authority (CDTA), Bus and Bus Facilities	2,655,932	
NY	Brooklyn, downtown intermodal transit district	491,839	
NY	Broome County, Binghamton Intermodal Terminal	983,679	
NY	Buffalo Intermodal Transportation Center	4,918,393	
NY	Central New York Regional Transportation Authority	2,951,036	
NY	City of Schenectady, bus and bus facilities	491,839	
NY	Jamaica Intermodal Facilities	1,475,518	
NY	Lower Hudson Intercounty Bus Program	786,943	
NY	Mobile Health Service Buses, NYC	491,839	
NY	Oneonta Public Transit Buses	737,759	
NY	Orange County, Buses	737,759	
NY	Rochester-Genesee Regional Transportation Authority (RGRTA) - Rochester Central Station	2,951,036	
NY	Utica Transit Authority Buses	885,311	
OH	Cincinnati Government Square Transit Transfer Center	3,934,715	
OH	Lorain Renovation Train Depot in a Multi-modal Hub	983,679	
OH	Ohio Public Transportation Association - Bus and Bus Facilities for the State of Ohio	2,564,288	
OK	Central Oklahoma Transportation & Parking Authority (COPTA)	1,909,197	
OK	Metropolitan Tulsa Transit Authority (MTTA)	983,679	
OK	Oklahoma Transit Association - Bus and Bus Facilities	4,368,393	
OK	OSU Multimodal Transportation Facility	2,951,036	
OR	Albany, Buses	216,409	
OR	Eugene Lane Transit District	1,967,357	

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION
OR	Wilsonville, South Metro Area Rapid Transit (SMART)	245,920
PA	Adams Transit Authority Buses and Bus Facility	393,471
PA	Allentown Intermodal Transportation Center	1,967,357
PA	Altoona Metro Transit Buses	491,839
PA	AMTRAN Bus and Transit System Improvements	737,759
PA	Beaver County Transit Authority Buses	147,552
PA	Berks Area Reading Transportation Authority - Buses and Facilities	279,679
PA	Bucks County, SEPTA Intermodal facility improvement	983,679
PA	Butler Township/City Joint Municipal Transit Multi-Modal Transfer Center	418,063
PA	Capital Area Transit Buses	491,839
PA	Easton Intermodal Terminal	1,967,357
PA	Endless Mountain Transportation Authority	295,104
PA	Hershey Intermodal Transportation Center	1,967,357
PA	Johnstown Inclined Plane visitors center	491,839 a/
PA	Mid-County Transit Authority, Facilities and Equipment	491,839
PA	Port Authority of Allegheny County Buses (including clean fuels)	1,746,030
PA	Pullman Multi-modal Center	491,839
PA	SEPTA - Paratransit Vehicles	491,839
PA	SEPTA Norristown Intermodal Facility	983,679
PA	Somerset County Transportation System	157,389
PA	Westmoreland County Transit Authority	1,426,334
PA	Wilkes-Barre Intermodal Facility	245,920
PA	Williamsport Bureau of Transportation City Bus - Lycoming County	1,229,598
PA	York County Transit Authority Buses	491,839
PR	Puerto Rico Metropolitan Bus Authority (MBA), bus and bus facilities	245,920
SC	Intermodal/Inland Port Terminal	983,679
SC	Myrtle Beach Regional Multimodal Transit Center	1,106,638
SC	North Charleston Regional Intermodal Transportation Center	491,839
SC	South Carolina Vehicles and Facilities	6,885,751
SC	Sumter Intermodal Transportation Center (Union Station)	2,951,036
SD	South Dakota Statewide - Bus and Bus Facilities	10,011
TN	Knoxville Electric Transit Intermodal Center	3,344,507
TN	Memphis Airport Intermodal Facility Improvements	2,951,036
TN	Tennessee Bus Replacements & Bus Facilities	7,772,000
TX	Beaumont Buses	98,368
TX	Corpus Christi Regional Transportation Authority (RTA) Bus & Bus Facilities	491,839
TX	El Paso Bus Projects	1,475,518
TX	Fort Worth Transportation Authority	2,711,036
TX	Galveston Buses	983,679
TX	Laredo, Administrative/Operations/ Maintenance Facility	1,721,438
TX	Odessa & Midland, TX - Alternative Fuel Buses	983,679
TX	Waco Transit, Buses,Maintenance and Administration Facilities	1,868,989
UT	State of Utah - Buses and Facilities	84,753
UT	UTA and Park City Transit Buses	531,187
VA	Arlington Bus Transfer Stations	491,839
VA	Greater Roanoke Transit Company (GRTC) Buses	1,032,863
VA	Hampton Roads Bus and Bus Facilities	1,500,110
VA	Petersburg Area Transit	737,759
VA	Potomac & Rappahannock Transportation Commission	2,065,725
VA	Potomac Yard Transitway	786,943
VI	Virgin Islands Transit (VITRAN)	491,839
VT	Chittenden County Transit Authority Bus and Facility	1,967,357
VT	Montpelier Multimodal Center	1,967,357
VT	St. Johnsbury Transit Center Rehabilitation	245,920
VT	Winooski Falls Downtown Multimodal Transportation Center	491,839
WA	Aurora Avenue Bus Rapid Transit	1,475,518
WA	Burien transit center transit oriented development	1,967,357
WA	Clark County, WA C-TRAN Vancouver Mall Transit Center	2,557,565
WA	Edmonds Crossing multi-modal project	3,442,875
WA	Issaquah Highlands Park & Ride	1,377,150
WA	Jefferson Transit Facilities	983,679
WA	King Street Station Multimodal Facility	245,920
WA	Mason County Transportation Authority Facilities	295,104
WA	Mercer Island Transit Center, Park and Ride	491,839

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS AND BUS-RELATED ALLOCATIONS

STATE	PROJECT	ALLOCATION	
WA	Pierce County bus and bus facilities	2,951,036	
WA	Port Angeles International Gateway project	1,475,518	
WA	Snohomish County Community Transit park and ride	2,951,036	
WA	Sound Transit regional transit hubs	136,745	
WA	Spokane bus and bus facilities	2,459,197	
WI	Wisconsin Statewide Bus & Bus facilities	10,967,230	
WV	Huntington, Tri-State Transit Authority (TTA) buses and vans	1,770,622	
WV	Monongalia Courthouse Annex in Morgantown - Intermodal Parking Facility	3,442,875	
WY	Wyoming Department of Transportation	2,459,197	
	Subtotal FY 2003 Unobligated Allocations	*$456,693,956*	
	TOTAL UNOBLIGATED ALLOCATION	**$624,654,956**	
Fiscal Years 1998, 1999, 2000, and 2001 Extended Allocations			
AL	University of Alabama Birmingham fuel cell buses, 2001	$1,980,630	
AL	City of Montgomery's Rosa Parks bus project, 2001	247,579	a/
AK	Homer Alaska Maritime Wildlife Intermodal and welcome center, 2001	841,768	
CA	City of Fresno intermodal facility, 2001	495,157	a/
CT	Norwich bus terminal and pedestrian access, 2001	990,315	
MI	Traverse City Transfer station, 2001	990,315	
NV	Lake Tahoe CNG buses and fleet conversion, 2001	167,397	
NY	Binghamton Intermodal Transportation Center, 2000	1,103,732	
NY	Bronx Zoo intermodal transportation facility	247,579	a/
NY	Sullivan County, buses, bus facilities and related equipment, 2001	1,237,894	
PA	Somerset County ITS related equipment, 2001	99,032	
PA	Wilkes Barre intermodal transportation center, 2001	990,315	
PA	Wilkes Barre intermodal facility, 2000	1,226,369	
PA	Wilkes Barre intermodal facility, 1999	1,240,625	
PA	Wilkes Barre intermodal facility, 1998	1,465,794	
VA	Falls Church Buses, 2001	728,045	a/
VT	Bellows Falls Multimodal, 2001	1,485,472	
VT	Brattleboro multimodal center, 2001	2,475,786	
VT	Burlington multimodal transportation center, 2001	495,159	
VT	Vermont Agency of Transportation buses and bus facilities	1,485,472	a/
WY	Cheyenne transit and operation facility, 2001	911,089	
	Total Extended Allocation	**$20,905,524**	c/

a/ Clarification and/or name change in FY 2004 conference report.

b/ Balance reallocated to Reno/Sparks intermodal tansportation terminals

c/ Period of availability for remaining unobligated funds is extended one additional year and will lapse September 30, 2004. Projects extended in the FY 2003 Conference Report whose funds were obligated as of September 30, 2003 are not listed.

FEDERAL TRANSIT ADMINISTRATION

Table 10

FY 2004 NATIONAL PLANNING AND RESEARCH PROGRAM ALLOCATIONS

STATE	PROJECT	ALLOCATION	AVAILABLE ALLOCATION
AL	Center for Composite Manufacturing, Alabama	$968,254	483,821
AL	JSU Bus Technology Research Center	994,100	496,736
CA	CALSTART/Weststart Bus Rapid Transit; Clean Mobility and Transit Enhancements	2,112,462	1,055,563
DC	Community Transportation Association of America's National Joblinks Program	994,100	$496,736
DC	Project ACTION (TEA-21)	2,982,300	1,490,207
FL	Center for Intermodal Transportation, Florida A&M University	745,575	372,552
FL	State University System of Florida Intermodal Transportation Safety Initiative	6,958,700	3,477,149
MD	Transit Technology Career Ladder Partnership Training Program	497,050	248,368
MN	Hennepin County community transportation, Minnesota	1,192,920	596,083
NC	North Carolina State University Center for Transportation and the Environment	99,410	49,674
ND	NDSU Transit Center for small urban areas, North Dakota	397,640	198,694
NY	NYU-Wagner Rudin Center Americas Mega City Project, NY	74,558	37,255
OK	Fischer-Tropsch clean diesel technology demonstration, Oklahoma	994,100	496,736
OK	Oklahoma Transportation Center	1,491,150	745,103
PA	National Bio-Terrorism Civilian Medical Response Center, Pennsylvania	994,100	496,736
TN	Advanced Transportation Technology Institute, Tennessee	994,100	496,736
VA	Interior Air Quality Industrial Engine Control Demonstration, Bristol, Virginia	844,985	422,225
WA	Vashon Island Passenger-Only Ferry Initiative, Washington	994,100	496,736
WV	WVU exhaust emissions testing, West Virginia	1,355,555	677,349
	TOTAL ALLOCATION	**$25,685,159**	**$12,834,459**

FEDERAL TRANSIT ADMINISTRATION

TABLE 11

FY 2004 JOB ACCESS AND REVERSE COMMUTE PROGRAM ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	ALLOCATION	AVAILABLE ALLOCATION
AK	Craig Transit Service JARC Program	$49,563	$26,348
AK	MASCOT Matanuska-Susitna Valley JARC Project	198,252	105,392
AK	Mobility Coalition	495,630	263,479
AK	North Pole Transit System JARC Program	74,344	39,522
AK	Seward Transit Service JARC Program	198,252	105,392
AK	Sitka Community RIDE	594,756	316,175
AL	Alabama Disabilities Advocacy Program [ADA] Rural Transportation Services	495,630	263,479
AL	Easter Seals West Alabama JARC Program	991,260	526,959
AL	Jefferson County Job Access Reverse Commute Projects	2,973,779	1,580,876
AR	Fort Smith Transit Job Access Reverse Commute Program	198,252	105,392
AR	West Memphis Transit Services	247,815	131,740
AZ	Maricopa Association of Governments JARC Projects	1,734,705	922,178
CA	AC Transit CalWORKS Welfare to Work	1,485,898	789,911
CA	City of Irwindale Senior Transportation Services	64,432	34,252
CA	Guaranteed Ride Home, Santa Clarita	396,504	210,784
CA	Mendocino Transit Authority Job Access Reverse Commute	99,126	52,696
CA	Metro Link San Bernadino Platform Extension	991,260	526,959
CA	Sacramento Region Job Access Reverse Commute Project	1,486,890	790,438
CA	Ways to Work	991,260	526,959
CT	Connecticut Statewide	3,221,594	1,712,616
DC	Georgetown, Washington DC - Metro Connection	991,260	526,959
DC	Washington Metropolitan Area Transit Authority	991,260	526,959
DE	Delaware Statewide Welfare to Work	743,445	395,219
FL	Jacksonville, FL Transportation Authority, Community Transportation Coordinator Program	2,973,779	1,580,876
FL	Key West, Florida Job Access Reverse Commute	495,630	263,479
GA	Chatham Area Transit Job Access Reverse Commute (JARC)	991,260	526,959
IA	Iowa Statewide JARC	991,260	526,959
IL	Illinois Statewide JARC	198,252	105,392
IL	Operation Ride DuPage	495,630	263,479
IL	Ray Graham Association for People With Disabilities	123,907	65,870
IN	IndyGo IndyFlex Job Access Reverse Commute Program	743,445	395,219
KS	ADA Mobility Planning	361,810	192,340
KS	JARC Program, MidAmerica Regional Council Kansas City	495,630	263,479
KS	Topeka Metropolitan Transit Authority JARC	693,882	368,871
KS	Unified Government of Wyandotte County JARC	1,362,982	724,568
KY	Bowling Green KY Housing Authority Reverse Access Commute	297,378	158,088
MA	Holyoke Community Access to Employment and Adult Education	74,344	39,522
MA	Pioneer Valley Access to Jobs and Reverse Commute Program	451,023	239,766
MA	Worcester Regional Transit Authority JARC Projects	148,689	79,044
MD	Maryland Statewide JARC	3,965,039	2,107,835
MD	VoxLinx Voice-Enabled Transit Trip Planner	1,288,638	685,046
ME	Maine Statewide JARC	489,682	260,318
MI	Detroit Job Access Reverse Commute	1,586,016	843,134
MI	Flint Transit Job Access Reverse Commute Program	743,445	395,219
MI	Grand Rapids/Kent County JARC	1,189,512	632,351
MI	North Oakland Transportation Authority	148,689	79,044
MN	Metropolitan Council Job Access	495,630	263,479
MO	Kansas City Job Access Partnership	495,630	263,479
MO	Missouri Statewide JARC	3,965,039	2,107,835
ND-MN	Metropolitan Access to Jobs Initiative Fargo, North Dakota & Moorehead Minnesota	99,126	52,696
NJ	New Jersey Community Development Corporation Transportation Opportunity Center	297,378	158,088

FEDERAL TRANSIT ADMINISTRATION

TABLE 11

FY 2004 JOB ACCESS AND REVERSE COMMUTE PROGRAM ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	ALLOCATION	AVAILABLE ALLOCATION
NJ	New Jersey Statewide JARC	4,708,484	2,503,054
NM	New Mexico Statewide JARC	594,756	316,175
NV	Lake Tahoe Public Transit Services JARC Project	99,126	52,696
NV	Nevada Statewide small urban and rural Job Access Reverse Commute	396,504	210,784
NY	Broome County Transit JARC	99,126	52,696
NY	Capital District Transportation Authority JARC	495,630	263,479
NY	Central New York Regional Transportation Authority JARC	396,504	210,784
NY	Chautauqua County Job Access/Reverse Commute Project	99,126	52,696
NY	City of Hornell Job Access Reverse Commute Program	99,126	52,696
NY	City of Poughkeepsie Underserved Population Bus Service	99,126	52,696
NY	Essex County Job Access Reverse Commute Project	99,126	52,696
NY	Franklin County Job Access Reverse Commute Project	198,252	105,392
NY	MTA Long Island Bus Job Access Reverse Commute Project	247,815	131,740
NY	New York Statewide JARC	991,260	526,959
NY	North Country County Consortium	4,956,299	2,634,794
NY	Oneida/Herkimer County JARC Project	99,126	52,696
NY	Orange County JARC Project	99,126	52,696
NY	Rochester-Genesee Regional Transportation Authority JARC	743,445	395,219
NY	Tompkins Consolidated Area Transit	74,344	39,522
NY	Ulster County Area Transit Rural Feeder Service	49,563	26,348
OH	Akron Metro Regional Transit Authority Job Access and Reverse Commute Program	297,378	158,088
OH	Central Ohio Transit Authority's [COTA] Job Access & Mobility Management Program	495,630	263,479
OH	Greater Cleveland Regional Transit Authority JARC Program	743,445	395,219
OH	Nile/Trumbull Transit	198,252	105,392
OH	Toledo Job Access Reverse Commute	346,941	184,436
OK	Oklahoma Statewide JARC	5,947,550	3,161,746
OR	Jackson-Josephine County JARC	198,252	105,392
OR	Portland Region Job Access Reverse Commute	495,630	263,479
OR	Salem Area Transit Reverse Commute Project	396,504	210,784
PA	Port Authority of Allegheny County JARC Program	3,612,150	1,920,238
PA	SEPTA JARC Program	4,460,669	2,371,314
RI	Rhode Island Statewide JARC	1,399,659	744,066
SD	Cheyenne River Sioux Tribe Public Bus System	247,815	131,740
TN	Access to Healthcare for Children-Children's Health Fund	371,722	197,610
TN	Knox County Community Action Committee Transportation Program	396,504	210,784
TN	Knoxville Area Transit Job Access	545,193	289,827
TN	Monroe County TN Job Access Reverse Commute Program	99,126	52,696
TN	Tennessee Statewide JARC	5,699,743	3,030,013
TX	CityLink public transportation services	99,126	52,696
TX	Corpus Christi Welfare to Work Project	372,714	198,136
TX	El Paso Sun Metro Job Access Program	768,226	408,393
TX	Galveston Job Access Reverse Commute Program	470,848	250,305
TX	Lubbock Citibus Job Access Reverse Commute Program	227,990	121,201
TX	San Antonio VIA Metropolitan Transit JARC Program	545,193	289,827
TX	South East Texas Transit Facility Improvements and Bus Replacements	297,378	158,088
TX	Texas Colonias JARC Initiative	2,379,023	1,264,701
TX	Ways to Work, Tarrant County	297,378	158,088
VA	Bay Area Transit	198,252	105,392
VA	Bedford Ride	59,476	31,618
VA	Statewide Ways to Work	991,260	526,959
VA	Virginia Beach Paratransit Services	198,252	105,392

FEDERAL TRANSIT ADMINISTRATION

TABLE 11

FY 2004 JOB ACCESS AND REVERSE COMMUTE PROGRAM ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	ALLOCATION	AVAILABLE ALLOCATION
VA	Virginia Regional Transportation Association	198,252	105,392
VT	Chittenden County Transportation Authority JARC Program	247,815	131,740
WA	I-405 Congestion Relief Project	1,982,519	1,053,918
WA	Link Transit JARC Program	495,630	263,479
WA	Vanpooling Enhancement and Expansion Project	743,445	395,219
WA	Vehicle Trip Reduction Incentives	991,260	526,959
WA	Washington State Transit car-sharing Job Access	495,630	263,479
WI	Wisconsin Statewide JARC	2,577,275	1,370,093
WV	West Virginia Statewide JARC	991,260	526,959
---	Community Transportation Association of America's National Joblinks program	2,478,149	1,317,397
DC	Technical Assistance Support & Performance Reviews of the JARC Grants Program	298,230	158,996
	TOTAL ALLOCATIONS	**$104,380,500**	**$55,489,667**

FEDERAL TRANSIT ADMINISTRATION

TABLE 11A

PRIOR YEAR UNOBLIGATED SECTION 3037 JARC CONGRESSIONAL AND COMPETITIVE ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	AGENCY	UNOBLIGATED ALLOCATIONS
FY 2002 Unobligated Congressional Allocations			
AK	Seward Transit Service, Alaska		$200,000
AL	Jefferson County, Alabama		231,278
AL	Tuscaloosa, Alabama Disabilities Advocacy Program		1,000,000
AR	Central Arkansas Transit Authority		500,000
CA	Del Norte County, California		73,400
CA	Los Angeles, California		2,000,000
DC	Community Transportation Association of America		25,000
DC	Washington Area Metropolitan Transit Authority		175,000
GA	Macon-Bibb County, Georgia		400,000
IL	Bloomington to Normal, Illinois, Wheels to work		388,000
IL	DuPage County, Illinois		500,000
IN	Indianapolis Public Transportation Corporation , Indiana (Indyflex)		1,000,000
KS	Wichita, Kansas Transit		1,450,000
MD	State of Maryland		86,063
MO	Mid America Regional Council in Kansas City		1,200,000
ND	Oglala Sioux Tribe, North Dakota		150,000
NM	Santa Fe, New Mexico		630,000
NY	Broome County, New York		500,000
NY	Columbia County, New York		100,000
NY	New York Metropolitan Area Transportation Authority		1,000,000
OH	State of Ohio		128,000
OK	Oklahoma Transit Association		800,000
PA	State of Pennsylvania		240,000
TN	State of Tennessee		289,538
TX	Abilene, Texas Citilink Program		150,000
TX	Austin, Texas		500,000
TX	Corpus Christi, Texas		550,000
VA	Winchester, Virginia		1,000,000
WA	State of Washington		2,955,440
WA	WorkFirst Transportation Initiative, State of Washington		1,226,060
WI	State of Wisconsin		1,114,502
WV	State of West Virginia		475,192
	Subtotal FY 2002 Unobligated Congressional Allocations		*$20,837,473*
FY 2003 Unobligated Congressional Allocations			
AK	Alaska Mobility Coalition		$495,335
AK	Kenai Peninsula Transit Planning		495,335
AZ	AJO to Phoenix Rural Express Bus Service		198,134
AZ	Maricopa County Worklinks Project		247,668
AZ	Southwest Transit Assessment & Review Team Bus Route 131		297,201
AZ	Valley Metro (RPTA), City of Phoenix		1,089,738
CA	AC Transit - CalWORKS		1,981,342
CA	County of Santa Clara Guaranteed Ride Home Program		495,335
CA	East Palo Alto Shuttle Service		693,470
CA	LA County UTRANS		495,335
CA	Los Angeles County, MTA Ride Share program		866,837
CA	Low-Income LIFT Program SF MTC		990,671
CA	Southern California Regional Rail Authority, Metrolink double tracking		990,671
CO	Colorado Statewide - Colorado Association of Transit Agencies (CASA)		553,850
CT	Connecticut Statewide		3,487,348
DC	Georgetown Metro Connection - Washington, DC		1,089,738
DC	WMATA (DC, Maryland, and Virginia)		2,105,178
DE	Delaware Welfare to Work Initiative		743,003
FL	Jacksonville Trans. Authority Choice Ride Program		1,609,840
FL	Key West		990,671
FL	LYNX Central Florida Regional		198,134
GA	Chatham		433,914
GA	Macon - Bibb County Reverse Commute Program		787,770
IA	Iowa Statewide		990,671
IL	DuPage County Coordinated Paratransit Program		495,335
IL	Illinois Ways to Work		495,335
IL	Ways-to-Work – IL - MO		990,671
IN	Fort Wayne's Hanna Creighton Transit Center		743,003
IN	IndyGo Service		990,671
KS	KW Paratransit Vehicle		29,720

FEDERAL TRANSIT ADMINISTRATION

TABLE 11A

PRIOR YEAR UNOBLIGATED SECTION 3037 JARC CONGRESSIONAL AND COMPETITIVE ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	AGENCY	UNOBLIGATED ALLOCATIONS
KS	Mid America Regional Council (MARC)		495,335
KS	Wyandotte County		1,139,271
LA	Lafayette Ways to Work Program		99,067
MA	Brockton Area Tmsit Authority		222,901
MA	Community Transportation Association of America		990,671
MA	Northern Tier Dial-A-Ride		396,268
MA	Transportation Services of Northern Berkshire, Inc.		396,268
MD	Maryland Statewide (Montgomery County, $600,000)		4,953,354
MI	Grand Rapids/Kent County Job Access Plan		929,249
MN	Minneapolis / St. Paul, Met Council		990,671
MO	Metrolink Corridor Access to Jobs		2,972,013
MO	Metropolitan Kansas City Job Access Partnership		990,671
MO	Missouri Statewide		1,386,939
MO	Ways to Work Missouri		222,901
NC	Community Transportation Association of America's Joblinks Employment Transportation Initiative		990,671
NC	Wake County Coordinated Transportation System		767,770
NH	Lancaster - Littleton Transit Project		49,534
NJ	New Jersey Statewide		4,953,354
NY	Broome County Transit - Binghamton, NY		247,668
NY	Central NY Regional Transportation Authority		495,335
NY	Chautauqua Area Rural Transportation System		49,534
NY	Chemung County Transit		74,300
NY	Columbia County		99,067
NY	Franklin County Expansion of Hour Service		74,300
NY	Hornell Trans. Alternatives for NY		49,534
NY	Ithaca Service		74,300
NY	MTA - Long Island Bus		247,668
NY	New York State DOT		495,335
NY	Orange County		99,067
NY	Rochester-Genesee Regional Transportation Authority (RGRTA)		109,403
NY	Tompkins Consolidated Area Transit, Tompkins County		297,201
OH	Central Ohio Transit Authority (COTA) - Mobility Management		594,403
OH	Northwest Ohio Commuter LINK Toledo		371,502
OH	STEP-UP Job Access Project Dayton		123,834
OK	Oklahoma Transit Association		1,268,902
OR	Jackson-Josephine County		198,134
OR	Oregon Ways to Work Loan Program		247,668
OR	Salem Area Transit		495,335
PA	Port Authority of Allegheny County Access to Jobs		3,962,683
PA	SEPTA		1,584,402
TN	Chattanooga		495,335
TN	Knoxville		743,003
TN	State of Tennessee		1,486,006
TX	Abilene Citylink Program		99,067
TX	Austin Capital Metros Access		2,476,677
TX	Citibus, Lubbock		227,854
TX	Corpus Christi		1,213,572
TX	East Texas Just Transportation Alliance (ETJTA): Tyler Transit		198,134
TX	El Paso		247,668
TX	Galveston		594,403
TX	San Antonio Access to Jobs Program		1,077,850
VA	Fairfax County, Short-Term Transit Improvements		1,585,073
WA	Community Transportation Association of America		148,601
WA	WA WorkFirst Initiative		4,705,687
WA	Ways to Work - EPIC Yakima		495,335
WI	Wisconsin Statewide		5,151,488
WV	West Virginia Statewide		990,671
	Subtotal FY 2003 Unobligated Congressional Allocations		***$82,174,829***

Unobligated Competitive Allocations

AZ	Ajo/Phx Rural Express Bus Service	Maricopa Association Of Governments	$125,000
AZ	START	Maricopa Association Of Governments	250,000
AZ	Work Links	Maricopa Association Of Governments	1,125,000
CA	Reverse Commute Expansion	San Luis Obispo Council Of Governments	25,000
CO	Job Access Route	City Of Loveland	97,355

FEDERAL TRANSIT ADMINISTRATION

TABLE 11A

PRIOR YEAR UNOBLIGATED SECTION 3037 JARC CONGRESSIONAL AND COMPETITIVE ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	AGENCY	UNOBLIGATED ALLOCATIONS
IL	Transportation Information Clearinghouse	Regional Transportation Authority	100,000
MA	Night Owl Service	Pioneer Valley TA	300,000
MO	Corridor for Work and Learning	East - West Gateway Coordinating Council	305,197
NC	New Hanover County	North Carolina Department Of Transportation	122,000
NH	Job Access Program	City of Nashua	149,302
NY	Rides for Work-Mobility Management Center	Central New York Regional Transportation	104,167
NY	Project Renewal	New York Metropolitan Transportation Council	396,941
OR	Central Oregon Commuter Network	City Of Bend	350,000
TX	CityLink Evening Service	City Of Abilene	100,000
TX	Job Express	City Of El Paso Mass Transit Department	250,000
TX	Individual Trips	Fort Worth Transportation Authority	200,000
	Subtotal Unobligated Competitive Allocations		*$3,999,962*
	TOTAL UNOBLIGATED ALLOCATIONS		**$107,012,264**

FEDERAL TRANSIT ADMINISTRATION

TABLE 12

FY 2004 APPORTIONMENT FORMULA FOR FORMULA PROGRAM

Percent of Formula Funds Available

Section 5310: 2.4% States - allocated to states based on state's population of elderly and persons with disabilities

Section 5311: 6.37% Nonurbanized Areas - allocated to states based on state's nonurbanized area population

Section 5307: 91.23% Urbanized Areas (UZA)

UZA Population and Weighting Factors

50,000-199,999 in population : (Apportioned to Governors)

9.32% of available Section 5307 funds

50% apportioned based on population

50% apportioned based on population x population density

200,000 and greater in population: (Apportioned to UZAs)

90.68% of available Section 5307 funds

33.29% (Fixed Guideway Tier*)

95.61% (Non-incentive Portion of Tier)

— at least 0.75% to each UZA with commuter rail and pop. 750,000 or greater

60% - fixed guideway revenue vehicle miles

40% - fixed guideway route miles

4.39% ("Incentive" Portion of Tier)

-- at least 0.75% to each UZA with commuter rail and pop. 750,000 or greater

-- fixed guideway passenger miles x fixed guideway passenger miles/operating cost

66.71% ("Bus" Tier)

90.8% (Non-incentive Portion of Tier)

73.39% for UZAs with population 1,000,000 or greater

50% - bus revenue vehicle miles

25% - population

25% - population x population density

26.61% for UZAs pop. < 1,000,000

50% - bus revenue vehicle miles

25% - population

25% - population x density

9.2% ("Incentive" Portion of Tier)

-- bus passenger miles x bus passenger miles/operating cost

*Includes all fixed guideway modes, such as heavy rail, commuter rail, light rail, trolleybus, aerial tramway, inclined plane, cable car, automated guideway transit, ferryboats, exclusive busways, and HOV lanes.

FEDERAL TRANSIT ADMINISTRATION

TABLE 13

FY 2004 SECTION 5309 FIXED GUIDEWAY MODERNIZATION PROGRAM APPORTIONMENT FORMULA

Tier 1 — First $497,700,000 to the following areas:

Baltimore	$	8,372,000
Boston	$	38,948,000
Chicago/N.W. Indiana	$	78,169,000
Cleveland	$	9,509,500
New Orleans	$	1,730,588
New York	$	176,034,461
N. E. New Jersey	$	50,604,653
Philadelphia/So. New Jersey	$	58,924,764
Pittsburgh	$	13,662,463
San Francisco	$	33,989,571
SW Connecticut	$	27,755,000

Tier 2 — Next $70,000,000 as follows: Tier 2(A): 50 percent is allocated to areas identified in Tier 1; Tier 2(B): 50 percent is allocated to other urbanized areas with fixed guideway tiers in operation at least seven years. Funds are allocated by the Urbanized Area Formula Program fixed guideway tier formula factors that were used to apportion funds for the fixed guideway modernization program in FY 1997.

Tier 3 — Next $5,700,000 as follows: Pittsburgh 61.76%; Cleveland 10.73%; New Orleans 5.79%; and 21.72% is allocated to all other areas in Tier 2(B) by the same fixed guideway tier formula factors used in fiscal year 1997.

Tier 4 — Next $186,600,000 as follows: All eligible areas using the same year fixed guideway tier formula factors used in fiscal year 1997.

Tier 5 — Next $70,000,000 as follows: 65% to the 11 areas identified in Tier 1, and 35% to all other areas using the most current Urbanized Area Formula Program fixed guideway tier formula factors. Any segment that is less than 7 years old in the year of the apportionment will be deleted from the database.

Tier 6 — Next $50,000,000 as follows: 60% to the 11 areas identified in Tier 1, and 40% to all other areas using the most current Urbanized Area Formula Program fixed guideway tier formula factors. Any segment less than 7 years old in the year of the apportionment will be deleted from the database.

Tier 7 — Remaining amounts as follows: 50% to the 11 areas identified in Tier 1, and 50% to all other areas using the most current Urbanized Area Formula Program fixed guideway formula factors. Any segment that is less than 7 years old in the year of the apportionment will be deleted from the database.

FEDERAL TRANSIT ADMINISTRATION

TABLE 14

FISCAL YEAR 2004 FORMULA GRANT APPORTIONMENTS - UNIT VALUES OF DATA

	APPORTIONMENT UNIT VALUE	AVAILABLE APPORTIONMENT UNIT VALUE
Section 5307 Urbanized Area Formula Program - Bus Tier		
Urbanized Areas Over 1,000,000:		
Population	$2.88676808	$1.53897651
Population x Density	$0.00073247	$0.00039049
Bus Revenue Vehicle Mile	$0.39234655	$0.20916544
Urbanized Areas Under 1,000,000:		
Population	$2.64560930	$1.41041138
Population x Density	$0.00115755	$0.00061711
Bus Revenue Vehicle Mile	$0.52282496	$0.27872531
Bus Incentive (PM denotes Passenger Mile):		
Bus PM x Bus PM = / Operating Cost	$0.00630992	$0.00336391
Section 5307 Urbanized Area Formula Program - Fixed Guideway Tier		
Fixed Guideway Revenue Vehicle Mile	$0.59368549	$0.31650205
Fixed Guideway Route Mile	$32,973	$17,578
Commuter Rail Floor	$7,384,783	$3,936,931
Fixed Guideway Incentive:		
Fixed Guideway PM x Fixed Guideway PM = / Operating Cost	$0.00056456	$0.00030098
Commuter Rail Incentive Floor	$339,077	$180,767
Section 5307 Urbanized Area Formula Program - Areas Under 200,000		
Population	$5.34049101	$2.84709058
Population x Density	$0.00265084	$0.00141320
Section 5311 Nonurbanized Area Formula Program		
Areas Under 50,000		
Population	$2.66076635	$1.42003749

Section 5309 Capital Program - Fixed Guideway Modernization

Apportionment Unit Values

	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7
Legislatively Specified Areas:						
Revenue Vehicle Mile	$0.03043443	-------	$0.13683131	$0.03651184	$0.02407374	$0.12333530
Route Mile	$2,122.43	-------	$7,832.52	$2,723.57	$1,795.76	$9,200.10
Other Urbanized Areas:						
Revenue Vehicle Mile	$0.16377360	$0.00579309	$0.13683131	$0.08794439	$0.07179134	$0.55170519
Route Mile	$4,772.78	$168.83	$7,832.52	$2,635.90	$2,151.75	$16,535.88

Available Apportionment Unit Values

	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7
Legislatively Specified Areas:						
Revenue Vehicle Mile	$0.01646528	-------	$0.07402690	$0.01975322	$0.01302410	$0.06672544
Route Mile	$1,148.25	-------	$4,237.46	$1,473.48	$971.52	$4,977.33
Other Urbanized Areas:						
Revenue Vehicle Mile	$0.08860290	$0.00313411	$0.07402690	$0.04757866	$0.03883972	$0.29847718
Route Mile	$2,582.11	$91.34	$4,237.46	$1,426.04	$1,164.12	$8,946.05

FEDERAL TRANSIT ADMINISTRATION

TABLE 15

2000 CENSUS URBANIZED AREAS WITH POPULATION 200,000 OR GREATER ELIGIBLE TO USE FY 2004 SECTION 5307 FUNDS FOR OPERATING ASSISTANCE

State	Urbanized Area Description	Population	FY 2002 Apportionment	FY 2004 Apportionment Operating Limitation a/	FY 2004 Available Operating Limitation b/
AL	Huntsville, AL	213,253	$1,677,473	$1,677,473	$760,281
CA	Antioch, CA	217,591	$1,914,688	$1,914,688	$1,914,688
CA	Indio--Cathedral City--Palm Springs, CA (Indio-Coachella, CA -- $621,797) (Palm Springs, CA -- $1,227,811)	254,856	$1,849,608	$1,849,608	$1,463,347
CA	Lancaster--Palmdale, CA	263,532	$2,206,544	$2,206,544	$2,206,544
CA	Santa Rosa, CA	285,408	$2,636,339	$2,636,339	$1,580,475
CA	Victorville--Hesperia--Apple Valley, CA	200,436	$1,311,837	$1,311,837	$988,092
CA	Temecula--Murrieta, CA	229,810	----------	$1,247,633	$784,228
CO	Fort Collins, CO	206,757	$1,156,197	$1,156,197	$937,347
CT	Bridgeport--Stamford, CT--NY (Stamford, CT-NY -- $5,332,860) (Norwalk, CT -- $4,343,565)	888,890	$9,676,425	$9,676,425	$8,546,081
CT	Hartford, CT (Bristol, CT -- $983,277) (New Britain, CT -- $1,841,176)	851,535	$2,824,453	$2,824,453	$2,824,453
FL	Port St. Lucie, FL (Fort Pierce, FL -- $1,142,501) (Stuart, FL -- $839,705)	270,774	$1,982,206	$1,982,206	$941,434
FL	Bonita Springs--Naples, FL	221,251	$954,953	$954,953	$565,368
FL	Tallahassee, FL	204,260	$1,617,975	$1,617,975	$1,117,368
GA	Savannah, GA	208,886	$1,824,225	$1,824,225	$1,416,206
ID	Boise City, ID	272,625	$2,021,464	$2,021,464	$1,140,074
IL	Round Lake Beach--McHenry--Grayslake, IL--WI	226,848	$1,088,609	$1,088,609	$1,088,609
IL	Chicago, IL--IN (Aurora, IL -- $2,290,318) (Crystal Lake, IL -- $748,464) (Elgin, IL -- $1,852,124) (Joliet, IL -- $1,910,334)	8,307,904	$6,599,240	$6,599,240	$6,599,240
IN	Evansville IN--KY	211,989	$2,251,898	$2,251,898	$927,311
MA	Barnstable Town, MA	243,667	$538,120	$538,120	$538,120
MA	Boston, MA--NH--RI (Brockton, MA -- $1,906,558) (Lowell, MA-NH -- $2,366,926) (Taunton, MA -- $487,189)	4,032,484	$4,760,673	$4,760,673	$4,760,673
MD	Baltimore, MD (Annapolis, MD -- $858,335)	2,076,354	$858,335	$858,335	$858,335
MO	Springfield, MO	215,004	$1,748,930	$1,748,930	$936,730
MS	Gulfport--Biloxi, MS	205,754	$1,687,127	$1,687,127	$867,845
NC	Winston-Salem, NC	299,290	$1,811,413	$1,811,413	$1,219,287
NC	Asheville, NC	221,570	$968,044	$968,044	$703,518
NC	Greensboro, NC	267,884	$2,211,540	$2,211,540	$1,347,978
NE	Lincoln, NE	226,582	$2,658,761	$2,658,761	$1,232,731
NJ	Atlantic City, NJ	227,180	$1,842,968	$1,842,968	$1,842,968
NY	Poughkeepsie--Newburgh, NY (Poughkeepsie, NY -- $1,507,504) (Newburgh, NY -- $717,643)	351,982	$2,225,147	$2,225,147	$1,716,835
OH	Youngstown, OH--PA (Sharon, PA-OH -- $485,043)	417,437	$465,043	$465,043	$465,043
OH	Cincinnati, OH--KY--IN (Hamilton, OH -- $1,384,842)	1,503,262	$1,384,842	$1,384,842	$1,384,842
OR	Eugene, OR	224,049	$2,559,936	$2,559,936	$2,072,105
OR	Salem, OR	207,229	$2,070,221	$2,070,221	$1,489,199
PA	Reading, PA	240,264	$2,636,837	$2,636,837	$1,236,677
PA	Lancaster, PA	323,554	$2,258,871	$2,258,871	$1,613,901
PR	Aguadilla--Isabela--San Sebastian, PR	299,086	$1,148,984	$1,148,984	$652,360

FEDERAL TRANSIT ADMINISTRATION

TABLE 15

2000 CENSUS URBANIZED AREAS WITH POPULATION 200,000 OR GREATER ELIGIBLE TO USE FY 2004 SECTION 5307 FUNDS FOR OPERATING ASSISTANCE

State	Urbanized Area Description	Population	FY 2002 Apportionment	FY 2004 Apportionment Operating Limitation a/	FY 2004 Available Operating Limitation b/
PR	San Juan, PR (Caguas, PR -- $2,811,557) (Cayey, PR -- $831,273) (Humacao, PR -- $719,451) (Vega Baja-Manati, PR -- $1,562,942)	2,216,616	$5,925,223	$5,925,223	$5,925,223
RI	Providence, RI--MA (Newport, RI -- $644,329) (Fall River, MA-RI -- $2,051,153)	1,174,548	$2,695,482	$2,695,482	$2,695,482
TX	Lubbock, TX	202,225	$1,939,424	$1,939,424	$1,193,106
TX	Denton--Lewisville, TX (Denton, TX -- $599,570) (Lewisville, TX -- $692,152)	299,823	$1,291,722	$1,291,722	$985,638
VA	Richmond, VA (Petersburg, VA -- $1,016,957)	818,836	$1,016,957	$1,016,957	$1,016,957

a/ The amount shown represents the maximum emount ellowable (in accordance with Pub.L. 107-232 and the Surface Transportation Extension Act of 2003 (Pub. L. 108-88)) besed on funding provided in the Consolidated Appropriations Act, 2004. In cases where an urbanized aree's FY 2004 apportionment is less than the maximum, FTA will set the operating essistance budget, in TEAM-Web, at an emount not to exceed the FY 2004 apportionment. Funds are subject to the one percent set-aside required for Transit Enhancements and will be adjusted accordingly

b/ The amount shown rapresents funds currently availebility for obligation for operating assistance. Funds ara subject to the ona percent set-aside required for Transit Enhancements and will be adjusted accordingly

Note: For informationel purposes, the affected 1990 census small urbanized arees (less than 200,000 population) that were merged into an existing urbanized area of at least 200,000 population ere shown in parentheses immediately below the eligible 2000 census urbenized area. FTA is unable to identify tha urbanized areas which now incorporate rural areas that received Section 5311 in FY 2002 and they are not included in this table.

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February 11, 2004

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 119

Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 119

[Docket No. 1995N–0304]

RIN 0910–AA59

Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, our) is issuing a final regulation declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act (the act) because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. We are taking this action based upon the well-known pharmacology of ephedrine alkaloids, the peer-reviewed scientific literature on the effects of ephedrine alkaloids, and the adverse events reported to have occurred in individuals following consumption of dietary supplements containing ephedrine alkaloids.

DATES: This rule is effective on April 12, 2004.

FOR FURTHER INFORMATION CONTACT: Wayne Amchin, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6733.

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Why Have We Concluded That Dietary Supplements Containing Ephedrine Alkaloids Present an Unreasonable Risk?

We conclude that dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) (21 U.S.C. 342(f)(1)(A)) of the act because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. Dietary supplements containing ephedrine alkaloids are most often used for weight loss, energy, or to enhance athletic performance.

By its plain language, section 402(f)(1)(A) of the act requires evidence of "significant or unreasonable risk" of illness or injury. There is no requirement that there be evidence proving that the product has caused actual harm to specific individuals, only that scientific evidence supports the existence of risk. The Government's burden of proof for "unreasonable risk" is met when a product's risks outweigh its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use. "Unreasonable risk," thus, represents a relative weighing of the product's known and reasonably likely risks against its known and reasonably likely benefits. In the absence of a sufficient benefit, the presence of even a relatively small risk of an important adverse health effect to a user may be unreasonable. Because it is not reasonable to conclude that a product is too risky in the absence of any significant evidence, some weight of evidence of risk is required to meet this standard. For example, isolated adverse events alone might not be expected to constitute substantiation of risk, but adverse event reports combined with pharmacological and other clinical evidence might be expected to do so.

In considering whether dietary supplements containing ephedrine alkaloids present an unreasonable risk, we considered evidence from three principal sources: (1) The well-known, scientifically established pharmacology of ephedrine alkaloids; (2) peer-reviewed scientific literature on the effects of ephedrine alkaloids; and (3) the adverse events (including published case reports) reported to have occurred following consumption of dietary supplements containing ephedrine alkaloids.

Ephedrine alkaloids are members of a large family of pharmacological compounds called sympathomimetics. Sympathomimetics mimic the effects of epinephrine and norepinephrine, which occur naturally in the human body. Multiple studies demonstrate that dietary supplements containing ephedrine alkaloids, like other sympathomimetics, raise blood pressure and increase heart rate. These products expose users to several risks, including the consequences of increased blood pressure (*e.g.*, serious adverse events such as stroke, heart attack, and death) and increased morbidity and mortality from worsened heart failure and pro-arrhythmic effects. Based on the best available scientific data and the known pharmacology of ephedrine alkaloids and similar compounds, we conclude that dietary supplements containing ephedrine alkaloids pose short-term and long-term risks. This is clearest in long-term use, where sustained increased blood pressure in any population will increase the risk of stroke, heart attack, and death, but there is also evidence of risk from shorter-term use in patients with heart failure or underlying coronary artery disease.

The data do not indicate that these products provide a health benefit sufficient to outweigh these risks. The best clinical evidence for a benefit is for weight loss, but even there the evidence supports only a modest short-term weight loss, insufficient to positively affect cardiovascular risk factors or health conditions associated with being overweight or obese. Even if long-term weight loss could be achieved with the use of dietary supplements containing ephedrine alkaloids, we believe that the risks posed by these products when used continuously in the long term generally could not be adequately mitigated except through physician supervision. Other possible benefits, such as enhanced athletic performance, enhanced energy, or a feeling of alertness, lack scientific support and/or provide only temporary benefits that we consider trivial compared to the risks of these products, which may include long-term or permanent consequences like heart attack, stroke, and death. Therefore, we have determined that the risks of dietary supplements containing ephedrine alkaloids, when used for their labeled indications or under ordinary conditions of use, outweigh the benefits of these products. We do not believe these risks can be adequately mitigated through other regulatory measures available to FDA for dietary supplements, such as warnings in labeling.

As with other sympathomimetics, we believe that the risks posed by dietary supplements containing ephedrine alkaloids, when used continuously over the long term, generally cannot be adequately mitigated except through physician supervision. Similar to over-the-counter (OTC) single ingredient ephedrine and pseudoephedrine products, we expect that dietary supplements containing ephedrine alkaloids could be marketed without physician supervision for a very temporary, episodic use that provides a benefit that outweighs the known and reasonably likely risks of these products. However, we are currently unaware of any such use, and our experience with ephedrine alkaloid-containing OTC drug products suggests that such benefits will be demonstrable only for disease uses.

B. What Are the Ephedrine Alkaloids and Where Do They Come From?

The ephedrine alkaloids, including, among others, ephedrine, pseudoephedrine, norephedrine, methylephedrine, norpseudoephedrine, methylpseudoephedrine, are chemical stimulants that occur naturally in some botanicals (Refs. 1 through 5), but can be synthetically derived. The ingredient sources of the ephedrine alkaloids in dietary supplements include raw botanicals (i.e., plants) and extracts from botanicals. Ma huang, *Ephedra*, Chinese *Ephedra*, and epitonin are several names used for botanical ingredients, primarily from *Ephedra sinica* Stapf, *Ephedra equisetina* Bunge, *Ephedra intermedia* var. tibetica Stapf and *Ephedra distachya* L. (the *Ephedras*), that are sources of ephedrine alkaloids (Refs. 1, 6, and 7). Other plant sources that contain ephedrine alkaloids include *Sida cordifolia* L. and *Pinellia ternata* (Thunb.) Makino (Refs. 8 and 9). Common names that have been used for the various plants that contain ephedrine alkaloids include sea grape, yellow horse, joint fir, popotillo, and country mallow. The names desert herb, squaw tea, Brigham tea, and Mormon tea refer to North American species of *Ephedra* that do not contain ephedrine alkaloids but have been misused to identify ephedrine alkaloid containing ingredients. Although the proportions of the various ephedrine alkaloids in botanical species vary from one species to another, in most species used commercially, ephedrine is typically the predominant alkaloid in the raw material (Ref. 10).

Dietary supplements containing ephedrine alkaloids are widely sold in the United States (Refs. 11 through 13).[1] Over the last decade, dietary supplements containing ephedrine alkaloids have been labeled and used primarily for weight loss, energy, or to enhance athletic performance. Additional scientific evidence, and numerous reports of serious adverse events, including death, following consumption of dietary supplements containing ephedrine alkaloids, have raised concerns about their safety. Consequently, we have taken a number of actions in an attempt to protect the public from the risks of these products.

C. What Regulatory Actions Have We Taken Regarding Dietary Supplements Containing Ephedrine Alkaloids?

In the **Federal Register** of June 4, 1997 (62 FR 30678) (June 1997 proposal), we published a proposed rule on dietary supplements containing ephedrine alkaloids. In this document, we proposed to make a finding, with the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in an intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids. The June 1997 proposal would also have required that the label of dietary supplements containing ephedrine alkaloids state that the product should not be used for more than 7 days. We also proposed to prohibit the use of ephedrine alkaloids in dietary supplements with other ingredients that have a known stimulant effect that may interact with ephedrine alkaloids, and to prohibit labeling claims, such as weight loss or body building, that require long-term intake to achieve the purported effect. In addition, the June 1997 proposal would have required a statement accompanying claims that encourage short-term excessive intake to enhance a purported effect, such as an increase in energy, that taking more than the recommended serving may result in serious adverse health effects. We also proposed to require that the labels of all dietary supplements containing ephedrine alkaloids bear a statement warning consumers not to use the product if they are taking certain drugs;

[1] We use the term "dietary supplements containing ephedrine alkaloids" in this final rule to refer to dietary supplements containing botanical sources of ephedrine alkaloids. We use the term "ephedra" to refer to botanical sources of ephedrine alkaloids, whether derived from a member of the *Ephedra* genus or another botanical, such as *Sida cordifolia* L. or *Pinellia ternata* (Thunb.) Makino. We use the term "*Ephedra*" to refer specifically to the Ephedra genus of plants.

advising them to contact a health care professional before use if they have certain diseases or health conditions; and warning them to stop use and call a health care professional if they develop certain signs or symptoms. We proposed these actions in response to reports of serious illnesses and injuries, including a number of deaths, associated with the use of dietary supplements containing ephedrine alkaloids and our investigations and assessment of these illnesses and injuries. These actions were also supported by many of the recommendations made during the October 1995 meeting of an ad hoc Working Group of the FDA Advisory Committee (Working Group) and the August 1996 meeting of the Food Advisory Committee (FAC) and the Working Group concerning the potential public health problems associated with the use of dietary supplements containing ephedrine alkaloids and what action FDA should take to address the serious health concerns associated with their use (Refs. 14 and 15).

The comment period for the June 4, 1997, proposed rule ended on August 18, 1997. In a document published in the **Federal Register** of August 20, 1997 (62 FR 44247), we announced our intent to reopen the comment period after we corrected a number of inadvertent omissions in the administrative record. Subsequently on September 18, 1997 (62 FR 48968), we reopened the comment period until December 2, 1997.

During this second comment period, the Commission on Dietary Supplement Labels (the Commission) released its final report on November 24, 1997. The Commission, an independent agency established by section 12 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103–417), was charged with conducting a study on, and providing recommendations for, the regulation of label claims and statements for dietary supplements. The Commission's members included several scientists from academia and industry. In its report, the Commission divided its conclusions into three categories: findings, guidance, and recommendations. The Commission Report defined "findings" as conclusions reached by the Commission based on information and data it received during its deliberations. The Commission defined "guidance" that was directed to FDA as advice that we should consider as we developed or implemented activities related to the availability of dietary supplements in the marketplace. The Commission defined "recommendations" as suggested changes to FDA regulations or the development of new regulations governing dietary supplements.

One guidance statement in the Commission Report pertains to the safety of dietary supplements containing ephedrine alkaloids. In the report, the Commission urges FDA to use its authority under DSHEA to take swift enforcement action to address potential safety issues such as those posed recently by products containing ephedrine alkaloids. While it is expected that a responsible industry will avoid marketing unsafe products and that the industry will react promptly to remove products shown to be associated with significant or serious adverse events, in the final analysis there must be a strong and reliable enforcement system to back up the safety provisions of DSHEA. Failure by FDA to act when strong enforcement is needed undermines public confidence in the ability of not only the Federal Government but also the dietary supplement industry to ensure safety and avoid harm to the public (Ref. 16 at p. VII of Executive Summary).

In a notice published in the **Federal Register** on April 29, 1998 (63 FR 23633), we announced our views on the recommendations and guidance of the Commission, as presented in the Commission's report. In this notice, we stated that we take seriously our public health protection mission and are committed to removing unsafe dietary supplements from the market (63 FR 23633 at 23634). The direction taken in the current rulemaking on dietary supplements containing ephedrine alkaloids is consistent with the Commission's advice.

In September 1998, the U.S. General Accounting Office (GAO) began a study on FDA's June 1997 proposal. GAO's work culminated in the issuance of a July 1999 report (Ref. 17). GAO concluded that the evidence supported concern that ephedrine alkaloid-containing supplements can cause serious health problems and it recommended further data collection and review. At the same time, GAO criticized FDA's reliance on adverse event reports (AERs) as the basis for the proposed restrictions on dosage, frequency and duration of use.

In the **Federal Register** of April 3, 2000 (65 FR 17474, April 3, 2000), we withdrew parts of the June 1997 proposal. More specifically, we withdrew the proposed finding that a dietary supplement is adulterated if it contains 8 mg or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in the intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids; the proposed compliance procedures (regarding the analytical method FDA would use to determine the level of ephedrine alkaloids in a dietary supplement); the proposed label statement "Do not use this product for more than 7 days;" the proposed prohibition on labeling claims for uses that encourage long-term intake; and the proposed label statement to accompany claims for short-term uses ("Taking more than the recommended serving may cause heart attack, stroke, seizure, or death.").

We stated in our 2000 partial withdrawal of the June 1997 proposal that we continued to have a public health concern about the use of dietary supplements containing ephedrine alkaloids and that we would continue to monitor and provide appropriate followup on adverse events associated with the use of these products. We also stated that withdrawal of certain provisions of the June 1997 proposal did not limit our discretion to initiate enforcement actions with respect to dietary supplements containing ephedrine alkaloids.

On the same day as the 2000 partial withdrawal of the June 1997 proposal, we announced the availability of certain documents to update the administrative docket of the proposed rule (65 FR 17509, April 3, 2000). The documents consisted of additional information about some of the 270 adverse event reports (AERs) received by FDA between February and September 1997. In a separate **Federal Register** notice also issued on April 3, 2000, we announced the availability of additional AERs and related information received after publication of the proposed rule. The additional information included the analyses of these new AERs by experts both inside and outside the agency; review of labels of products associated with these adverse events; review of the use of *Ephedra* species in traditional Asian medicine; analysis of the likelihood and factors affecting the reporting of adverse events; and summaries of the known physiological, pharmacological, and toxic effects of ephedrine alkaloids (Ref. 18). This announcement was made in part to prepare for a meeting convened by the U.S. Department of Health and Human Services (HHS) Office of Women's Health (OWH) in August 2000 to discuss information about the safety of dietary supplements containing ephedrine alkaloids. Shortly before that meeting, FDA announced (65 FR 46721, July 31, 2000) that it would again reopen the comment period for the June 1997

proposal from August 10, 2000 (the day after the OWH meeting) until September 30, 2000. In that notice, we also announced the availability of a report on phenylpropanolomine and hemorrhagic stroke (Ref. 19).

In April 2001, HHS's Office of the Inspector General issued a report entitled "Adverse Event Reporting For Dietary Supplements: An Inadequate Safety Valve" (Ref. 20) that assessed the effectiveness of FDA's Adverse Event Reporting System. This report found that adverse event reporting systems typically detect only a small proportion of the events that actually occur.

In the **Federal Register** of March 5, 2003 (68 FR 10417), we published a notice making available new information about dietary supplements containing ephedrine alkaloids and requesting public comment on the new information and on regulation of these products (68 FR 10417, March 5, 2003) (March 2003 notice). We specifically sought comments on whether, in light of current information, we should determine that dietary supplements containing ephedrine alkaloids are adulterated because they present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling or under ordinary conditions of use if the labeling is silent. The notice also sought comment on a revised version of the warning statement first proposed on June 4, 1997. The revised warning statement had two components, a short warning that would be required to appear on the principal display panel (PDP) and a longer warning that could appear elsewhere in labeling. The proposed PDP warning stated that strokes, heart attacks, seizures, and death have been reported after consumption of dietary supplements containing ephedrine alkaloids and that the risks of adverse events increase with strenuous exercise and with use of other stimulants, including caffeine. The longer proposed warning included more detailed information about risks associated with the use of the product and recommended that consumers avoid using the product and/or consult a doctor under certain circumstances.

In the March 2003 notice, we asked for public comment on all additional evidence developed since the publication of the June 1997 proposal. One such study was a report by the Southern California Evidenced Based Practice Center (the RAND report, RAND, or RAND Corp.), commissioned by the National Institutes of Health (NIH) (Refs. 21 and 22). RAND reviewed recent evidence on the risks and benefits of ephedra and ephedrine[2] and found that dietary supplements containing ephedrine alkaloids are associated with higher risks of mild to moderate side effects such as heart palpitations, psychiatric effects, and upper gastrointestinal effects, and symptoms of autonomic hyperactivity such as tremor and insomnia, especially when they are taken with other stimulants. The RAND report identified 21 "sentinel events" among the adverse event reports it reviewed, including stroke, heart attack, and death.[3] RAND also found limited evidence of an effect of ephedra on short-term weight loss. Furthermore, RAND found limited evidence that synthetic ephedrine and caffeine in combination have a short-term enhancement effect on athletic performance in certain physical activities. RAND concluded that the scientific literature does not support an effect of ephedrine alone on athletic performance, and there were no clinical trials on the effects of dietary supplements containing botanical ephedrine alkaloids on athletic performance. One of the studies reviewed by RAND, a study by Boozer, *et al.* (2002), though frequently relied on by the dietary supplement industry to demonstrate the safety of ephedrine alkaloids, raised additional concerns about the effects of dietary supplements containing ephedrine alkaloids on blood pressure. This evidence, discussed in section V.B of this document, added significantly to the evidence suggesting that dietary supplements containing ephedrine alkaloids as currently marketed are associated with unreasonable safety risks.

At about the same time as we published the March 2003 notice, we issued warning letters to 26 firms for making unsubstantiated claims concerning the use of dietary supplements containing ephedrine alkaloids to enhance athletic performance. We also issued warning letters to firms promoting dietary supplements containing ephedrine alkaloids as alternatives to illicit street drugs.

In July 2003, GAO testified at a House Subcommittee hearing on issues relating to dietary supplements containing ephedrine alkaloids. GAO's testimony discussed and updated some of its findings from its prior 1999 report on dietary supplements containing ephedrine alkaloids (Ref. 23). The testimony provided new information, including an evaluation of Metabolife International's records of health-related calls from consumers of Metabolife 356 (Ref. 24). GAO noted that the types of adverse events identified in the health-related call records from Metabolife International were consistent with the types of adverse events reported to us, as well as with the scientifically documented physiological effects of ephedrine alkaloids. GAO also noted that despite the limited information contained in most of the call records, 14,684 call records contained reports of at least one adverse event among consumers of Metabolife 356. The GAO testimony identified 92 serious events that included heart attacks, strokes, seizures, and deaths and emphasized that these findings were similar to other reviews of the call records, including those done by Metabolife International and its consultants. The GAO testimony noted that, in those call records where age was documented, many of the serious adverse events occurred in relatively young consumers, with more than one-third being under the age of 30. Furthermore, for those call records in which quantity of use and/or frequency and duration of use were noted, most of the serious adverse events occurred among Metabolife 356 users who used the product within the recommended guidelines, i.e., they did not take more of the product nor consume it for a longer period of time than the product label recommended.

[2] The RAND report uses the term "ephedra" to refer to ephedrine alkaloids from botanical sources, whether or not they are contained in dietary supplements. RAND uses the term "ephedrine" to refer to pharmaceutical sources of ephedrine.

[3] RAND defined a "sentinel event" as a case that met all three of the following criteria: (1) Documentation of an adverse event that met the selection criteria; (2) documentation that the person having the adverse event took an ephedra-containing supplement or ephedrine within 24 hours prior to the event (for cases of death, myocardial infarction [heart attack], stroke, or seizure); and, (3) documentation that alternative explanations for the adverse event were investigated and were excluded with reasonable certainty. These criteria were subject to procedures which included the following (among other procedures): medical record documentation that an adverse event had occurred; documentation that the subject had consumed ephedra or ephedrine within 24 hours prior to the adverse event, or that a toxicological examination revealed ephedrine or one of its associated products in the blood or urine. Cases with no such documentation were not reviewed further. For the Metabolife cases, ephedra was assumed to have been used within the prior 24 hours for all but psychiatric events. All cases of stroke that met the criterion of having consumed ephedra or ephedrine within 24 hours were reviewed in more detail; to be classified as a "sentinel event," reports of thrombotic stroke needed to have an assessment for a hypercoagulable state and vasculitis, reports of embolic stroke needed to have an embolic evaluation performed, and reports of hemorrhagic stroke required an examination to assess structural problems with the circulatory system of the brain.

D. Petitions Received Relating to Dietary Supplement Containing Ephedrine Alkaloids

We received three petitions relating to dietary supplements containing ephedrine alkaloids. The first petition, dated August 27, 1998, was submitted by the American Obesity Association and requested that we issue a final rule on dietary supplements containing ephedrine alkaloids that adopts the regulations in the June 1997 proposal. The second petition, dated October 25, 2000, was filed jointly by the American Herbal Products Association, the Consumer Healthcare Products Association, the National Nutritional Foods Association, and the Utah Natural Products Alliance and requested that we withdraw the remaining portions of our June 1997 proposal and adopt and implement in its place an industry-developed standard for the labeling and marketing of dietary supplements containing ephedrine alkaloids.

The third petition, dated September 5, 2001, was submitted by Public Citizen. This petition requested that we declare dietary supplements containing ephedrine alkaloids adulterated because they present a significant or unreasonable risk of illness or injury under section 402(f) of the act and ban, all production and sales of these products under section 301(a) (21 U.S.C. 331(a)) of the act. The petition also requested that we issue an advisory to stop the use of dietary supplements containing ephedrine alkaloids due to the established risks of injury.

The information cited in support of this petition included:

- Summaries of the updated numbers and types of adverse events reported to us for ephedrine-alkaloid containing dietary supplements compared to the lower incidence of the same types of adverse events reported for all other dietary supplements;
- An FDA preliminary analysis of data collected by and purchased from the American Association of Poison Control Centers (AAPCC) that showed an increase in the number of ephedrine alkaloid-related AERS from 211 in 1997 to 407 in 1999; and
- Adverse events reported to Public Citizen.

The petition also cited the known pharmacological and toxicological properties of ephedrine alkaloids, recent published articles and case reports, the fact that adverse events are invariably underreported, and the lack of any evidence of long-term benefits for the products.

We have considered the information submitted by these petitions, as well as the comments received in response to these petitions and all other information in the docket. For the reasons summarized in section I.A of this document, we have concluded that dietary supplements containing ephedrine alkaloids are adulterated.

II. Summary of Letters and Comments

We have received more than 48,000 comments in three dockets pertaining to ephedrine alkaloids, Docket Nos. 1995N–0304, 2000N–1200, and 2001P–0396. These comments include all letters received prior to the June 1997 proposal, all comments received in response to **Federal Register** notices, and all submissions related to public meetings pertaining to dietary supplements containing ephedrine alkaloids. The 48,000 comments include more than 41,000 form letters received in the 1997 docket. Many comments submitted identical or nearly identical statements to more than one docket or in response to more than one **Federal Register** notice. Most of the comments were submitted by individual consumers who use dietary supplements containing ephedrine alkaloids or by independent distributors of these products. Other comments were received from persons who had, or who knew persons who had, suffered adverse events or who were reporting adverse events associated with the use of an ephedrine alkaloid-containing dietary supplement. The remaining comments included those submitted by medical professionals, scientists, medical or scientific associations, State or local health departments, Government agencies, members of Congress, dietary supplement manufacturers, traditional Asian medicine practitioners and associations, dietary supplement industry trade associations, public health associations, and consumer groups.

The form letters, while not submitting substantive evidence or analyses, expressed strong views about our regulation of these products. Most of these letters opposed further federal regulation of dietary supplements containing ephedrine alkaloids. More than 13,000 comments opposed a ban of these products and indicated that further restrictions on these products would infringe on personal choice. Thousands of comments requested that FDA not impose stricter regulations on dietary supplements containing ephedrine alkaloids than those imposed on OTC drugs that contain synthetic ephedrine alkaloids. Hundreds of comments requested that we not ban or reclassify ephedra as a prescription drug because, they claimed, such action would result in illegitimate profits for the pharmaceutical companies. Many expressed the view that we should only ban supplements containing excessive amounts of ephedrine alkaloids and those marketed to adolescents and children or to others who may abuse and misuse these products.

Some form letters supported further regulation of these dietary supplement products. Several stated that dietary supplements containing ephedrine alkaloids are dangerous and asked us to ban them. Others requested that we impose more stringent requirements such as mandatory warning labels and maximum dosage levels. Thousands of form letters stated that DSHEA provides us with the necessary authority to protect the public health and that we do not need additional authority. Numerous comments criticized us for failing to exercise the enforcement powers authorized by DSHEA. Numerous form letters requested that ephedrine alkaloids be allowed for professional use by traditional Asian medicine practitioners and dispensed by licensed health care professionals.

We have also received approximately 2,500 individual comments that, although not form letters, did not contain substantive information, analyses, or data. Many of these individual comments raised the same issues as raised in the form letters. Many comments were personal testimonials of how dietary supplements containing ephedrine alkaloids are effective for weight control, improving stamina, or treating medical conditions, and should not be banned or further restricted. Several comments stated that the June 1997 proposal lacked scientific basis and that there are many legitimate studies that support the responsible use of dietary supplements containing ephedrine alkaloids; however, these comments did not submit any additional scientific evidence. Others stated that dietary supplements containing ephedrine alkaloids are safe when used appropriately. Others were personal testimonials of adverse events related to these products that urged a ban or tighter restrictions of these products. Some comments criticized the proposed label warning as too long and ineffective.

Other comments came from members of Congress, with many echoing the issues raised by the form letters. Several congressional representatives commented that Americans are increasingly turning to dietary supplements to improve their health and that Congress passed DSHEA to ensure that these products are regulated

as foods rather than drugs. They cited our own statements that DSHEA gives FDA sufficient authority to remove unsafe dietary supplements from the market. Many urged us to ensure that there was ample opportunity to submit scientific evidence related to dietary supplements containing ephedrine alkaloids. Many urged us to base our decisions on sound science and not rely too heavily on AERs. Some expressed concern about alleged FDA bias against dietary supplements containing ephedrine alkaloids. Others passed on concerns expressed by constituents about adverse health effects from these products. Several comments from members of Congress expressed concern about consumers' ability to read and properly use labels and warnings.

Many of the substantive comments submitted data and other information regarding the use of ephedrine alkaloids. Some comments contained legal analyses of DSHEA and other provisions of the act. Many comments related to provisions of the June 1997 proposal that were withdrawn in 2000 or that have become moot as a result of the action taken in this final rule and, therefore, do not require a response. Examples of moot issues are the proposed prohibition on claims that encourage long-term use and the proposed label statement that the product should not be used for more than 7 days. Other comments addressed issues outside the scope of the rulemaking (*e.g.*, comments about the diversion of ephedrine alkaloids for the illegal manufacture of methamphetamine and methcathinone) and will also not be addressed in this document.

A summary of all relevant comments and our responses to those comments follow. To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before the comment summary and the word "Response," in parentheses, will appear before our response. We have also numbered each comment summary to help distinguish between different comment summaries. The number assigned to each comment summary is purely for organizational purposes and does not signify the comments' value or importance or the order in which they were received.

III. Finding of Adulteration

A. What Does the Final Rule Do?

This final rule declares dietary supplements containing ephedrine alkaloids to be adulterated under section 402(f)(1)(A) of the act. We have determined that these products present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling or, if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. We are taking this action based upon the well-known and scientifically established pharmacology of ephedrine alkaloids, the peer-reviewed scientific literature about the effects of ephedrine alkaloids, published case reports of adverse events, and the adverse events reported to us that have occurred in individuals using products containing ephedrine alkaloids, particularly dietary supplements. We have concluded that dietary supplements containing ephedrine alkaloids pose a risk of serious adverse events, including heart attack, stroke, and death, and that these risks are unreasonable in light of any benefits that may result from the use of these products under their labeled conditions of use, or under ordinary conditions of use if the labeling is silent. We are not addressing the issue of whether these products present a "significant" risk under section 402(f)(1)(A) of the act.

B. What Products are Covered?

This final rule applies to dietary supplements containing ephedrine alkaloids, including, but not limited to, those from the botanical species *Ephedra sinica* Stapf, *Ephedra equisetina* Bunge, *Ephedra intermedia* var. tibetica Stapf, *Ephedra distachya* L., *Sida cordifolia* L. and *Pinellia ternata* (Thunb.) Makino or their extracts. The ingredient sources of the ephedrine alkaloids include raw botanicals and extracts from botanical sources. Although synthetic ephedrine (in the form of ephedrine hydrochloride) has been found in products labeled as dietary supplements, ephedrine hydrochloride was approved for use as a human drug as early as the late 1940s and, to the best of our knowledge there is no evidence that it was marketed prior to that time as a dietary supplement or food. Furthermore, ephedrine hydrochloride and other synthetic sources of ephedrine cannot be dietary ingredients because they are not constituents or extracts of a botanical, nor do they qualify as any other type of dietary ingredient. For these reasons, products containing synthetic ephedrine cannot be legally marketed as dietary supplements (*See* section 201(ff)(1) and 201(ff)(3)(B) of the act (21 U.S.C. 321(ff)(1) and (ff)(3)(B))). In October 2001, we brought a seizure action against $2.8 million worth of finished drug products containing synthetic ephedrine hydrochloride that were labeled as dietary supplements (*United States* v. *1009 Cases * * * E'ola International AMP II*, No. 2:01CV–820C (D. Utah filed October 22, 2001)). As a result of this seizure, in 2002, the manufacturer signed a consent decree agreeing to the condemnation and destruction of the seized products and prohibiting it from manufacturing or distributing violative ephedrine hydrochloride products. In other actions, we have sent warning letters to multiple firms that were marketing products containing synthetic ephedrine alkaloids as dietary supplements, resulting in the removal of the illegal products from the market.

The final rule does not apply to conventional food products that contain ephedrine alkaloids. Substances intentionally added to a conventional food are generally considered to be food additives under section 201(s) of the act. Ephedrine alkaloids contained in conventional foods would generally be considered unsafe food additives (*see* section 409 of the act (21 U.S.C. 348)). A food that contains an unsafe food additive is adulterated under section 402(a)(2)(C) of the act.

This final rule also does not include OTC or prescription drugs that contain ephedrine alkaloids. The use of ephedrine or pseudoephedrine for the treatment of asthma, colds, allergies, or any other disease is beyond the scope of this final rule. Ephedrine is allowed as an active ingredient in oral OTC bronchodilator drugs for use in the treatment of medically diagnosed mild asthma (§ 341.16 (21 CFR 341.16)), when used within the established dosage limits and when the product is labeled in accordance with the required statements of identity, indications, warnings, and directions for use found in § 341.76. In the near future, we intend to propose revisions to § 341.76 to reflect current scientific information about the risks of ephedrine. Both ephedrine (topical) and pseudoephedrine (oral) are permitted as active ingredients for use as nasal decongestants (§ 341.20), when they are used within the dosage limits established by and labeled in accordance with § 341.80. The topical use of ephedrine will not be further discussed in this rule because it is not relevant to oral consumption of ephedrine in dietary supplements. The use of ephedrine alkaloids in drug products is discussed in more detail in section V.B.3 of this document.

Several *Ephedra* species (including those known as ma huang) have a long history of use in traditional Asian medicine. These products are beyond the scope of this rule because they are

not marketed as dietary supplements. The use of ephedrine alkaloids in traditional Asian medicine is discussed in more detail in section V.B.5 of this document. As we describe there, this rule does not change how these products are regulated under the act.

(Comment 1) One comment stated that we coined the term "ephedrine alkaloids" to improperly broaden the scope of the published scientific literature and AERs cited in the June 1997 proposal. The comment pointed out that ephedrine, pseudoephedrine, and phenylpropanolamine (PPA) are all different chemical entities and stated the opinion that only data on ephedrine are relevant to the June 1997 proposal.

(Response) Although we agree that the terms ephedrine, pseudoephedrine, and PPA refer to different chemical entities, we disagree with the rest of the comment and its conclusions. The term "ephedrine alkaloids" refers to a class of naturally occurring compounds structurally related to ephedrine, and the term has been used in that manner in the scientific literature (Refs. 25 and 26). We chose this particular term, rather than several alternatives, such as "*Ephedra* bases" and "ephedrine type alkaloids," to limit the scope of the June 1997 proposal to those compounds that are natural constituents of the aerial parts of the *Ephedra* plant or other botanical sources of ephedrine and related alkaloids. We also defined the term by listing the six principal natural alkaloids in the June 1997 proposal and other FDA documents (Refs. 6 and 27). The ephedrine alkaloids in botanicals include l-ephedrine, d-pseudoephedrine, l-norephedrine, l-methylephedrine, d-norpseudoephedrine, d-methylpseudoephedrine, and minor related alkaloids. All of these compounds are pharmacologically active substances in the plant. Therefore, we considered all of them in our evaluation of the risks associated with the use of the botanical or extracts from the botanical. However, as discussed in the response to comment 24 in section VI.B.1 of this document, we recognize that there are some differences between ephedrine and PPA.

(Comment 2) Several comments asked whether North American species of *Ephedra* (*e.g.*, Mormon Tea) are covered in this rulemaking.

(Response) Most North American species of *Ephedra* (*e.g.*, Mormon tea) do not contain ephedrine alkaloids (Refs. 2 and 26). Nonetheless, any dietary supplement that contains ephedrine alkaloids from any botanical source, including from a North American species of *Ephedra*, is subject to this rulemaking.

IV. Legal Issues

A. What Is Our Legal Authority Under the Act?

We are issuing this final regulation under sections 402(f)(1)(A) and 701(a) of the act (21 U.S.C. 371(a)). Section 402(f)(1)(A) of the act deems a food to be adulterated for the following reasons:

If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.

This regulation makes a finding that dietary supplements containing ephedrine alkaloids are adulterated because they present an unreasonable risk within the meaning of section 402(f)(1)(A) of the act. This finding is based on our conclusion that the risks of these products outweigh their benefits. Our legal interpretation of "unreasonable risk" is discussed in detail in section V.D.1 of this document. This regulation does not address the meaning of "significant risk" or whether dietary supplements containing ephedrine alkaloids present a significant risk under section 402(f)(1(A) of the act.

Section 701(a) of the act gives FDA authority to issue regulations for the efficient enforcement of the act. We are using this rulemaking authority for dietary supplements containing ephedrine alkaloids because we are articulating a standard for unreasonable risk under 402(f)(1)(A) of the act for the first time and because it is more efficient to declare these products adulterated as a category than to remove them from the market in individual enforcement actions in which we would have to establish, for each individual product, that they present a significant or unreasonable risk.

The March 2003 notice asked about the adequacy of FDA's authority to regulate dietary supplements containing ephedrine alkaloids. More specifically, we sought comments on "what additional legislative authorities, if any, would be necessary or appropriate to enable us to address this issue most effectively" (68 FR 10417 at 10420).

(Comment 3) Many comments expressed the view that we already have the authority we need to take action against dietary supplements containing ephedrine alkaloids. These comments cited our authority to declare these supplement products to be a significant or unreasonable risk or imminent hazard under section 402(f)(1) of the act or to regulate the products as containing a poisonous or deleterious substance that may render them injurious to health under section 402(a). The comments differed as to whether we had the necessary evidence to utilize these provisions. Several comments opposed any additional authority and criticized us for allegedly not fully implementing the authority we already have.

(Response) We agree that we have the authority to take action against dietary supplements that contain ephedrine alkaloids. All three authorities mentioned by the comments are available to us when circumstances warrant. In this instance, we have chosen to proceed under the adulteration standard in section 402(f)(1)(A) of the act. We believe that we have sufficient evidence to meet this standard.

(Comment 4) In contrast, other comments stated that our legal authority should be strengthened. Several comments expressed the view that DSHEA needs to be amended because it cannot adequately protect public health. One public interest group noted that our delay in acting reflects the difficulty we encounter implementing DSHEA. Several comments offered suggestions for amendments that would strengthen our legal authority, including mandatory reporting of adverse events, certain sales restrictions (*e.g.*, restricting sales to behind the counter only, prohibiting sales to individuals under the age of 18), special labeling requirements for dietary supplements containing ephedrine alkaloids, registration and listing, premarket approval for safety and efficacy (particularly for all new stimulants and steroid substitutes), and repeal of the de novo review provision so that we would receive judicial deference on adulteration issues. A few comments suggested that dietary supplements be regulated as drugs. One comment suggested new legislation to classify dietary supplements according to a risk-based regulatory scheme.

(Response) We must regulate dietary supplements under our existing authority. Accordingly, we are unable to take action regarding suggestions for amendments to DSHEA because any such amendments must result from congressional action rather than rulemaking. Therefore, we are not addressing those suggestions in this rule.

(Comment 5) One comment stated that conventional food safety standards, i.e., the generally recognized as safe (GRAS) standard or the standard for

FDA approval as a food additive, do not apply to dietary ingredients.

(Response) We agree that the standards referred to in this comment do not apply to dietary ingredients. Premarket approval is required of substances that are food additives as defined in section 201(s) of the act. Substances that would otherwise fall under the food additive definition but are generally recognized as safe by experts are not food additives and do not require premarket approval. Dietary ingredients contained in, or intended for use in, a dietary supplement are explicitly excluded from the food additive definition in section 201(s)(6) of the act. Therefore, neither the premarket approval regime for food additives nor the GRAS standard applies to dietary ingredients. We are instead basing this final rule on the dietary supplement adulteration standard set forth in section 402(f)(1)(A) of the act.

(Comment 6) One comment stated we are violating the First Amendment of the U.S. Constitution and the Administrative Procedure Act (APA) by requiring a much higher standard of safety for dietary supplements than for conventional foods. Another comment also raised concerns about the First Amendment limits of FDA's authority to regulate dietary supplements containing ephedrine alkaloids.

(Response) We disagree with these comments. There are a number of different safety standards for foods (*see, e.g.*, section 402(a)(1) and section 402(a)(2)(C) of the act), and whether these standards are higher or lower than the "significant or unreasonable risk" standard for dietary supplements in section 402(f)(1)(A) of the act is not relevant to the legal sufficiency of this rule. To the extent that we regulate dietary supplements and conventional foods differently, these differences are justified by the differences in the statutory provisions that apply to these two categories of products. Although some parts of the act apply to both dietary supplements and conventional foods, other provisions apply only to one or the other. Where Congress expressly provided for dietary supplements to be subject to a requirement or standard that does not apply to conventional foods, we may implement that provision without violating the APA. Further, this final rule does not violate the First Amendment. This rule does not restrict speech; rather, it makes a finding of adulteration that results in a prohibition on the distribution and sale of a product that presents unreasonable health risks. Such restrictions on purely commercial, nonexpressive conduct are not subject to First Amendment scrutiny. *See, e.g., United States* v. *O'Brien*, 391 U.S. 367, 376 (1968).

(Comment 7) Several comments expressed the view that these products should be regulated as drugs under our existing authority. Some comments stated that we should make these products available only by prescription, arguing that the potential health hazards associated with dietary supplements containing ephedrine alkaloids are too serious for OTC use and that restricting access by requiring a prescription would insert trained medical professionals into a case-by-case decision on the appropriateness of these products to an individual consumer. Further, one comment recommended that if the frequency of adverse events under prescription status does not improve, more restrictive action should be implemented, including the withdrawal of all products containing ephedrine alkaloids from the market.

(Response) We do not agree that all dietary supplements containing ephedrine alkaloids may be regulated as drugs under our existing authority. Products are drugs only if they meet the definition of drug in section 201(g)(1) of the act. Products containing ephedrine alkaloids are regulated as drugs if they are intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease (section 201(g)(1)(B) of the act). Without evidence of intended use for such purposes, the product is not a drug under the act. Some dietary supplements containing ephedrine alkaloids are promoted for disease uses, *e.g.*, to treat obesity. In such instances, we can and have taken action against certain dietary supplement products as drugs. Under the act, considerations such as potential risks to health, need for medical supervision, and pharmacology of a product that meets the dietary supplement definition are not by themselves sufficient to subject the product to regulation as a drug.

To the extent that comments suggest that these products could somehow remain dietary supplements but be available only by prescription, we note that we do not have authority to take such action. The act gives us the authority to restrict drugs and devices to prescription use; it does not give us the authority to restrict dietary supplements to prescription use.

(Comment 8) One comment stated that the generally accepted definition of safety for a drug, i.e., a low incidence of adverse reactions or significant side effects under appropriate conditions of use, and a low potential for harm, which might result from abuse situations, is equally applicable to dietary supplements or food.

(Response) We do not agree that the safety standards for drugs apply to dietary supplements or other foods. As explained previously, dietary supplements are not drugs unless they meet the definition of drug in section 201(g)(1) of the act. The same is true for conventional foods. We are basing this final rule on the dietary supplement adulteration standard set forth in section 402(f)(1)(A) of the act. The adulteration standard for dietary supplements set forth in section 402(f)(1)(A) of the act implies a risk-benefit calculus. While we also use a risk-benefit evaluation in the drug evaluation process (*see* § 312.21(c), § 314.50(c)(5)(viii), and § 330.10(a)(4) (21 CFR 312.21(c), 314.50(c)(5)(viii), and 330.10(a)(4))), the act creates different evidentiary standards for dietary supplements and drugs. Therefore, we are not applying the drug safety standard to dietary supplements.

B. Do the Ephedrine Alkaloid-Containing Products Covered by this Rule Fall Within the Definition of Dietary Supplement Under the Act?

A threshold issue is whether the products covered by this rule meet the definition of a dietary supplement under section 201(ff) of the act.

(Comment 9) One comment from a State department of health stated the opinion that dietary supplements containing ephedrine alkaloids present significant risks when they are consumed as a regular part of the diet and do not fall within section 201(ff)(1) of the act. The comment explained that because these products cannot be used on a daily basis without presenting significant risks they cannot be "intended to supplement the diet" and are not dietary supplements within the meaning of the act. A related comment expressed the opinion that, for a substance to be a dietary supplement, it must be proven that the human body needs the substance to establish a need for supplementation.

(Response) We agree with these comments in part and disagree in part. We agree that dietary supplements containing ephedrine alkaloids present a risk when consumed as a regular part of the diet; as discussed in section V.B of this document, they present a risk to some users even when consumed occasionally. We do not agree, however, that dietary supplements containing botanical ephedrine alkaloids do not fall within the definition of a dietary supplement in section 201(ff) of the act. Section 201(ff)(1) of the act, added by

DSHEA, provides, in part, that the term "dietary supplement" means a product "intended to supplement the diet" that bears or contains one or more dietary ingredients. Among the dietary ingredients listed in section 201(ff)(1) of the act are herbs and other botanicals. Therefore, botanical sources of ephedrine alkaloids, such as *Ephedra sinica* Stapf and the other botanicals described in section III.B. of this document, are dietary ingredients. Further, we do not agree that the phrase "intended to supplement the diet" authorizes the exclusion of a product from the dietary supplement definition solely on the basis of risk. Given the explicit references to risk in section 402 of the act and the inclusion of botanicals as a category of dietary ingredients in section 201(ff)(1) of the act, it seems clear that Congress intended us to regulate botanical products as dietary supplements (provided that they are not drugs and otherwise meet the dietary supplement definition) and to evaluate their risks under the adulteration provisions in section 402 of the act.

We also do not agree that, under the dietary supplement definition, it must be proven that the human body needs a particular substance to establish a need for supplementation. Under DSHEA, a substance does not necessarily have to be shown to be essential to human nutrition to be marketed as a dietary supplement. Although no provision in the act or legislative history directly addresses this issue, section 201(ff) of the act lists classes of dietary ingredients (*e.g.*, botanicals) that are not essential for growth or to maintain good health (Ref. 28). The fact that Congress classified such substances as dietary ingredients is clear evidence that Congress did not intend to limit dietary ingredients to substances that have been deemed to be essential in human nutrition.

(Comment 10) Several comments, including one from an industry medical consultant, stated that herbal products should not be regulated under DSHEA because they have physiologic effects and significant potential for toxicity. The comment encouraged us to work with industry to establish an appropriate regulatory category for botanicals.

(Response) Under the act (as amended by DSHEA), botanicals can be marketed as dietary supplements provided that they otherwise meet the dietary supplement definition, and are safe and properly labeled. If botanicals meet the drug definition in section 201(g) of the act, they are properly regulated as drugs. In this regard, we published a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded" (67 FR 3060, January 23, 2002). This rule defines the term "botanical drug substance" and explains how to submit a time and extent application to request that a botanical drug substance be included in an OTC drug monograph (*see* § 330.14). In addition, we recognize, and are addressing, the current need for guidance for manufacturers seeking to develop botanicals as either OTC or prescription drug products under the applicable statutory and regulatory requirements. (*See* Guidance for Industry: Botanical Drug Products (Draft Guidance) (August 2000) (available at *http://www.fda.gov/cder/guidance/1221dft.pdf*).)

C. Administrative Procedures

(Comment 11) Several comments stated that it is premature to request comments on whether dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk before we define that standard. These comments urged us to undertake a rulemaking, or a guidance document, on this new standard so that it can be applied in the future to all dietary supplements posing health concerns. One comment suggested that defining "significant or unreasonable risk" may require new legislation.

(Response) We do not agree that we must define the term "unreasonable risk" standard through regulation or guidance before taking action against dietary supplements containing ephedrine alkaloids based upon this standard. An agency may interpret a statutory provision through rulemaking or case-by-case adjudication (*SEC* v. *Chenery*, 332 U.S. 194 (1947)). We conclude, based upon available evidence discussed in section V of this document, that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury because their risks outweigh their benefits, and that these products are therefore adulterated under section 402(f)(1)(A) of the act. We are using our general rulemaking authority to issue regulations for the efficient enforcement of the act (section 701(a) of the act) to issue a regulation applying the standard in the context of a particular category of dietary supplements—those that contain botanical ephedrine alkaloids. We are not required to issue a separate rule or guidance defining the 402(f)(1)(A) standard before issuing such a regulation. Similarly, lack of a regulation or guidance defining the standard neither prevents us from taking enforcement action against dietary supplements that present an "unreasonable risk," nor is it new legislation necessary for us to interpret the meaning of "unreasonable risk." If Congress has clearly spoken to a question of statutory interpretation, the agency charged with administering the statute must implement the unambiguous intent of Congress ("*Chevron* step one") (*Chevron U.S.A., Inc.* v. *Natural Resource Defense Council*, 467 U.S. 837, 842–843 (1984)). If a statute is silent or ambiguous on the question, however, the agency may interpret the ambiguous provision ("*Chevron* step two") *Id.* at 843–844. When such administrative interpretations are made through rulemaking, they will be upheld as long as they are reasonable and consistent with the statute's purpose and legislative history (*Christensen* v. *Harris County*, 529 U.S. 576, 587 (2000); *Chevron U.S.A., Inc.* v. *FERC*, 193 F.Supp.2d 54, 68 (D.D.C. 2002)). As discussed in the response to comment 59 in section V.D.1 of this document, we have concluded under *Chevron* step one that the phrase "unreasonable risk" clearly directs FDA to conduct a risk-benefit analysis. Even if a court were to find that phrase ambiguous, however, our interpretation is reasonable under *Chevron* step two.

(Comment 12) Several comments urged us not to act against all dietary supplements containing ephedrine alkaloids because all such products are different and must be considered individually. The comments cited differences in dosages, formulations, labeling, etc., across products and, thus, each product must be analyzed on its own merits. One industry comment argued that we exceeded our statutory authority in trying to regulate all dietary supplements containing ephedrine alkaloids through notice and comment rulemaking.

(Response) We do not agree that we may not regulate the entire category of dietary supplements containing ephedrine alkaloids through rulemaking. We recognize that there are differences between different dietary supplements containing ephedrine alkaloids. However, we conclude, based on available science, that all dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury, regardless of how they are formulated or labeled, because the risks outweigh any benefits that may result from use of the products. Therefore, we may issue a rule finding the entire class of products adulterated.

(Comment 13) A few comments noted that we bear the burden of proof to show

dietary supplements are adulterated under section 402(f)(1) of the act.

(Response) We agree with this comment. Section 402(f)(1) of the act clearly states that in any proceeding under that provision, "the United States shall bear the burden on each element to show that a dietary supplement is adulterated." We have met that burden in this rulemaking.

(Comment 14) Several comments discussed our ability to declare dietary supplements containing ephedrine alkaloids an imminent hazard under section 402(f)(1)(C) of the act.

(Response) We are not addressing these comments because we have chosen to proceed under section 402(f)(1)(A).

(Comment 15) One industry comment stressed that comments to the June 1997 proposal may not be used to authorize other final regulations. The comment expressed concern that comments to a proposed warning statement would be used as a basis for another FDA action to regulate these supplements.

(Response) We disagree with this comment. FDA may issue this final regulation based on a finding that dietary supplements containing ephedrine alkaloids are adulterated because they present an unreasonable risk under section 402(f)(1)(A) of the act. APA requires agencies to provide the public with notice and an opportunity for comment before issuing a new regulation (5 U.S.C. 553(b) and (c)). In keeping with this requirement, a final rule may differ from a proposed rule if the final rule is a "logical outgrowth" of a proposed rule (*Small Refiner Lead Phase-Down Task Force* v. *EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983)). The inquiry into whether a final rule is a logical outgrowth of the proposed rule is often stated as whether the regulated party "should have anticipated that such a requirement might be imposed" (*Small Refiner*, 705 F.2d at 549). Agencies "undoubtedly have authority to promulgate a final rule that differs in some particulars from its proposed rule* * * '[a] contrary rule would lead to the absurdity that * * * the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary'" (*Small Refiner*, 705 F.2d at 546–547 (quoting *International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 632 n.51 (D.C. Cir.1973))). The D.C. Circuit has also stated: "The APA notice requirement is satisfied if the notice fairly apprises interested person of the subjects and issues the agency is considering; 'the notice need not specifically identify "every precise proposal which [the agency] may adopt as a final rule"' (*Chemical Manufacturers Association Waste Mfrs.* v. *EPA*, 870 F.2d 177, 203 (5th Cir. 1989) (quoting *United Steelworkers of Am.* v. *Schuylkill Metals*, 828 F.2d 314, 317 (5th Cir. 1987) (internal citations omitted))).

Our June 1997 proposal, along with our March 5, 2003 **Federal Register** notice, provided a sufficient basis to allow the public to anticipate our actions in this final rule. Through our proposed actions on dietary supplements containing ephedrine alkaloids, the public was properly notified of the possibility that we would find such products to be adulterated under section 402(f)(1)(A) of the act. In fact, our March 2003 notice specifically asked for comment on whether dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk under section 402(f)(1)(A) of the act. We also sought comment on new evidence concerning the safety of dietary supplements containing ephedrine alkaloids (68 FR 10417 at 10420). In addition, the restriction on ephedrine alkaloid/stimulant combinations proposed in 1997, which was unaffected by the 2000 partial withdrawal proposal, was based in part on a finding of adulteration under section 402(f)(1)(A) of the act (62 FR 30678 at 30696). Though we did not specifically propose to codify a finding of adulteration based on significant or unreasonable risk in the March 2003 notice, it was clear that we were contemplating the possibility that dietary supplements containing ephedrine alkaloids were adulterated under section 402(f)(1)(A) of the act. Courts have upheld final rules that contained new elements when the public was made aware that the agency was contemplating such a change (*See Chem. Mfrs. Ass'n.* , 870 F.2d 202–203). Furthermore, we received several comments regarding the possibility of a finding that all dietary supplements containing ephedrine alkaloids would be deemed adulterated under section 402(f)(1)(A) of the act. Though not determinative of logical outgrowth in and of themselves, comments on the issue are evidence that the public received adequate notice of our final rule (*Shell Oil Co.* v. *EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991)). Based upon our explicit request for comments on the adulteration issue in our March 2003 notice, our reference to the section 402(f)(1)(A) of the act adulteration standard as a basis for our June 1997 proposal, and the fact that a number of parties commented on whether dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk, there was adequate notice to the public of our actions in this final rule.

(Comment 16) Several comments cited language in section 402(f)(1) of the act providing that courts must review any determination under section 402(f)(1) of the act *de novo* and further stated that we would not get judicial deference in any court review. The comments argued that, under this provision, it would make no difference whether we brought our case initially in court or whether we proceeded through rulemaking that was subsequently challenged in court. One trade association noted that such *de novo* review is a novel approach in that usually a court would just review the administrative record.

(Response) Section 402(f)(1) of the act states that a court will decide any issue under that paragraph on a *de novo* basis. We agree that the *de novo* standard of review applies to our factual findings under section 402(f)(1) of the act, but do not agree that it applies to our conclusion under *Chevron U.S.A., Inc.*, that "unreasonable risk" means a risk-benefit analysis (*see* section V.D.1 of this document). This interpretation of the *de novo* provision of section 402(f)(1) of the act is consistent with case law on the *Toxic Substances Control Act* (TSCA), which contains an unreasonable risk standard coupled with a "substantial evidence" standard of review, analogous to the act's unreasonable risk standard coupled with a *de novo* standard of review. In *Chem. Mfrs. Ass'n* v. *EPA*, 859 F.2d 977 (D.C. Cir. 1988), the D.C. Circuit distinguished EPA's legal interpretation of unreasonable risk, which received deference under *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984), from its burden of showing with "substantial evidence" in the record that it has met the standard. The court stated: "This fairly rigorous standard of record review should not * * * be confused with the substantive statutory standard * * * " (859 F.2d at 992). Thus, the court in *Chem. Mfrs. Ass'n.* held that the "substantial evidence" standard of record review applied to the factual basis of EPA's decision but not to its interpretation of the statutory standard. In applying *Chevron U.S.A., Inc.*, we have concluded that Congress unambiguously intended that unreasonable risk entails a risk-benefit calculus. If a court were to find the phrase "unreasonable risk" ambiguous, however, our interpretation of unreasonable risk as meaning a risk-benefit calculus should receive *Chevron U.S.A., Inc.* deference, like EPA's

interpretation of the statutory standard in *Chem. Mfrs. Ass'n.*. The requirement for *de novo* review should be applied only to the factual basis of FDA's determination.

Regardless of which standard applies, however, our determination that dietary supplements containing ephedrine alkaloids present an unreasonable risk under section 402(f)(1)(A) of the act should be sustained by a court. Our conclusion that "unreasonable risk" entails a risk-benefit analysis is consistent with the express intent of Congress. The scientific evidence regarding the pharmacology of products containing ephedrine alkaloids, clinical studies showing that these products raise blood pressure, published case reports, and AERs, when compared with the evidence regarding the very modest benefits conferred by these supplements, forms a strong factual basis for finding that the known and reasonably likely risks of dietary supplements containing ephedrine alkaloids outweigh the known and reasonably likely benefits of these products. Therefore, dietary supplements containing ephedrine alkaloids present an unreasonable risk of injury or illness under section 402(f)(1)(A) of the act.

(Comment 17) One comment submitted by a trade association noted that, before requesting the Department of Justice to take any civil action against dietary supplements containing ephedrine alkaloids, we must give appropriate notice and opportunity to present oral and written arguments at least 10 days prior to the request.

(Response) We agree with this comment in part and disagree in part. Section 402(f)(2) of the act provides that "the person against whom such proceeding would be initiated" must be given notice and the opportunity to present views, orally and in writing, 10 days before we report a violation of section 402(f)(1)(A) of the act (the "significant or unreasonable risk" provision) to the Department of Justice for a civil proceeding. By the plain language of this provision, it applies to proceedings against persons, not to proceedings against products. Thus, the requirement applies to injunction actions, which are brought against a corporate or individual person, but not to seizures, which are brought against a product. Therefore, if we were to refer a seizure of dietary supplements containing ephedrine alkaloids to the Department of Justice, the notice requirement would not apply. We further note that the current proceeding is a rulemaking, not a civil action being referred to the Department of Justice, and therefore the 10-day notice requirement does not apply.

(Comment 18) One industry comment stated that the stringent 30-day timeframe allowed for comments in response to the March 2003 notice did not provide the industry with a fair opportunity to review the administrative record and fairly respond to "any alleged new evidence and analyses" by FDA. This comment urged us to allow for a comment period of 180 days. The comment stated that this procedural lapse would render the entire rulemaking process arbitrary and capricious.

(Response) We disagree with this comment. We believe that the 30-day comment period on the March 2003 notice provided interested persons with an adequate opportunity for review and comment. The information placed in the public docket at that time was limited, consisting of the RAND report plus six recent studies. APA requires only that an agency "give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments * * *" This opportunity to participate is all that the APA requires. There is no statutory requirement concerning how many days we must allow for comment, nor is there a requirement that we extend the comment period at the request of an interested person (*See Phillips Petroleum Co.* v. *EPA*, 803 F.2d 545, 559 (10th Cir. 1986)). Moreover, given that we first opened a docket on the issue of dietary supplements containing ephedrine alkaloids in 1995 and sought comments on this issue several times between then and 2003 (*see* section I.C of this document), there has been ample opportunity for all those interested to submit information and views.

V. Scientific Evaluation

A. How Did We Evaluate the Evidence?

To determine whether a dietary supplement presents an unreasonable risk of illness or injury, the agency performs a risk/benefit analysis to ascertain whether the risks of the product outweigh its benefits.

The risks and benefits of a dietary supplement must be evaluated in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use (section 402(f)(1)(A) of the act). Labeling claims for dietary supplements must be substantiated. Unless the manufacturer has substantiation that a labeling claim promoting a dietary supplement for a purported benefit is truthful and non-misleading, the claim misbrands the product (*See* section 403(a)(1) and 403(r)(6) of the act. We note that the standards for substantiating the efficacy of a drug for a labeled indication (i.e., the generally recognized as effective (GRAE) standard for OTC monograph ingredients and the substantial evidence standard for new drugs) do not apply to dietary supplements.

Substantiation of a benefit may not be necessary to lawfully market a dietary supplement if its labeling does not include a claim, and the product poses little or no risk. In weighing risks and benefits to determine whether dietary supplements containing ephedrine alkaloids present an unreasonable risk under section 402(f)(1)(A) of the act, we considered only known and reasonably likely benefits, not speculative benefits. A reasonably likely benefit is one that is supported by a meaningful totality of the evidence, given the current state of scientific knowledge, though the evidence need not necessarily meet the approval standard for a prescription drug.

Although Congress placed the burden on FDA to show "unreasonable risk," once a danger is identified, we do not believe that Congress intended us to delay action until double-blind, placebo-controlled clinical studies could be conducted or that no action be taken if such clinical studies are infeasible or unethical (*see* the response to comment 19 of this document). While such studies are the "gold standard" for determining effectiveness, they are not always available for dietary supplements because DSHEA does not require companies to conduct such studies before marketing a dietary supplement. DSHEA also does not require postmarketing safety and adverse event reporting from dietary supplement manufacturers. Accordingly, FDA is relying on the available scientific data and literature to support its conclusion that dietary supplements containing ephedrine alkaloids present an "unreasonable risk." The government's burden of proof for "unreasonable risk" can be met with any science-based evidence of risk and does not require a showing that the substance has actually caused harm in particular cases.

For example, there is clear scientific evidence that a sustained increase in blood pressure increases the risks of cardiovascular disease (Refs. 29, 29a, and 30). Thus, a dietary supplement that caused a sustained rise in blood pressure across the population would increase the risk of cardiovascular events including stroke, heart attack, or death to that population. Even risks that

may not be detectable in small studies or studies of short duration (which are not designed to detect such risks at a statistically significant level) could, over time, and on a population-wide basis, result in thousands of adverse health events.

In making a determination, we consider studies using closely related products. In considering the risks of a product, such as dietary supplements containing ephedrine alkaloids, it is appropriate to consider the safety of closely related products, such as those with the same active ingredient (*e.g.*, synthetic ephedrine products) or closely related ingredients (such as other sympathomimetics) because we would expect that dietary supplements containing ephedrine alkaloids will exhibit pharmacological effects similar to those other products and, therefore, pose similar risks. It is more difficult to extrapolate conclusions regarding the benefits between an ephedrine drug product and a dietary supplement containing ephedrine alkaloids since the ephedrine drug product is a well defined product with a known dose of ephedrine, while in the latter there is a complex mixture with, possibly, an unknown quantity of ephedrine plus other ephedrine alkaloids, and sometimes other active ingredients, many of which may not be fully characterized. We would need to know how the two products compare with regard to systemic delivery of ephedrine (*e.g.*, the pharmacokinetics profile) to make any judgments about comparable benefits of the two products. If ephedrine pharmacokinetics were the same in a synthetic and plant-derived product and there were no ingredients or components other than ephedrine, one might conclude that the plant-derived and synthetic products would behave similarly. In actual fact, that is not the case because plant derived ephedra products contain other ephedrine alkaloids in addition to ephedrine itself (*e.g.* pseudoephedrine, methylephedrine, and others listed in section I.B of this document). Moreover, if there were other active and inactive ingredients in the plant-derived product, their properties would need to be explored.

In evaluating whether dietary supplements containing ephedrine alkaloids present an unreasonable risk, we looked at the seriousness of the risks and the quality and persuasiveness of the totality of the evidence to support the presence of those risks. We then weighed the risks against the importance of the benefits and the quality and persuasiveness of the totality of the evidence to support the existence of those benefits. We give more weight to benefits that improve health outcomes, especially in the long term, than to benefits that are temporary or rely on subjective measures such as feeling or looking better. For example, sustained, long-term weight loss in an obese or overweight person is a much more important benefit than short-term weight loss because long-term weight loss in these individuals reduces the risk of serious morbidity and mortality (*e.g.*, heart attacks and strokes), while short-term weight loss does not.

In sections V.B, C, and D of this document, we describe the evidence FDA evaluated to reach its determination that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury.

(Comment 19) Many comments stated that any assessment of unreasonable risk must be based on sound science. Several comments stated that a conclusion about the safety and efficacy of dietary supplements containing ephedrine alkaloids is premature and that additional prospective or retrospective case controlled studies are needed to determine causality. A few comments recommended that FDA, NIH, or other parts of the federal government conduct such research to address unresolved issues of causation. Another trade association urged the government to collaborate with industry to design future controlled studies. Several of these comments cited RAND in support of the need for further research. Several comments noted that the National Center for Complementary and Alternative Medicine/NIH Working Group evaluated the RAND report and suggested a multi-site case-control study to assess the risks associated with these products, although it stated that such a study would take 4 to 8 years and cost $2 to $4 million per year (Ref. 31).

In contrast, several comments asserted that conducting clinical trials of ephedrine alkaloids would be unethical in light of the risks to the human subjects. A professional association stated that FDA regulations that govern drug development and approval would not allow such research, given the absence of information to suggest a benefit that would outweigh the risks. A few comments suggested that any study that could be approved by a human subjects committee would be required to exclude patients at risk and therefore, would not be useful in evaluating risk when the products are taken by the general population without medical supervision. Other comments expressed concern that the additional research recommended by RAND would delay efforts or render it virtually impossible to safeguard public health.

(Response) We recognize the value of properly conducted clinical trials to answer questions regarding the safety and effectiveness of FDA-regulated products. It is not clear, however, that clinical trials to evaluate the adverse effects of ephedrine alkaloids can be conducted. It would not be ethical to study the arrhythmogenic potential of ephedrine alkaloids in patients with coronary artery disease, the adverse effects of ephedrine alkaloids in people with heart failure, or the consequences of raising blood pressure in various populations. Moreover, there is now sufficient evidence, generated through multiple sources, including clinical trials, published literature, and other information, to reach the conclusion that dietary supplements containing ephedrine alkaloids have effects on blood pressure and other pharmacological risks that predict adverse effects in users. After considering the best available information, we conclude that these products present an unreasonable risk because the benefits that may result from use of these products are outweighed by the risks associated with such use (*see* discussion in section V.D of this document). Because of the nature of these risks, we do not believe it is appropriate to delay action until further clinical studies can be conducted to evaluate the safety of dietary supplements containing ephedrine alkaloids in the general population. We would, however, support the conduct of clinical investigations (carried out under the Investigational New Drug (IND) regulations with careful screening to exclude subjects at risk and careful safety monitoring during the trials) that examine the safety and efficacy of ephedrine alkaloids, with or without caffeine, as drugs such as for the treatment of obesity (*see* 21 CFR part 312).

(Comment 20) Two comments stated that there is an accepted scientific methodology for determining whether, and at what level, a food additive, dietary ingredient, OTC or prescription drug, or biologic may be hazardous to human health. The stated components of this methodology include reviews of the following reports: (1) The existing scientific literature on the substance, to determine what is known about the substance's risk, particularly at the levels to be used in a product; (2) clinical studies involving the substance; (3) available animal studies on the substance and, if necessary, the conduct of additional studies; and (4) adverse event reports caused by the substance.

In addition, the methodology includes a determination of whether individuals who consume the products suffer from a statistically significantly greater number of adverse (or beneficial) events than those who do not. One comment stated that the absence of premarket approval authority for dietary supplements does not preclude reliance on traditional methods of evaluating safety when making a decision about levels that are not safe.

(Response) We do not agree with the comments stating that there is a single accepted method of evaluation to determine when a food ingredient or dietary ingredient in a dietary supplement presents a hazard to the public health. In any evaluation of the risks presented by a substance in a product in the marketplace, the method of evaluating the risk must be applied on a case-by-case basis that is based on the available data concerning the substance being evaluated. We believe that our method of evaluation for ephedrine alkaloids is, however, consistent with that used for other substances. The scientific methodology we used to evaluate the risks associated with the use of dietary supplements containing ephedrine alkaloids consisted of a review and evaluation of the available scientific literature (including literature on pharmacology), clinical studies, published case reports, and other data, including adverse event reports. This is the same type of scientific methodology that is applied in the evaluation of adverse effects associated with other FDA-regulated products (Ref. 32), and includes most of the steps listed in the comments summarized above.

(Comment 21) A number of comments focused on FDA's obligation to ensure that its regulatory assessments are science-based. Two comments raised concern regarding our compliance with a statutory provision popularly known as the Data Quality Act (section 515 of the Consolidated Appropriations Act, 2001, Public Law 106–554, 44 U.S,C.A. 3516 note). One comment stated that we are vulnerable to challenge under the Data Quality Act because there is a disconnect between our proposed actions and the conclusions of the RAND report. Another comment pointed to our related guidance entitled "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (*http://www.hhs.gov/infoquality/fda.html#i*). FDA's guidance, which describes how we intend to meet our obligations under the Data Quality Act and the implementing Office of Management and Budget (OMB) guidelines, states that we are committed to ensuring that our regulatory decisions are based on objective information and notes our commitment to using the best available science conducted in accordance with sound and objective scientific practices, including peer reviewed science and supporting studies when available. This comment also cited the Center for Food Safety and Applied Nutrition's report "Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework" (*http://www.cfsan.fda.gov/~dms/rafw-toc.html*), which similarly stresses the importance of data quality and scientific objectivity in regulatory decisionmaking. Finally, this comment suggested that in evaluating the safety of dietary supplements containing ephedrine alkaloids, we should apply a rigorous scientific standard such as that used to evaluate whether a new drug application (NDA) should be approved or whether a health claim should be authorized under the significant scientific agreement standard (*See* §§ 314.125 and 314.126) (NDAs); Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (*http://www.cfsan.fda.gov/~dms/ssaguide.html*) (health claims).

(Response) We agree that we have an obligation to base regulatory assessments, including our regulatory assessment of the safety of dietary supplements containing ephedrine alkaloids, on sound science. We have spent a great deal of time and effort compiling and evaluating the best available scientific evidence relevant to this rulemaking, and our decision is based on a careful, objective analysis of the most current information, including peer reviewed studies. In considering whether dietary supplements containing ephedrine alkaloids present an unreasonable risk, we considered evidence from three principal sources: (1) The well-known, scientifically established pharmacology of ephedrine alkaloids; (2) peer-reviewed scientific literature on the effects of ephedrine alkaloids; and (3) the adverse events (including published case reports) reported to have occurred following consumption of dietary supplements containing ephedrine alkaloids. We believe that this final rule, and the data considered, are consistent with the principles set forth in the Data Quality Act and related guidances cited in the comments. We do not agree, however, that we should apply the same standard of scientific proof to a determination of adulteration under section 402(f)(1)(A) of the act, the "significant or unreasonable risk" provision, as we would apply to a decision whether to approve an NDA or authorize a health claim under other provisions of the act. Although our decision on dietary supplements containing ephedrine alkaloids must be based on sound science, that decision is not subject to, and need not meet, the very specific evidentiary requirements set out in the new drug and health claim provisions of the act (*See* 21 U.S.C. 355(d) and 21 U.S.C. 343(r)(3)(B)(i)).

B. What Are the Known and Reasonably Likely Risks Presented by Dietary Supplements Containing Ephedrine Alkaloids?

1. Pharmacology

We have reviewed numerous studies and other data related to the safety of dietary supplements containing ephedrine alkaloids. Evidence about the pharmacology of ephedrine alkaloids—as well as other evidence in the docket—shows that these products present a risk of serious adverse health effects. Information submitted to the docket in an effort to establish the safety of these products is inadequate to rebut the evidence of risk.

(Comment 22) Several comments focused on the known pharmacological and toxicological effects of ephedrine/ephedra on the cardiovascular and nervous systems, explaining that ephedra contains vasopressor amines that excite the heart and constrict the blood vessels, which in turn increases heart rate and raises blood pressure. The comments contended that, because of these effects, adverse events such as hypertensive episodes, arrhythmias (abnormal heart rhythms), heart attacks, seizures, and strokes can be anticipated and expected when millions of people are exposed to such products. Various comments maintained that dietary supplements containing ephedrine alkaloids have the same pharmacological and toxicological activity as prescription and OTC ephedrine alkaloid drugs and, thus, present the same risks. One comment emphasized that Chen and Middleton (Ref. 33) warned about ephedrine alkaloid-induced thromboembolism (blood clots that travel in the body) in 1927 and thereafter, reports of toxicity appeared in the medical literature, accompanied by warnings against indiscriminate use by doctors and sale to consumers. These early reports are relevant to current reports of myocardial infarctions (heart attacks) and stroke associated with products containing ephedrine alkaloids.

One comment stated that ephedra presents a danger of prolonged bleeding in those who undergo surgery, and that patients and doctors may not be aware of this potential complication. Another comment cited a review article (Ref. 2) that described myocardial depression occurring with repeated dosing of ephedrine, and cited a reference from a pharmacological textbook documenting ephedrine's tendencies to cause atrial and ventricular arrhythmias. Another comment suggested that we should not ignore the other ingredients commonly found in dietary supplements containing ephedrine alkaloids, such as caffeine, laxatives, and diuretics, because these ingredients can alter electrolyte levels and increase the risk of arrhythmias. One comment, citing a study by Haller *et al.*, contended that the apparent causal role of ephedrine alkaloids in severe adverse effects could be related to the additive stimulant effects of caffeine (Ref. 34). One comment submitted by a manufacturer attributed the good safety record of its product to, among other reasons, the absence of caffeine and other stimulants.

(Response) We agree that dietary supplements containing ephedrine alkaloids present risks of adverse physiological and pharmacological effects. Based on the best available scientific data and the known pharmacology of ephedrine alkaloids and other sympathomimetics, ephedrine alkaloids—including dietary supplements containing ephedrine alkaloids—pose short-term and long-term risks. This is clearest in long-term use, where increased blood pressure in any population will clearly increase the risk of stroke, heart attack, and death, but there is also evidence of increased risk from shorter-term use in patients with heart failure or underlying coronary artery disease.

Ephedrine alkaloids are members of a large family of sympathomimetic compounds that include dobutamine and amphetamine. Members of this family increase blood pressure and heart rate by binding to alpha- and beta-adrenergic receptors present in many parts of the body, including the heart and blood vessels (Refs. 35, 36, and 37). These compounds are called sympathomimetics because they mimic the effects of epinephrine and norepinephrine, which occur naturally in the human body. In addition to their direct pharmacological effects, many of these compounds also stimulate the release of norepinephrine from nerve endings. The release of norepinephrine further increases the sympathomimetic effects of these compounds, at least transiently. Sympathomimetic effects raise three concerns. First, sympathomimetics can induce cardiac arrhythmias in susceptible people, such as those with underlying coronary artery disease. Second, increased mortality has been observed in patients with congestive heart failure who were treated with sympathomimetic drugs, such as beta-agonists (early studies using such drugs as albuterol led to adverse outcomes) and xamoterol (Ref. 38), as well as phosphodiesterase inhibitors, which potentiate (increase the effect of) the effects of beta-agonists, including milrinone (Ref. 39) and enoximone (Ref. 40). The studies that showed these adverse effects occurred in about 3 months of product use. Third, sympathomimetics can raise blood pressure (Ref. 41).

Based on clinical data, the ephedrine alkaloids present in dietary supplements would be expected to have the same or similar effects as other sympathomimetics on heart rate and blood pressure. Controlled clinical trials using products containing ephedrine alkaloids confirm their typical sympathomimetic effects. Single-dose studies of dietary supplements containing ephedrine alkaloids show that these products cause increases in both heart rate and blood pressure in healthy subjects (Refs. 42, 43, and 44). In one such study of a dietary supplement containing ephedrine alkaloids, the peak increase in blood pressure following a single oral dose of ephedrine alkaloids and caffeine (20 mg/200 mg) was 14 millimeters of mercury (mm Hg) systolic and 6 mm Hg diastolic, occurring about 2 hours after the single dose was taken (Ref. 42).

The findings from these studies are complicated by the presence of caffeine in the dietary supplements used because caffeine is also known to have acute effects on blood pressure and heart rate. However, the effect of caffeine on blood pressure is transient and is lost within 2 weeks of continued use (Refs. 45 and 46). Evidence that ephedrine independently causes an increase in blood pressure when coadministered with caffeine comes from two sources. First, there are studies in which ephedrine and caffeine were tested separately so that their effects could be compared. In a study by Jacobs *et al.*, a group of healthy subjects received ephedrine (E, 0.1 mg/kilogram (kg) orally), caffeine (C, 4 mg/kg orally), the combination, or a placebo (P) (Ref. 47). Although caffeine caused a small increase in systolic blood pressure (average 3 to 6 mm Hg), ephedrine alone gave a 12 mm Hg effect, and when added to caffeine, increased systolic blood pressure by an additional 15 mm Hg (C+E = 156 +/- 29 mm Hg; E = 150 +/- 14; C = 141 +/- 16; P = 138 +/- 14) (Refs. 47 and 48). Second, ephedrine has been shown in a clinical study to increase blood pressure and heart rate acutely when administered intravenously to children to maintain blood pressure during surgery (Ref. 37). Therefore, these studies show a blood pressure effect from ephedrine itself, independent of any additional effect from caffeine.

In a multiple-dose controlled trial, Boozer *et al.* (2002) compared the effects of a combination of ephedrine alkaloids (from *Ephedra*) and caffeine (from kola nut) with placebo over a 6-month period in a highly selected population of obese and overweight individuals, who were carefully screened by medical history and medical evaluation to eliminate cardiovascular and other acute or chronic disorders (Ref. 49). The study measured sitting blood pressure in the clinic using the cuff method for all 6 months (at weeks 1, 2, 3, 4, and every 4 weeks thereafter) of the study; these cuff measurements were not taken throughout the day so they reflect only a snapshot of the blood pressure at the time of measurement. The study also measured changes in blood pressure throughout the day at weeks 1, 2 and 4 using an automated blood pressure monitoring device (ABPM); the ABPM method provides more frequent measurements of blood pressure and is, therefore, better able to evaluate blood pressure effects over time. The ephedrine alkaloids and caffeine-treated subjects did not show a difference in the blood pressure measurements taken at the clinic, but did show statistically significant higher average blood pressure measurements over 24 hours at week 4 measured by ABPM (approximately 4 mm Hg for both systolic and diastolic blood pressure) when compared to placebo treated subjects. The ABPM results are shown in a table in the paper. The difference in blood pressure between the two groups represented the sum of small downward changes in the placebo group (compared to baseline) and small upward changes, or no change, in the ephedra group. Boozer *et al.* reported numerous breakdowns of these data (*e.g.*, 6 a.m. to midnight and midnight to 6 a.m.) and characterized the difference between the ephedra and placebo groups as small (about 3 mm Hg) but for the most common ABPM measure, 24-hour value, the difference was 4/4 mm Hg. The observation that this difference (shown in table 2 of the paper) (Ref. 49) reflected a fall in blood

pressure in the placebo group as much as a rise in blood pressure in the ephedra group is not relevant. The only controlled and, therefore, reliable observation is the comparison of the two groups. Small changes from baseline can occur for a wide variety of reasons and are commonly observed in placebo and treated groups. Therefore, the ABPM data are important because they demonstrate that the effect of the ephedrine alkaloids, including dietary supplements containing ephedrine alkaloids, on blood pressure is not transient, but is still evident after 1 month of continued exposure (when measured by ABPM) and, therefore, would be expected to persist long term. The effect reported in the Boozer, *et al.* (2002) study cannot be attributed to the caffeine because the effect of caffeine on blood pressure (discussed previously) is transient, and the acute effect of caffeine to increase blood pressure is lost within 2 weeks of continued use (Refs. 45 and 46). While some effects of sympathomimetics show tachyphylaxis (i.e., decrease in response following repetitive administration of a pharmacologically active substance *http://www.stedmans.com/*) tachyphylaxis usually occurs rapidly. (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**.) Therefore, we believe, based upon these data and our experience, that the blood pressure effects of ephedrine alkaloids seen after 4 weeks of continued use will persist.

The Boozer *et al.* (2002) study (Ref. 49) was reviewed at our request by three outside scientific experts, Norman M. Kaplan, M.D. (Ref. 50), Richard L. Atkinson, M.D. (Ref. 51), and Mark Espeland, Ph.D. (Ref. 52). These experts were asked to give their independent, scientific opinion of whether the study provides adequate data to assess safety of ephedrine alkaloids and caffeine for weight loss—considering, among other things, the design and duration of the trial and subject selection—and whether further studies are needed. In general, the experts concluded that the safety of ephedrine alkaloid and caffeine containing products could not be established by this study because the study used a highly selected population (i.e., carefully screened by medical history and medical evaluation to eliminate cardiovascular and other acute or chronic disorders) and had relatively few subjects. One of the experts also concluded that the duration of the study was inadequate to establish safety. In general, the reviewers found that the results raised safety concerns. Dr. Kaplan, one of the reviewers, raised the concern that the size of the change in blood pressure observed with ABPM, when applied to a large population, could translate into a significant increase in the incidence of strokes and heart attacks. Dr. Kaplan's concern reflects the potential consequence of long-term use of ephedra (i.e., the consequence of a population increase in blood pressure). A short-term increase (*e.g.*, 1 to 2 months) would not be expected to have such an effect. Approximately one in four adults has high blood pressure. Of those with high blood pressure, 31 percent are unaware that they have it (Ref. 53). A relative increase in blood pressure in any population, even individuals with "normal" blood pressure, will increase the risk of heart attack, stroke, and death in that population (Refs. 29, 29a, and 54).

The extremely high prevalence of diagnosed and undiagnosed hypertension in the U.S. population and the likelihood that blood pressure in obese patients is already elevated make the 4 mm Hg effect shown by the Boozer *et al.* (2002) study (Ref. 49) one of great concern. Reductions in blood pressure of this magnitude (i.e., around 4 mm Hg diastolic or systolic) are clearly associated with substantial long-term reductions in the occurrence of heart attack, stroke and death, as seen in meta-analyses of antihypertensive drug trials (Refs. 55 and 56). While these trials were conducted in patients with hypertension, increasing blood pressure in any population, even in individuals with "normal" blood pressure, will increase the risk of cardiovascular disease (Ref. 29).

Epidemiological studies support a graded and continuous relationship between increased blood pressure and risk of stroke, heart attack, and sudden death, even when the increase is within the normal range (i.e., less than 140 mm Hg systolic and less than 90 mm Hg diastolic) (Refs. 29 and 30). This indicates that many people would be at an increased risk with long-term use of dietary supplements containing ephedrine alkaloids. Studies of hypertension treatments suggest that this increase in risk would occur fairly quickly in hypertensive individuals. Anti-hypertensive drugs that lower blood pressure by 4 to 6 mm Hg have been shown to significantly decrease the occurrence of cardiovascular morbidity (stroke, heart attack) and mortality (Refs. 55, 57, and 58). This effect is evident within 6 to 12 months in large outcome studies (Refs. 29 and 30). FDA is concerned about the adverse health effects that can occur with the use of agents that raise blood pressure, such as dietary supplements containing ephedrine alkaloids, for short- or long-term use. Even in the case of a controlled clinical trial of a possible hypertension treatment where subjects are closely monitored, we advise sponsors to limit the length of time subjects can be in a placebo/untreated group to about 8 weeks to minimize their exposure to cardiovascular risks from the absence of treatment.

As noted previously, the pharmacological effects of ephedrine alkaloids also present increased short-term risks of adverse health events in susceptible populations. For example, there is evidence from peer-reviewed scientific literature that a wide range of drugs with sympathomimetic activity, including beta-agonists, phosphodiesterase inhibitors, and dobutamine, have adverse effects (increased mortality due to heart failure and sudden death) in patients studied with congestive heart failure. These effects have been seen in relatively short-term studies (Refs. 59, 60, and 61) Similarly, there are studies that document that people with coronary artery disease are more susceptible to the well-known pro-arrhythmic effects of sympathomimetics (Refs. 62, 63, and 64) The occurrence of such an arrhythmic event is not one that requires prolonged exposure but would represent a risk associated with each use, including the first. Many individuals are unaware that they have coronary artery disease or early heart failure because these conditions may not cause prominent symptoms until later in the course of these conditions. As a result, we are concerned that such individuals will not know that they are at an increased risk for developing significant cardiovascular adverse events from even short-term use of dietary supplements containing ephedrine alkaloids. Overweight and obese individuals are particularly prone to hypertension, coronary artery disease, and/or heart failure, as overweight and obesity are associated with these conditions (Refs. 65 and 66). These conditions may not manifest clinically until later in the course of the condition and, therefore, individuals, including overweight and obese individuals, may be unaware they have these conditions. As a population, the overweight and obese are, thus, at a greater risk even from short-term use of sympathomimetics.

As summarized previously, the comments cited certain literature suggesting the possibility of additional adverse effects of ephedrine alkaloids,

such as prolonged bleeding in those who undergo surgery. Given the clear scientific evidence of this cardiovascular risks presented by dietary supplements containing ephedrine alkaloids, we have not relied on these other possible adverse effects noted in the comments in our determination of unreasonable risk.

(Comment 23) Various comments did not agree that there are risks with products containing ephedrine alkaloids and stated the opinion that cardiovascular side effects associated with products containing ephedrine alkaloids in several blinded studies were not significantly different in control and treatment groups. Several comments maintained that there is no evidence from clinical studies that ephedrine "supplementation" increases peak heart rate, peak blood pressure, or the prevalence of cardiac arrhythmias. Another comment contended that "clinically relevant doses" of ephedra have no clinically significant effect on pulse or blood pressure, and produce no measurable alterations in myocardial function. A number of comments noted that changes in heart rate and blood pressure are transient and similar to those produced by exercise. Several comments stated that the effects of ephedra combined with caffeine on blood pressure are modest and generally subside over the first few days of use. Other comments stated that, although dietary supplements containing ephedrine alkaloids have a relatively high incidence of subjective and cardiovascular side effects with first use, the side effects diminish with continued use due to tachyphylaxis. Several comments noted that the literature, including the obesity studies we cited in the June 1997 proposal (Refs. 36 and 67 through 80), indicated that tachyphylaxis sets in within a few days, at the most a few weeks, and results in a dramatic decrease in the likelihood of adverse events. Another comment suggested that pharmacological studies showed that peak ephedrine levels are reached within 1 to 4 days and that no further accumulation occurs thereafter. Another comment suggested that this fact means ephedrine alkaloids pose no risk of long-term toxicity.

One comment noted that ephedrine alkaloids are not toxic in the classic sense, that is, do not cause organ changes or damage to the metabolism. Other comments suggested that the available pathology data do not show any pattern consistent with ephedrine alkaloids as a cause of death.

(Response) We do not agree that ephedrine alkaloids pose no risk of adverse consequences. The suggestion that the cardiovascular effects of ephedrine alkaloids persist for only a few days is not supported by the Boozer *et al.* (2002) study (Ref. 49), which demonstrated a higher blood pressure (compared with placebo) at the end of 1 month of therapy (Ref. 80a). This difference was observed when blood pressure was measured throughout the day, using ABPM, but not with cuff blood pressure measurements (a less sensitive measure). This difference in results using different measurement methods may have confused some readers and led them to conclude that ephedrine alkaloids do not have a clinically meaningful effect on blood pressure. The fact that an effect on blood pressure (as measured using ABPM, which follows measurements throughout the day) was still present at 1 month strongly indicates that tachyphylaxis to the effects of ephedrine does not occur. As discussed in the response to comment 22 of this document, tachyphylaxis tends to occur rapidly, as with caffeine, whose blood pressure raising effect is lost within 2 weeks. Therefore, FDA does not agree with the comments expressing assurances that adverse effects will disappear with continued use of ephedrine alkaloids because of tachyphylaxis.

Additionally, some of the studies cited by the comments apparently measured cuff blood pressure only around the time of dosing, when minimal serum concentrations of ephedrine alkaloids and effects on blood pressure would be expected. Absence of an effect at this time cannot be seen as evidence that ephedrine alkaloids do not increase blood pressure.

The suggestion that "clinically relevant" or "clinically significant" doses of ephedrine have no effects on blood pressure is unsupported by the available data. What constitutes a "clinically relevant or significant" dose is undefined (and unlikely to be definable given the nature of the available efficacy data for ephedrine alkaloids). The difficulties in using the available clinical data to obtain such reassurance with regard to the safe use of ephedrine are discussed in the response to comment 26 of this document.

We do not agree that the clinical studies establish that ephedrine does not have adverse pharmacological and clinical effects. The published controlled studies of the use of ephedrine alkaloid products for weight loss cited by these comments cannot establish the safety profile of these products. First, many of the most serious risks, such as strokes or heart attacks (consequences of elevated blood pressure), arrhythmias, or worsened heart failure, are relatively infrequent or are delayed and, therefore, will not be detected in studies using small populations (such as under 100 patients per group) as these studies did. Second, these studies often had other important design limitations, such as lack of adequate controls (including the absence of placebo groups in some studies), and inadequate information about the causes that led to participants dropping out of the trial. In addition, persons with known cardiovascular disease or cardiovascular risks were usually excluded. Thus, these studies were not designed to detect serious adverse effects in susceptible individuals, nor to detect adverse effects that occur infrequently. As discussed in the following paragraphs, these studies were also not adequately designed to assess blood pressure effects. Given these limitations, it is not surprising that these published studies do not report serious adverse events (Refs. 21, 22, 50, 52, and 81).

These trials also would not have been able to detect effects on blood pressure because of other design limitations. For example, when sponsors of drug products seek to detect a drug-induced decrease in blood pressure in patients with hypertension, the trial is specifically designed to perform the following functions: (1) Assess the blood pressure effects at both peak and trough levels of the drug in the blood, and (2) measure blood pressure in a consistent and reproducible manner. This typically requires the enrollment of at least 100 patients to detect a difference from placebo of around 4 to 6 mm Hg systolic, multiple measures at each time point and careful attention to how blood pressure is measured. These design features are either lacking or not described in the publications cited by the comments summarized above, significantly limiting the trials' ability to detect any differences between the treatment and placebo groups with regard to blood pressure or heart rate. With regard to the timing of the measurement, the blood pressure measures appear to have been made at (or shortly after) the administration of the product containing ephedrine for almost all of the published trials. Absorption of the new dose would be minimal or incomplete and the dose taken the day before (8 to 12 hours earlier) would have been substantially removed from the circulation, given ephedrine's approximately 4-hour half-life. Blood levels of ephedrine would

thus be at or near their lowest values of the day ("trough level"), a time when minimal effects on blood pressure would be anticipated. Measurements made only at trough level might well miss a significant effect on blood pressure that would have been seen at or near peak concentrations of ephedrine. Thus, although some published studies on the cardiovascular effects of ephedrine (especially blood pressure) over a period of weeks or months have reported little or no effect of ephedrine on blood pressure and a variable effect on heart rate, these studies are severely limited in their ability to establish safety because of the clinical trial design limitations (Refs. 81a, 81b, and 81c), such that the true effects of ephedrine on heart rate and blood pressure cannot have been adequately assessed.

We do not agree with the comments that state that ephedrine alkaloids are not toxic because they do not induce specific organ pathology. Persistently elevated blood pressure can result in defined cardiovascular toxicity (Refs. 29, 29a, and 54), as can ephedrine's sympathomimetic effects in people with coronary artery disease or heart failure, but the kinds of damage seen in humans from these effects would look the same as similar damage that occurs from the underlying disease or from raised blood pressure or arrhythmia due to another cause.

(Comment 24) A number of comments discussed the relevance of PPA to regulatory decisions on dietary supplements containing ephedrine alkaloids. Several comments stated that PPA is a metabolite of ephedrine. Various comments contended that ephedrine and PPA are both partial agonists and that adverse events associated with dietary supplements containing ephedrine alkaloids are of the same type and greater in number than those associated with PPA, which was voluntarily withdrawn from the U.S. market for safety reasons. Other comments maintained that we should not use PPA data to support the hazards of dietary supplements containing ephedrine alkaloids. Several such comments stated that because PPA differs in pharmacological, pharmacokinetic, and pharmacotoxic effects from ephedrine or pseudoephedrine, it is scientifically inappropriate for us to assume that all ephedrine alkaloids are equivalent. Other comments asserted that the various isomers of ephedrine alkaloids have different actions, different favorable and adverse effects, different activation of receptors, and different effects on human tissues. Several comments indicated that norephedrine (an ephedrine alkaloid that makes up one component of PPA) is a metabolite of ephedrine and that interactions of the multiple ephedrine alkaloids in *Ephedra* and other botanicals and their *in vivo* metabolites should be considered in a safety evaluation of these ingredients and products containing them.

A few comments asserted that the Hemorrhagic Stroke Project (HSP) (Ref. 19) was not designed to assess ephedra exposure. These comments maintained that the HSP is limited by significant issues relating to observation bias, selection bias, and confounding. One comment complained that we reopened the ephedra docket requesting comment on the HSP, but we did not place in the docket, or request comment on, the many published and unpublished clinical studies submitted by one trade organization to support PPA's safety. The comment asserted that our review of the pharmacology of ephedrine alkaloids did not include most of the pivotal information on PPA submitted to us by the Consumer Healthcare Products Association (CHPA). Another comment expressed the view that, in our review of safety data related to ephedra, we should avoid relying on safety data concerning other ingredients.

(Response) The substance, l-norephedrine, also known as (-)-norephedrine, refers to the isomeric portion of PPA that occurs naturally in *Ephedra* and as a metabolite of ephedrine in the body. We agree that the l-norephedrine in racemic PPA is a metabolite of ephedrine, and further that ephedrine and its metabolites have potent vasoactive properties, reinforcing the view that dietary supplements containing ephedrine alkaloids have the pharmacological properties described in the response to comment 22 of this document. These properties, in turn, are linked to predictable adverse clinical outcomes both in the general population (*e.g.*, increased blood pressure) and in susceptible populations (*e.g.*, cardiac arrhythmias). Although there are some similarities between PPA and ephedrine, there are also differences. PPA shows tachyphylaxis to rises in blood pressure within approximately 24 hours and usage has been linked to hemorrhagic strokes (bleeding strokes due to a ruptured blood vessel). Ephedrine does not show such tachyphylaxis. In addition, use of ephedrine has been associated with ischemic strokes (a blood clot blocking off an artery causing a lack of oxygen to portions of the brain), but not hemorrhagic strokes. The major alkaloid in most dietary supplements containing ephedrine alkaloids is generally ephedrine, and not norephedrine (Ref. 82).

Therefore, we have not relied on the HSP or spontaneous reports of hemorrhagic stroke in patients receiving PPA for any of our conclusions about the risks of ephedrine alkaloids, and data regarding PPA is not as informative for drawing conclusions about the benefits and risks of dietary supplements containing ephedrine alkaloids as data on ephedrine. Of course, those supplements that contain meaningful amounts of PPA would pose additional serious risks expected from the use of PPA-containing products, such as hemorrhagic strokes. This adverse event can occur in healthy individuals with one dose of PPA. Reopening the docket to request comment on these data is unnecessary as we have not relied on the data for our determination in this final rule.

(Comment 25) One comment stated that l-ephedrine is both a direct and indirect-acting isomer with both alpha- and beta-agonist activity, while d-pseudoephedrine acts indirectly on both receptors. PPA, which is racemic (i.e., contains both the (+) and (-) forms of the chemical), is a direct and indirect agonist for alpha-receptors but has weaker beta-receptor activity. The comment suggested that ephedrine, pseudoephedrine, and PPA elevate blood pressure, but only l-ephedrine and d-pseudoephedrine increase heart rate. The comment cited Chua and Benrimoj (Ref. 83) stating that d-pseudoephedrine has half of the bronchodilator activity compared to l-ephedrine and one-quarter of the vasopressor effect. The comment argued that we cannot use the pharmacokinetic and toxicokinetic properties of any isomer to predict that of other ephedrine isomers.

(Response) Given that *Ephedra* and other botanicals used as dietary ingredients contain a mixture of ephedrine alkaloids, and given the small database on the supposed selective effects of the isomers, we cannot draw any reassurance from the possibility that one alkaloid has more or less of an effect on the vasculature (or organ systems) than another alkaloid. Further, the reported differences in receptor binding affinity or other *in vitro* tests cannot eliminate concern about the effects of ephedrine alkaloids in humans, because there is clinical evidence that ephedrine alkaloids have important pharmacological effects (*e.g.*, increased blood pressure, heart rate) that persist, particularly in the case of ephedrine, through at least 1 month of use. As noted previously in this document, the

major alkaloid in most dietary supplements containing ephedrine alkaloids is generally ephedrine (Ref. 82). The comments pointing to evidence of differences in the effects of different ephedrine alkaloids do not provide a basis to conclude that dietary supplements containing ephedrine alkaloids do not present an unreasonable risk of illness or injury.

(Comment 26) Some comments argued that the scientific literature indicates that single doses of ephedrine up to 60 mg generally do not increase blood pressure (Ref. 83). Other comments cited a handbook of intravenous drug therapy for nurses that states that ephedrine is of low toxicity. One comment stated that the scientific literature describing the effects of ephedrine in doses of 50 to 150 mg does not support the contention that ephedrine in dosages of 50 to 150 mg per day would represent a health hazard. Many comments stated that reviews of the literature and other data by independent experts reflect the scientific consensus that ephedrine alkaloids at 25 mg per dose are safe. One comment cited a clinical study of 98 elderly patients undergoing hip surgery who received 0.6mg/kg ephedrine by intramuscular injection. One out of 48 patients in the placebo group and two out of 50 in the ephedrine group experienced increased heart rate or increased systolic blood pressure greater than 20 percent from baseline. The comment concluded that the dosages used are greater than the dosages found in any dietary supplement containing ephedrine alkaloids and that the results of the study are consistent with the conclusion that, as also asserted by other comments, no significant injury has been clearly associated with dietary supplements containing ephedrine alkaloids when used as directed.

We received numerous other comments dealing with the issue of "safe" doses for ephedrine alkaloids in dietary supplement products. Many expressed the view that low doses of ephedrine alkaloids in dietary supplements do not pose a safety concern and should remain on the market.

(Response) We do not agree that the scientific literature indicates that there is a dose of ephedrine or ephedrine alkaloids that does not present a risk of adverse events. Although dosages vary in dietary supplements containing ephedrine alkaloids, most products are labeled with 20–25 mg ephedrine alkaloids per recommended serving and 100–150 mg ephedrine alkaloids per day. Some of the doses described in the comments as safe (50 to 150 mg ephedrine alkaloids per day) are in the range studied by Boozer *et al.* (90 mg ephedrine alkaloids per day) (Ref. 49) and, thus, could cause an increase in blood pressure, a significant health concern (*see* previous discussion). We also do not agree that some lower dose of ephedrine has been demonstrated not to increase blood pressure and heart rate. The relationship between a given dose of ephedrine and changes in heart rate and blood pressure has been poorly characterized, although it is clear that ephedrine is capable of increasing both. As discussed in the response to comment 23 of this document, the published studies that have found no effects on blood pressure and/or heart rate have had methodological deficiencies that limited their ability to detect such changes. With respect to the clinical study of 98 elderly patients, the failure to find serious adverse events is understandable, as the study was designed to demonstrate that intramuscular ephedrine was effective to prevent hypotension related to spinal anesthesia. The concern that led to the study was adverse events related to an expected decrease in blood pressure resulting from the anesthesia. As would be expected based on the pharmacology of ephedrine, the study showed that ephedrine is effective in maintaining blood pressure in patients receiving spinal anesthesia.

We do not agree with comments that suggest that low doses of ephedrine alkaloids in dietary supplements do not present an unreasonable risk and should remain on the market. Because this issue was raised in comments responding to the June 1997 proposal, we commissioned a scientific review that was placed in the 2000 docket (Refs. 84 and 85). This review concluded that a "safe dose" of ephedrine alkaloids cannot be identified. The review determined that even "a dose of 1.5 mg every 4 hours (a daily dose of 9 mg) would produce cardiovascular effects that may be dangerous alone, or in association with risk factors* * *" (Ref. 84 at p. 6). We also note that in the 1996 FAC meeting, several committee members stated that, based on the available data, no safe level of ephedrine alkaloids could be identified for use in dietary supplements (Ref. 86). Consequently, they recommended removing dietary supplements containing ephedrine alkaloids from the market (Ref. 87). Although the CANTOX Health Sciences International (CANTOX) review attempted to establish a level of ephedrine alkaloids at which there were no adverse effects, we do not consider the information submitted sufficient to establish a "safe" dose (*see* discussion of CANTOX in the response to comment 32 of this document).

(Comment 27) Many comments raised the issue of the safety of dietary supplements containing ephedrine alkaloids for use in sensitive or special populations. A number of comments indicated that certain individuals may be relatively more sensitive to the stimulant effects of ephedrine alkaloids, and as a result, at greater risk for adverse health consequences. One comment from a physician noted that he does not recommend the use of ephedra products by pregnant women. Another comment indicated a particular safety concern with the use of dietary supplements containing ephedrine alkaloids in older persons; according to the comment, many elderly persons take medications for which the use of dietary supplements containing ephedrine alkaloids would be contraindicated. Citing a survey that indicated that shift workers frequently use stimulants, including ephedrine alkaloids, in combination with coffee, depressants and/or pain relievers that contain caffeine, one comment expressed the view that ephedrine alkaloids pose a significant health risk to the shift worker population (Ref. 88). The comment further submitted that 69 percent of shift workers are overweight, that shift work is likely to involve physical labor, often performed in hot conditions, and that these factors increase the risks of adverse cardiovascular effects when shift workers use ephedrine alkaloids. Other comments stated that the presence or absence of a susceptible population cannot be determined with the available data. Several comments stated that dietary supplements containing ephedrine alkaloids are not for everyone, and consumers should consult a physician prior to use if they have specified preexisting health conditions.

(Response) We agree with the comments that expressed concern about the effects of ephedrine alkaloids on susceptible populations and have previously discussed long-term and short-term risks to susceptible populations in the response to comment 22 of this document. There is every reason to expect that certain populations will be more susceptible to the adverse effects of ephedrine alkaloids and that many such people will not be aware of their greater susceptibility. As noted previously, people with coronary artery disease, early congestive heart failure, and high blood pressure, all of which are more

common in obese individuals, are often unaware of these risk factors. Thus, the recommendations contained in the comments regarding the suitability of dietary supplements containing ephedrine alkaloids for certain populations and the need to consult a physician if the consumer has certain preexisting conditions are ineffective to mitigate the risk that dietary supplements containing ephedrine alkaloids pose to these susceptible populations.

(Comment 28) Several comments stated that warning labels on dietary supplements containing ephedrine alkaloids are not sufficient to protect the public health because many individuals are not aware they have medical conditions or individual sensitivities that put them at greater risk for experiencing serious adverse effects.

The comments stated that warnings are ineffective for individuals who are not aware that they have disease conditions such as high blood pressure or other cardiovascular diseases, hyperactive thyroid function, undiagnosed cerebrovascular abnormalities, or a propensity for cardiac arrhythmia, seizure or certain psychiatric disorders. The same comments maintained that even small amounts of ephedrine alkaloids can be potentially dangerous to otherwise healthy individuals who may have a genetically predetermined sensitivity to ephedrine alkaloids or other sympathomimetic agents. Other comments asserted that warning labels are ineffective because serious adverse events have occurred after the initial or first few uses.

(Response) We generally agree with the comments. Warning labels may be beneficial when people are able to identify the risk factors about which they are being warned. As explained in section V.B.3 of this document, OTC drug products containing ephedrine or pseudoephedrine bear warnings that they should not be used by certain populations. Despite the identified risks of these products, we have determined that the demonstrated health benefits for the labeled OTC drug uses outweigh their risks for certain temporary, episodic disease uses when appropriate warnings are contained in the product labeling. While dietary supplements containing ephedrine alkaloids present the same risks, there are no health benefits for the labeled uses sufficient to outweigh their risks (*see* discussion in sections V.C and V.D of this document). A more detailed discussion on why a warning label would be insufficient to make the risks of dietary supplements containing ephedrine alkaloids reasonable appears in section VI.A of this document.

(Comment 29) A number of comments indicated that ephedrine alkaloids could only be used safely under the supervision of a health professional or that products containing ephedrine alkaloids should be restricted to prescription use only. Reasons given for these opinions included the potential for interactions between dietary supplements containing ephedrine alkaloids and caffeine or other commonly available products (predominantly drugs) that might not be identified by the typical consumer. Other comments stated that consumers could not self diagnose many of the conditions where the use of ephedrine alkaloids would either be contraindicated or pose a potential safety concern.

In contrast, a physician who used dietary supplements containing ephedrine alkaloids in his practice stated that he was as comfortable with people using dietary supplements containing ephedrine alkaloids on their own, as he was with people using an OTC drug product on their own.

(Response) We generally believe that the risks posed by dietary supplements containing ephedrine alkaloids when used continuously, particularly in obese patients who may already have underlying illnesses that can be aggravated by these products (such as hypertension), cannot be adequately mitigated without physician supervision. Sustained high blood pressure has significant consequences, including increased risk of stroke, heart attack, and death. As noted previously, even short-term use of dietary supplements containing ephedrine alkaloids poses certain risks, such as arrhythmias in patients with coronary artery disease. While we allow ephedrine and pseudoephedrine in OTC drugs for temporary, episodic uses, such as the temporary relief of symptoms (shortness of breath, tightness of chest, and wheezing) of certain diseases (*e.g.*, colds, allergies, previously diagnosed bronchial asthma, colds, allergies) individuals who use dietary supplements containing ephedrine alkaloids for reasons other than to improve their health (*e.g.*, to lose weight for improved appearance) obtain no health benefits and at the same time are at risk for the types of adverse events that can occur with both short and long-term use of ephedrine alkaloids. As discussed more thoroughly in section V.C.1 of this document, use for relatively short term weight loss would give, at best, a weight loss of a few pounds, which would not be sufficient to result in any health benefit. However, use for weight loss is likely to be longer term, giving a sustained increase in blood pressure in addition to the short-term risks. If these products met prescription drug standards, then it is possible that the risks of use for weight loss could be mitigated by a physician's evaluation of the patient's medical history and appropriate monitoring during treatment. We note that manufacturers can conduct clinical investigations of ephedrine alkaloids under an IND application and can seek approval of ephedrine alkaloid-containing products as new drugs for the treatment of obesity or other diseases under a NDA if sufficient evidence is provided to support such use. It is also possible that products containing ephedrine alkaloids might not present an unreasonable risk, even without physician supervision, if they were marketed as dietary supplements for a use that results in a meaningful health benefit and that requires only temporary, episodic use to achieve the benefit. However, based on the information we have now, we believe that it is unlikely that any such nondisease use could be identified.

(Comment 30) Another comment, citing a study by Haller *et al.*, contended that the apparent causal role of ephedrine alkaloids in severe adverse effects could be related to the additive stimulant effects of caffeine (Ref. 34). One comment submitted by a manufacturer attributed the good safety record of its product to, among other reasons, the absence of caffeine and other stimulants.

(Response) While caffeine would be expected to have additive effects with ephedrine alkaloids, acute administration of ephedrine alone increases blood pressure and heart rate (Refs. 37 and 47). The available evidence shows that chronic use of caffeine has no effect on blood pressure that persists beyond 2 weeks (Refs. 45 and 46), in contrast to ephedrine, which does have a persistent effect (Boozer) (Ref. 49).

(Comment 31) Many comments contended that we failed to consider the differences among ephedrine alkaloids from the raw botanical; extracts from the raw botanical that contain unaltered proportions of alkaloids and other substances; concentrated and/or otherwise manipulated ephedra extracts such that naturally occurring proportions and/or quantities of ephedrine alkaloids are changed; and synthetic or pure isolated ephedrine (extracted as a single entity from the plant). Because these products have chemical differences and differences in

potency, toxicity, pharmacokinetics, and pharmacological and physiological effects, the comments maintained they should be considered separately in scientific, medical, and regulatory contexts.

Other comments, citing a study by White *et al.*, stated that other natural constituents, including other alkaloids and ephedradines in the raw botanical, modify or attenuate the physiological and pharmacological effects of the ephedrine contained in dietary supplements (Ref. 43). Numerous comments maintained that raw *Ephedra* and/or *Ephedra* extracts are safer than ephedrine that is synthetic or that has been isolated and that serious adverse events associated with the appropriate use of ephedra have been rare. Several comments asserted that the ephedradines have hypotensive effects and are found in ephedra roots, rather than the aerial portions of the plant. One comment maintained that ephedradines are thought to occur in small amounts in *Ephedra* stems. One comment stated that ephedra extract is safer than pharmaceutical ephedrine based on the fact that the LD_{50} is higher for the botanical extract (5.4g/kg) when compared to the LD_{50} for pharmaceutical ephedrine (64.9 mg/kg) ("LD_{50}" refers to the amount of a material that causes death in 50 percent of test animals).

Several comments stated that pharmaceutical ephedrine is more potent than ephedrine from botanical sources because ephedrine comprises only 30 to 90 percent of the total alkaloids of the raw botanical, with the remaining portion containing potentially less potent stimulants such as pseudoephedrine. Several comments claimed that the various ephedrine alkaloids from botanical sources have a slower rate of absorption due to the plant matrix as compared to the rate of absorption for pharmaceutical ephedrine (Ref. 43). These comments stated that delayed effects diminish side effects and provide for the cardiovascular adaptation of effects, thereby diminishing cardiovascular response. One comment stated that except for absorption rate, ephedrine alkaloids from the plant have the same pharmacokinetics as pharmaceutical ephedrine (Ref. 43). Other comments note that botanical ephedrine from formulations containing whole *Ephedra* is absorbed more slowly than dietary supplements formulated with standardized extracts (Ref. 44). A few comments suggested that ephedra extract has higher neurocytotoxic (toxic effect on nerve cells) potential than synthetic ephedrine hydrochloride due to combinations of different ephedrine alkaloids or other unknown compounds found in ephedra extract that are not found in ephedrine hydrochloride (Ref. 89).

Other comments maintained that there is no difference between blood levels of ephedrine from botanical sources and ephedrine contained in OTC drugs. Comments from a State Board of Pharmacy stated that ephedrine from botanical sources is neither safer than, nor different from, pharmaceutical ephedrine. One comment objected to our including clinical studies using pharmaceutical ephedrine in our evaluation. A number of comments suggested that naturally occurring ephedrine is more potent than its synthetic counterpart. A few comments stated that the presence of varying amounts, proportions and chemical configurations of ephedrine alkaloids in crude *Ephedra* and prepared *Ephedra* extracts, as well as the presence of unknown compounds, leads to uncertainty in dose, purity, and composition and a greater risk for adverse effects. Comments noted that this variability is not an issue for synthetic or pure isolated ephedrine alkaloids.

(Response) The data are wholly inadequate to demonstrate that any differences among forms of naturally occurring ephedrine alkaloids and synthetic ephedrine have a meaningful impact on risks to health. The overall database of clinical trials, including trials using both natural and synthetic ephedrine, does not lead to the conclusion that one form of ephedrine is safer than the other form.

We are not persuaded by any of the available evidence that ephedrine from botanical sources is materially different from ephedrine from pharmaceuticals with respect to chemistry, potency, or physiological and pharmacological effects. Chemically, any isomer with the same conformation from one source, including botanical sources, is identical to the same isomer from another source. For example, (-)-ephedrine from *Ephedra* (*Ephedra sinica* Stapf) is chemically indistinguishable from synthetic (-)-ephedrine manufactured by a pharmaceutical company.

Regarding the ephedradines, we are not aware of any evidence in the scientific literature, nor were any data provided in the comments, that indicate that these compounds are present in *Ephedra*, in other botanical sources of ephedrine alkaloids, or in extracts from these botanicals. The ephedradines are known constituents of the roots of the species *Ephedra sinica* Stapf (Ref. 90). In traditional Asian medicine, the roots and rhizome of the plant are referred to as "ma huang gen," while the aerial parts of the plant are referred to as "ma huang" (Ref. 3). The ephedradines are not ephedrine alkaloids. Nor are they present in the aerial parts of the plant that are used in dietary supplements. The scientific evidence, thus, does not support the opinion that the other ephedradrines in the raw botanical act to modify or attenuate the physiological and pharmacological effects of the ephedrine alkaloids contained in these products.

We do not agree, therefore, that current evidence establishes that ephedrine alkaloids from botanical sources, including botanical extracts, are different from, or are any safer than, pharmaceutical ephedrine alkaloids. With regard to the comment asserting that ephedra extract is safer than pharmaceutical ephedrine because the LD_{50} is higher for the botanical extract than the LD_{50} for pharmaceutical ephedrine, we note that scientific views on this point differ. Another scientific reference suggests that a mixture of ephedrine alkaloids from a botanical extract may be more toxic, based on LD_{50} calculations, than an equal amount of pharmaceutical ephedrine (Ref. 91). While there is not enough scientific evidence to draw a conclusion, we acknowledge the possibility that other components in the concentrated extracts (*e.g.*, tannins derived from the botanical) may affect the toxicity of botanical preparations of ephedrine alkaloids (Refs. 89 and 92).

2. Other Safety Data

(Comment 32) Many comments cited multiple data and information sources as support for the safety of dietary supplements containing ephedrine alkaloids. These cited sources have been submitted to the docket and include the CANTOX review, RAND Report, the Ad Hoc Committee on the Safety of Ma Huang report and the Ad Hoc Committee on the Safety of Dietary Supplements, *Ephedra* Education Council Expert Panel Report, and a 6-month clinical trial by Boozer *et al.* (2002) (Refs. 21, 49, 93, 94, and 95). Some comments also claimed that the toxicological database supports clinical evidence of safety; that no serious adverse events have been reported in controlled clinical trials using products containing ephedrine alkaloids for weight loss, and that few or no serious adverse events have been reported to manufacturers of dietary supplements containing ephedrine alkaloids.

One trade association commented that a valid and quantitative scientific process is needed to identify intakes

and conditions of use that do not cause significant or unreasonable risk, and urged us to adopt scientific conclusions based on the CANTOX risk assessment, which was based on methods developed by the Institute of Medicine (IOM) (Ref. 28). A number of comments argued that the results of the CANTOX review established that dietary supplements containing ephedrine alkaloids are safe when used in accordance with the industry standard.

One comment stated that the methods employed by CANTOX were not appropriate for use in evaluating the safety of dietary supplements containing ephedrine alkaloids. Several comments stated that there are no data that establish that ephedrine alkaloids are an ordinary component of food, that there is a need for ephedrine alkaloids in the diet, or that some deficiency state exists when ephedrine alkaloids are not a normal component of the diet.

(Response) We do not agree with the methodology or conclusions of the risk assessment performed by CANTOX. The CANTOX review, sponsored by an industry trade group, was a quantitative risk assessment that used IOM methods to determine a safe upper level (called the No Observed Adverse Effect Level (NOAEL)) for botanical ephedrine alkaloids as used in dietary supplements. We believe that this review cannot be used to establish a NOAEL for ephedrine alkaloids used in dietary supplements because it was flawed. Its flaws include use of an inappropriate risk assessment model and deviation from the criteria and procedures established by IOM, including relying on abstracts and unpublished articles, using an unsuitable definition of "Tolerable Upper Intake Level" (UL), and using an overly narrow definition of "adverse effect."

The IOM model referenced by CANTOX is the Food and Nutrition Board's report entitled "Dietary Reference Intakes: A Risk Assessment Model For Establishing Upper Intake Levels For Nutrients." The introduction to this report states that dietary reference intakes are being established for "nutrients and food components" which include nutrients, dietary antioxidants, micronutrients including electrolytes and fluid, macronutrients, "and other food components not traditionally classified as "nutrients," but purported to play a beneficial role in human diets" (Ref. 28 at pp. 1 and 2). The IOM report defined dietary reference intakes, in part, as "reference values that are quantitative estimates of nutrient intakes to be used for planning and assessing diets for healthy people. They include both recommended intakes and [tolerable upper intake levels] as reference values" (Ref. 28 at p. 2). The report defined "Tolerable Upper Intake Level" (UL) as "the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases" (Ref. 28 at p. 3). The rationale for establishing such a risk assessment model is that nutrients are an essential part of the diet and deficiency states result when they are absent from the diet or are available in too low of a concentration.

CANTOX claimed that the use of this model was appropriate for ephedrine alkaloids in dietary supplements because nutrients, like all chemical agents, can produce adverse health effects if intakes are excessive. However, ephedrine alkaloids are not nutrients. The CANTOX report did not include any data establishing that there is a need for ephedrine alkaloids in the diet, or that some deficiency state exists when ephedrine alkaloids are not present in the diet. Therefore, we conclude that the use of the IOM risk assessment method based on the model of a nutrient is inappropriate for the evaluation of the safety of dietary supplements containing ephedrine alkaloids.

Even if the IOM dietary reference intakes model were an appropriate risk assessment model for dietary supplements containing ephedrine alkaloids, we note that CANTOX deviated from the IOM's criteria and procedures in several important ways. For instance, the IOM report used studies published in peer-reviewed journals as the principal sources of data for its evaluations. In contrast, while CANTOX did use some publications, it also relied on abstracts and unpublished studies. For example, CANTOX cited the study by Boozer, *et al.* as the pivotal study demonstrating the safety of dietary supplements containing ephedrine alkaloids and the establishment of the NOAEL. However, the Boozer (Ref. 96) study was only available in abstract form at the time of the CANTOX review. Abstracts are not subject to the same rigorous peer review that full manuscripts go through. Further, abstracts do not contain sufficient information to enable a reader fully to evaluate a study's methodology or independently to interpret or verify a study's results. As a result, abstracts should not be given the same weight as the full reports of studies themselves. In the case of the Boozer study, the abstract did not provide details on the exclusion or inclusion criteria for the study, so a reader could not determine how the subjects were selected or how they were monitored during the study. The CANTOX authors also did not acknowledge the significance of the blood pressure findings in the Boozer *et al.* As we have discussed extensively in section V.B.1 of this document, this study by Boozer *et al.* (Ref. 49) clearly demonstrates a higher blood pressure in ephedra plus caffeine treated subjects (compared to placebo), which translates into serious long-term risks in the general population and serious short-term risks in susceptible populations. Furthermore, as stated by outside scientific experts who reviewed this study, the Boozer *et al.* (2002) study cannot establish the safety of dietary supplements containing botanical ephedrine alkaloids and caffeine because the study used a highly selected population, had relatively few subjects and was carried out for too short a period of time. Rather, the Boozer study raises questions about the safety of these products.

Indeed, of the 20 studies that CANTOX considered in identifying the NOAEL, four were abstracts, and two were unpublished reports. Thus, unlike the IOM report's reliance on peer-reviewed journal articles, a significant proportion of the CANTOX "studies" were not subject to peer review.

We also note a number of other deviations from the IOM's application of its risk assessment model (Ref. 28). Compared to the definition in the IOM report, CANTOX expanded the definition of the UL and narrowed the population to which it applies. As noted earlier, the IOM report defined the UL, in part, as "the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population." The IOM report stated that the term "tolerable" was chosen "because it connotes a level of intake that can, with high probability, be tolerated biologically by individuals; it does not imply acceptability of that level in any other sense." The IOM report also noted that "the UL is not intended to be a recommended level of intake" (Ref. 28 at pp. 3, 4, and 5). The IOM report also stated that "the critical endpoint used to establish a UL is the adverse biological effect exhibiting the lowest NOAEL (for example, the most sensitive indicator of a nutrient or food toxicity). The derivation of a UL based on the most sensitive endpoint will ensure protection against all other adverse effects" (Ref. 28 at p. 18). The IOM report also explained that, "When possible, the UL is based on a NOAEL, which is the highest intake (or

experimental oral dose) of a nutrient at which no adverse effects have been observed in the individuals studied. This is identified for a specific circumstance in the hazard identification and dose-response assessment steps of the risk assessment" (Ref. 28 at p. 10).

Although CANTOX defined the UL as "the maximum level of chronic daily intake of a substance judged unlikely to pose a risk to the most sensitive members of the health population," their UL determination was based upon the "specified conditions of use," which includes label warnings that these products not be used by many in the general population (including those under 18 years, pregnant or lactating women, and persons with certain health conditions, including those most sensitive to the effects of these products, *e.g.*, persons with hypertension and coronary artery disease). In contrast, the IOM concept of the UL is the highest level of intake likely to pose no risk of adverse health effects to almost all individuals in the general population. Thus, the CANTOX UL is less protective than the IOM UL because it removes from its risk assessment the members of the population who would be most at risk for adverse effects of dietary supplements containing ephedrine alkaloids.) (Ref. 93 at p. 5).

It also appears that CANTOX deviated from the IOM model in its assessment of what constituted an "adverse effect." Although the CANTOX report failed to define the endpoints (potential adverse effects) that were considered in the determination of a NOAEL, the report stated that "the selection of 90 mg/day is an appropriate value for a NOAEL for ephedra in light of the evidence of no significant increases in frequency of adverse effects or changes in heart rate or blood pressure at or below this level leading to cardiac arrhythmias." Thus, it appears that CANTOX did not consider changes in heart rate or blood pressure to be "adverse effects," although these biological effects can lead to serious adverse health consequences, such as arrhythmias and strokes. In addition, in discussing the Boozer *et al.* study, the CANTOX report described the statistically significant 4 mm Hg elevation in systolic blood pressure in the ephedra plus caffeine treated group as compared to the placebo group, as well as other self-reported symptoms (dry mouth, heartburn and insomnia) in the treated group, as "minimal side effects." This choice of terminology suggests that CANTOX did not consider the well-described pharmacological effects of ephedrine alkaloids to have potentially serious adverse health effects. This difference would affect the NOAEL, which, in turn, would lead to different UL determinations. We further address the definitional issue of adverse events versus side effects later in section V.B.6. of this document.

We also note that CANTOX's stated study objective, "to provide and justify a safe upper intake level for ephedrine alkaloids from ephedra used as a dietary supplement," appears to assume that such a safe dose exists. This assumption indicates a bias towards finding a safe dose, rather than an unbiased assessment of whether any safe dose exists.

Finally, we discuss the inadequacies of the publications used by CANTOX to assess the safety of ephedrine alkaloids in section V.B.2 of this document. Whatever methods are employed, these deficiencies in the data used in CANTOX's analysis significantly undermine any conclusions reached in the CANTOX report.

(Comment 33) Several comments objected that we did not consider animal studies using ephedrine alkaloids to evaluate the safety of ephedrine alkaloids as dietary ingredients, as several comments noted had been done in the CANTOX review. One comment stated that the results of the National Toxicology Program's long-term rodent studies on ephedrine showed that a lethal dose of ephedrine alkaloids for most animal species, translated into human consumption, was between 200 and 400 25 mg tablets. A related comment referred to toxicity (LD_{50}) studies comparing pharmaceutical ephedrine with ma huang in mice, emphasizing lesser toxicity of ma huang: The LD_{50} for ephedrine alkaloids from ma huang was 5300 mg/kg body weight versus 689 mg/kg for pharmaceutical ephedrine. A related point from this comment was that wild and domestic animals consume *Ephedra* shrubs and there are no reports of adverse effects in these animals. One comment included data from rat, mouse, and dog toxicity studies on a specific ephedrine alkaloid-containing dietary supplement. The results and their interpretation by consultants were offered as demonstrating a very low toxicity for the supplement. One comment stated that no animal study suggests that the ephedrine alkaloids would be harmful at human doses of 25 mg per serving. One comment stated that animal and laboratory testing may be informative on some issues but, in and of itself, cannot answer the human causation question.

(Response) We recognize the value of animal studies in identifying or predicting the toxicological properties of substances for human exposure. In fact, animal studies do identify the sympathomimetic effects of ephedrine that underlie our concern. These would not be expected to lead to harm in healthy laboratory animals because these animals do not have coronary artery disease or other susceptibility to arrhythmias or congestive heart failure. An effect of elevated blood pressure, if large and sustained, might perhaps show effects in very large, long-term animal studies, but there is no reason to think that a modest effect, one that would increase hypertensive risk in humans but still lead to a low overall risk in any individual, would be detectable in animals. The animal data are, therefore, not at all reassuring. The discussion of the consumption of wild *Ephedra* species by wild and domestic animals contributes no relevant safety information, since these animals also lack pertinent human risk factors (coronary artery disease, heart failure, elevated blood pressure). Also, were these animals to have an adverse effect, there would be no way to identify it. However, we believe, as stated previously, that there is sufficient scientific evidence from multiple sources, including clinical trials and the published literature pertaining to use of ephedrine alkaloids in humans, to conclude that dietary supplements containing ephedrine alkaloids pose serious risks of illness or injury.

3. Comparison with Drug Products Containing Ephedrine Alkaloids

(Comment 34) One comment asserted that our proposal to treat dietary supplements more restrictively than OTC drugs containing ephedrine and pseudoephedrine is in violation of the Administrative Procedure Act's prohibition on rulemaking that is arbitrary and capricious. According to the comment, OTC ephedrine and pseudoephedrine products contain higher doses of ephedrine alkaloids and therefore are potentially more dangerous than dietary supplements that contain these substances at lower levels.

(Response) Our decision in this rulemaking to treat dietary supplements that contain ephedrine alkaloids differently from OTC drugs that contain ephedrine or pseudoephedrine is not arbitrary or capricious. Our decision is based on differences in the intended uses of these products, as well as differences in the scientific evidence available to support the risk-benefit ratio for the products. The risk-benefit ratio is dependent on several factors, including the product's intended use, the product's benefits, if any, and the

availability of adequate measures to control risk.

As discussed previously, dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury because their risks outweigh their benefits. Like dietary supplements containing ephedrine alkaloids, OTC drug products containing ephedrine or pseudoephedrine have risks related to these ingredients. However, unlike dietary supplements, such OTC drug products have demonstrated benefits in the treatment and mitigation of disease. Through the OTC drug review process, we have determined that drug products containing ephedrine are GRASE for OTC use as a bronchodilator for the temporary relief or symptomatic control of bronchial asthma (*see* §§ 341.16 and 341.76), and that drug products containing pseudoephedrine are GRASE for OTC use as a nasal decongestant for the temporary relief of nasal congestion due to the common cold or hay fever (allergic rhinitis) (*See* §§ 341.20 and 341.80). Based on controlled clinical investigations (*See* § 330.10(a)(4)(ii)), we have determined that the benefits associated with the use of OTC drug products containing ephedrine and pseudoephedrine for these disease indications outweigh the risks and justify the use of these products despite their risks. However, such uses for disease mitigation and treatment are beyond the scope of permissible dietary supplement uses.

Moreover, we do not agree that dietary supplements containing ephedrine alkaloids are safer than OTC drugs containing ephedrine or pseudoephedrine based on the relative doses of ephedrine alkaloids in these products. We consider an OTC drug product's safety in the context of its conditions of use (*See* § 330.10(a)(4)(i)). OTC drugs containing ephedrine and pseudoephedrine are marketed to persons with specific disease conditions or symptoms for temporary, episodic relief. In fact, OTC ephedrine bronchodilator drug products are required to bear a warning limiting the use of these products to persons who have been diagnosed with asthma by a doctor (*See* § 341.76(c)(1)). Additionally, although drug products containing ephedrine and pseudoephedrine are permitted to be marketed OTC at specific doses, these doses have been determined based on the specific indications of these drugs. As previously discussed, the indications and benefits applicable to OTC drugs containing ephedrine and pseudoephedrine do not apply to dietary supplements. Thus, the safety of dietary supplements containing ephedrine alkaloids cannot be established merely by showing that the level of ephedrine alkaloids in these products falls within or under the dose ranges permitted for OTC drug products. Furthermore, these dietary supplements contain several ephedrine alkaloids, making it difficult to draw any conclusions about benefits from studies using OTC drug products that contain a single ephedrine alkaloid.

(Comment 35) Several comments pointed out that we have concluded that the ephedrine levels permitted in OTC drugs are generally recognized as safe. Other comments maintained that the long-term marketing and favorable safety record of OTC drugs containing ephedrine alkaloids is evidence of the safety of dietary supplements containing ephedrine alkaloids. Several comments asserted that there is a lack of serious AERs for both traditional Asian herbal products and OTC ephedrine drugs with dosages based on FDA's monograph (less than or equal to 25 mg per serving and less than or equal to 150 mg in a 24-hour period) and that these dosages are, thus, safe.

One comment maintained that the nonserious events identified by RAND are consistent with the side effects of caffeine and OTC ephedrine listed in the OTC drug review and do not pose an unreasonable risk. Other comments referred to statements made during the 1996 FDA Food Advisory Committee that there are no serious adverse effects reported with drugs containing ephedrine alkaloids within the allowable dosage range and to a February 28, 2003 FDA press release relating to ephedra that stated there are fewer AERs linked to OTC ephedrine drug products than to dietary supplements containing ephedrine alkaloids.

(Response) We do not agree that the safety of dietary supplements containing ephedrine alkaloids can be established by reference to the safety of OTC drug products containing ephedrine or pseudoephedrine, two ephedrine alkaloids currently included in OTC drug monographs.

As discussed previously, all sympathomimetics may pose risks for adverse events even after a single dose. GRASE status does not mean that an OTC drug product may not cause adverse events. In fact, there have been adverse events reported to FDA concerning ephedrine- and pseudoephedrine-containing OTC drugs. There are also numerous adverse event reports for dietary supplements containing ephedrine alkaloids. The incidence and type of adverse event reports related to dietary supplements containing ephedrine alkaloids are discussed in section V.B.6 of this document, which also contains our discussion on the significance of these AERs in our determination of unreasonable risk.

As part of our OTC drug review, we have determined that ephedrine and pseudoephedrine are GRASE OTC drug ingredients for certain indications. Ephedrine is GRASE for the temporary relief or symptomatic control of bronchial asthma (*See* §§ 341.16 and 341.76). Pseudoephedrine is GRASE for the temporary relief of nasal congestion due to the common cold or hay fever (allergic rhinitis) (*See* §§ 341.20 and 341.80). OTC ephedrine and pseudoephedrine drug products have been studied in controlled trials that establish their safe and effective dose for specific disease indications (labeled uses) (41 FR 38312 at 38371 and 38402 to 38403, September 9, 1976) (Refs. 97 and 98). These OTC drug products provide health benefits when used by the population experiencing the particular disease. We note that these OTC drug products bear warnings that certain populations should not use them, and they are not risk free. However, we have determined that the demonstrated benefits for the labeled OTC drug uses outweigh their risks (*See* § 330.10(a)(4)(iii)). The labeling of OTC ephedrine and pseudoephedrine drug products warns consumers not to use the products if they have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to an enlargement of the prostate gland unless directed by a doctor (§§ 341.76(c)(2) and 341.80(c)(1)(C)). In addition, OTC ephedrine bronchodilator drug products are labeled with a warning not to use the product unless a diagnosis of asthma has been made by a doctor (§ 341.76(c)(1)). Moreover, the labeling directs users not to continue to use ephedrine drug products but to seek medical assistance immediately if symptoms are not relieved within 1 hour or become worse (§ 341.76(c)(5)). As discussed in the response to comment 34 of this document, the benefits of ephedrine and pseudoephedrine drug products for disease claims are different from the benefits of dietary supplement products for nondisease claims, so it would be inappropriate to conclude based on OTC drug product information that these dietary supplements do not present an unreasonable risk. No data demonstrate that dietary supplements containing ephedrine alkaloids provide a meaningful health benefit to a particular

population for any specific use and for short periods of time, as is the case for OTC ephedrine or pseudoephedrine drug products. Therefore, we have determined that the risks presented by dietary supplements containing ephedrine alkaloids (including heart attack, stroke, and death) outweigh their benefits, and that these products are adulterated regardless of what warnings are included in their labeling. We note that dietary supplements containing ephedrine alkaloids may also present other, less serious risks listed in the required warnings for OTC drugs containing ephedrine and pseudoephedrine; however, because we are removing these dietary supplement products from the market based on their cardiovascular risks, we are not addressing these other risks in this rule.

With regard to the comments that discussed safety data for OTC ephedrine bronchodilator drugs specifically, we note that the studies used to evaluate ephedrine for the treatment of asthma and those using ephedrine alkaloids for weight loss and other nondisease uses enrolled different populations and used different study designs, endpoints, and monitoring protocols. Therefore, comparisons across patient populations or indications (*e.g.*, asthma treatment versus weight loss) for a risk benefit analysis is not justified. FDA's 1986 final rule finding ephedrine GRASE as a bronchodilator was based on the 1976 recommendation of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) (*See* 51 FR 35326, October 2, 1986 and 41 FR 38312 at 38370 to 38372, September 9, 1976). The Panel relied on data from studies conducted in 1973 and 1975 (Refs. 97 and 98). These studies were designed to examine the efficacy of terbutaline as a bronchodilator. The patient population enrolled in these studies were not only clinically stable (i.e. normal electrocardiogram, blood pressure, and pulse) but also had no apparent history of adverse events related to treatment with other stimulant bronchodilators used at the time. These studies support the use of ephedrine for patients with asthma who are otherwise clinically stable (i.e. not found by a physician to have high blood pressure or other cardiovascular risk); however, they do not support the safety or efficacy of dietary supplements containing ephedrine alkaloids for weight loss or other nondisease uses.

(Comment 36) Several comments asserted that it is misleading to compare the safety and efficacy of ephedra to OTC drugs because all drugs are toxic to some individuals and all products must be evaluated on the basis of their benefits relative to their risks. These comments expressed the view that dietary supplements containing ephedrine alkaloids have only limited benefit for weight loss over placebo and that this modest weight loss has never been shown to reduce the increased morbidity that is associated with obesity.

(Response) We agree that dietary supplements containing ephedrine alkaloids and OTC drug products must be evaluated based on a comparison of their risks and benefits. It should be noted, however, that the evidentiary standards for evaluating these two categories of products are different. We have done a risk-benefit analysis for dietary supplements containing ephedrine alkaloids for weight loss, as well as other uses, and have discussed our analysis and conclusions regarding weight loss in section V.C.1 of this document.

(Comment 37) Numerous comments asserted that herbal medicines, including ephedra, have a favorable safety record when compared to approved pharmaceuticals. Several comments cited the numbers of serious adverse events associated with approved pharmaceuticals, including deaths, among the U.S. population that are not due to medication errors. For example, various authorities estimate that more than 100,000 deaths per annum are associated with approved pharmaceuticals (Refs. 99 and 100). One comment stated that the rate of severe adverse reactions to prescription drugs, without necessarily including misuse, ranks as the fourth to sixth leading cause of death in the United States (Ref. 100). The comment expressed the view that ephedrine alkaloids do not carry a significant or unreasonable risk of harm when compared to the high incidence of serious adverse effects with prescription drugs.

(Response) While we agree that serious adverse events can occur with the use of prescription drugs, that fact does not change our determination that dietary supplements containing ephedrine alkaloids present an unreasonable risk. Prescription medications, although considered safe and effective for their labeled indications, are not free from all risks. However, the benefit of using prescription medications outweighs such risks for particular patients with particular disease conditions, in part because the risk is managed through the physician supervision required for the use of prescription medications. Although dietary supplements need not be free of risks to be lawfully marketed, the risks of using dietary supplements containing ephedrine alkaloids are not outweighed by any benefit. Moreover, it would not be surprising to see more AERs for prescription drugs than for dietary supplements. Healthcare professionals, who are aware of the drugs prescribed for their patients, are the primary source of drug AERs reported to us directly or through manufacturers. They may not be similarly aware of their patients' use of dietary supplements. In addition, there are no mandatory reporting requirements for dietary supplement manufacturers, unlike for prescription drug manufacturers. Finally, the comments and literature cited pertain to adverse events for all prescription drugs combined. This information has no meaningful bearing on whether dietary supplements containing ephedrine alkaloids present risks.

(Comment 38) One comment contended that dietary supplements containing ephedrine alkaloids should be banned because we have already banned OTC drugs containing ephedrine in combination with caffeine. Numerous other comments stated that our November 18, 1983 (48 FR 52513), prohibition of ephedrine alkaloids combined with caffeine and other stimulants (48 FR 52513) was due to such products' potential for abuse and misuse as illicit street drug alternatives and not because of safety issues. One comment stated that our proposal (60 FR 38643, July 27, 1995) (July 1995 proposal) to amend the final monograph for OTC bronchodilator drug products to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride and to classify these ingredients as not generally recognized as safe and effective for OTC use was proposed to restrict the OTC availability of ephedrine because of its illicit use as the primary precursor in the synthesis of the controlled substances methamphetamine and methcathinone. The comment stated that the July 1995 proposal does not discuss the safety of the use of ephedrine and thus does not support our actions.

(Response) We do not agree that our July 1995 proposal did not discuss the safety of OTC bronchodilator drug products containing ephedrine alkaloids (60 FR 38643 at 38644). In any event, comments about the basis and scope of our 1983 prohibition on ephedrine and caffeine combinations in OTC drug products and the 1995 ephedrine drug product proposal are not relevant to this rulemaking because we are not relying on those actions as a basis for the

removal of dietary supplements containing ephedrine alkaloids.

4. Abuse and Misuse

(Comment 39) Many comments asserted that we must consider directions for use, warnings, and other labeling when making an assessment of significant or unreasonable risk. The comments stated that we cannot consider misuse or abuse of properly labeled dietary supplements. One comment urged that any evaluation of significant or unreasonable risk be based on the standards specified in the American Herbal Products Association's (AHPA) *Ephedra* Trade Recommendation, which recommends that dietary supplements containing ephedrine alkaloids be formulated to contain no more than 25 mg of ephedrine alkaloids per serving, that such products bear a warning statement and that directions for use limit consumption to 100 mg of ephedrine alkaloids per day (Ref. 101).

(Response) We agree that directions for use, warnings, and other labeling must be considered when making an assessment of significant or unreasonable risk. Section 402(f)(1)(A) of the act provides that whether a dietary ingredient or dietary supplement presents a significant or unreasonable risk must be evaluated "under conditions of use recommended or suggested in labeling," except that ordinary conditions of use may be considered if the labeling is silent on conditions of use. Thus, for purposes of the "significant or unreasonable risk" provision, unless no conditions of use are recommended or suggested in labeling, we must consider a dietary supplement's labeled use rather than its actual use. We do not agree, however, that our evaluation of significant or unreasonable risk should be based on the standards specified in AHPA's *Ephedra* Trade Recommendation (Ref. 101). These standards are voluntary recommendations by a trade association and are not universally followed. We must consider all dietary supplements containing ephedrine alkaloids, not just those formulated and labeled in accordance with the *Ephedra* Trade Recommendation. In this instance, we conclude that all dietary supplements containing ephedrine alkaloids present an unreasonable risk, regardless of whether they are formulated and labeled in accordance with the *Ephedra* Trade Recommendation, based on our evaluation of the totality of the evidence and a weighing of the risks and benefits of the products. As discussed in section VI.A of this document, the presence of a warning label or of directions recommending a limit on daily consumption of ephedrine alkaloids does not sufficiently reduce the risks of dietary supplements containing ephedrine alkaloids to allow them to continue to be marketed as currently labeled or under ordinary conditions of use, and the risks of these products outweigh their benefits regardless of labeling.

(Comment 40) Several comments compared the effects of ephedra to other sympathomimetics such as cocaine or amphetamine. Several other comments stated that while ephedrine, PPA, and amphetamine are similar in chemical structure, they differ in physiological effect, and that amphetamines have much stronger reinforcing effects and a much higher liability for abuse than ephedrine. One comment stated that the subjective effects of ephedrine more closely resemble caffeine. Another comment stated that amphetamines do not have direct agonist properties, but promote release of neurotransmitters and inhibit their deactivation and reuptake. One comment from a manufacturer of a dietary supplement containing ephedrine alkaloids stated that its product label warns consumers not to take the product longer than 12 weeks because it can be habit forming and to take it longer runs the danger of "getting hooked."

Several comments expressed the opinion that ephedrine alkaloid dependence is similar to amphetamine dependence, as are the psychological effects of abuse such as psychosis, paranoia, and the potential to cause mania in susceptible individuals. Comments from several individuals and the founder of a consumer advocacy Web site included anecdotal reports of individuals who reported dependence or apparent addiction associated with use of ephedrine and dietary supplements containing ephedrine alkaloids. Several other comments cited the German Commission E monograph's instructions to limit the use of ephedra preparations to short-term because of the danger of addiction. (The Commission E was a division of the German Federal Health Agency established in 1978 to evaluate the safety and efficacy of herbal medicines sold in Germany. It produced official monographs for botanicals and botanical formulations sold in German pharmacies.)

(Response) We agree that ephedrine alkaloids and amphetamines share some pharmacological and physiological properties that may be associated with abuse and dependence. Psychostimulant effects that have been reported with sympathomimetic agents include drug tolerance, dependence, or addiction, although these psychostimulant effects are better recognized for cocaine and amphetamines (Refs. 102 and 103 of English abstract), Ephedrine alkaloids exhibit physiological effects common to the amphetamines, but differ in the relative intensity of these effects. We agree that amphetamines and cocaine have been shown to have much greater reinforcing effects and higher liability for abuse than products containing ephedrine alkaloids, but also agree that the development of dependence from the use of ephedrine alkaloids has been noted with both pharmaceutical and botanical products (Refs. 104, 105, and 106). The greater possibility of dependence and abuse of amphetamine-containing and cocaine-containing drug products marketed in the United States is recognized by the placement of these substances in Schedule II of the Controlled Substances Act (CSA). Ephedrine-containing drug products are not scheduled under the CSA; however, ephedrine, its salts, optical isomers, and salts of optical isomers are List I chemicals under the CSA (*See* 21 U.S.C. 802(34)) because they are chemical precursors of methamphetamine (Schedule II) and are used in its illicit manufacture. As List I chemicals, these substances are subject to various Drug Enforcement Administration (DEA) requirements, including recordkeeping, reporting, and sale behind the counter (*See* 21 CFR 1310.03 through 1310.07). While we are concerned about the potential for abuse, we did not rely on evidence of abuse or dependence to make our determination under section 402(f)(1)(A) of the act.

(Comment 41) Some comments advocated use of ephedra as an alternative to more dangerous street drugs. They postulated that banning dietary supplements containing ephedrine alkaloids would push those products underground or drive consumers to seek out more dangerous drugs for stimulant effects.

(Response) No data were submitted with these comments to support their conclusions. We have no information regarding the extent of use of ephedra, or dietary supplements containing ephedrine alkaloids, as an alternative to more dangerous street drugs, nor do we have any information about whether users of ephedrine alkaloids would be likely to use other substances were ephedra to become unavailable. Regardless, such information would not affect the determination we have made that dietary supplements containing ephedrine alkaloids present an unreasonable risk.

(Comment 42) Several comments stated that we cannot stop the abuse of substances by regulation. Some comments cited tobacco and alcohol as examples. Another comment stated that if we regulated products that caused injury because of their potential for abuse, then common household products, such as aerosol paint, would be banned.

(Response) Our conclusion that dietary supplements containing ephedrine alkaloids present an unreasonable risk is based not on abuse or misuse but rather on evidence supporting the presence of risks under conditions of use recommended or suggested in the labeling, or if the labeling is silent, under ordinary conditions of use. Abuse or misuse of other products is not relevant to our determination that dietary supplements containing ephedrine alkaloids present an unreasonable risk.

(Comment 43) Several comments stated the opinion that we do not appear to distinguish between dietary supplements containing ephedrine alkaloids marketed for weight loss or energy from those products marketed as alternatives to illicit street drugs or as "legal highs."

(Response) We do not agree with these comments. Beginning with the June 1997 proposal on dietary supplements containing ephedrine alkaloids, we have repeatedly warned industry and the public that we do not consider products marketed as street drug alternatives to be dietary supplements because they are intended for recreational purposes to affect psychological states (*e.g.*, to get high) and are not intended to be used to augment the diet or to promote health (62 FR 30678 at 30699 and 306700). Since 1997, we have issued a series of warning letters to firms for marketing ephedrine alkaloid-containing products as street drug alternatives and warned consumers not to purchase or consume such products. In March 2000, we issued a guidance document stating that street drug alternatives are unapproved and misbranded drugs that are subject to regulatory action, including seizure and injunction (available at *http://www.fda.gov/cder/guidance/3602fnl.pdf*). Our position was that street drug alternatives are drugs, not dietary supplements, was upheld in *United States* v. *Undetermined Quantities of Articles of Drug (Street Drug Alternatives)*, 145 F. Supp. 2d 692 (D. Md. 2001). That case involved a seizure of numerous street drug alternatives marketed as dietary supplements, including four products containing botanical ephedrine alkaloids. In January 2003, we witnessed the voluntary destruction of $4 million worth of illegally marketed street drug alternative products containing ephedrine alkaloids. We continue to address the street drug alternatives with appropriate regulatory actions. We have determined that the appropriate regulatory action for dietary supplements containing ephedrine alkaloids—i.e., products marketed for weight loss, athletic performance, energy enhancement, or other nonstreet drug alternative uses—is to issue a final rule finding that these products present an unreasonable risk of illness or injury.

5. Traditional Asian Medicine

(Comment 44) Many comments stated that the use of ephedrine alkaloids in dietary supplements is safe based on its traditional use in Asian medicine for thousands of years. Several comments asserted that few or no adverse effects have been recorded with the use of *Ephedra* in traditional Asian medicine. Numerous other comments, including those by traditional Asian medicine practitioners, disagreed with these comments about dietary supplements, highlighting the differences in the products themselves and how they are used from what is used in traditional medicine.

Several comments suggested that the raw *Ephedra* and *Ephedra* extracts used in traditional Asian medicine formulae differ in potency, toxicity, pharmacokinetics, and pharmacological and physiological effects from many dietary supplements containing ephedrine alkaloids and, therefore, that these formulations should be considered distinct in scientific, medical, and regulatory contexts. Comments stated that "*Ephedra*" properly refers to dried aerial parts of medicinal plants, or crude extracts thereof, not to isolated alkaloidal constituents. Several comments further distinguished the various products containing *Ephedra* as follows: Herb and extracts of raw herb of medicinal *Ephedra* plants containing naturally occurring alkaloids and other compounds without further manipulation, concentration, or adulteration; *Ephedra* extracts that are concentrated, manipulated, or adulterated such that naturally occurring proportions and/or quantities of ephedrine alkaloids are altered; products containing ephedrine alkaloids combined with other agents such as caffeine, caffeine-containing herbs, salicylate-containing herbs, synephrine, and other substances; and traditional Asian herbal medicinal formulae.

Several comments asserted that traditional Asian medicine *Ephedra* formulae often deliver lower amounts of ephedrine alkaloids compared to other types of ephedrine alkaloid-containing products and that traditional formulae rarely contain more than 15 percent *Ephedra* in the herb mixture. Comments also asserted that *Ephedra* in traditional formulae is usually combined with other botanicals that typically modify *Ephedra*'s inherent stimulant effects. Another comment attributed the relative safety of *Ephedra* to the mixture of ephedrine alkaloid isomers not present in purified or synthetic alkaloids. One comment suggested that the established therapeutic dose range of *Ephedra sinica* in herbal medicine formulae is 60 to 90 mg total alkaloids per day (adults), which falls within the dosage range established for OTC ephedrine/pseudoephedrine-containing drugs (150 mg and 240 mg alkaloids daily, respectively), and the recommendations of the Germany Commission E (maximum daily *Ephedra* alkaloid dose of 300 mg daily). Other comments asserted that infusions or teas of *Ephedra* are effective in relieving respiratory symptoms but have fewer side effects and are safer than formulations containing isolated or synthetic ephedrine alkaloids or prescription drugs. Another comment stated that supplements in a liquid tea form greatly reduce the risk of excess acute consumption by the public.

In contrast, several other comments stated that the presence of varying amounts, proportions, and chemical configurations of ephedrine alkaloids in crude *Ephedra* and prepared *Ephedra* extracts, as well as the presence of unknown compounds, leads to uncertainty as to dose, purity, and composition and to a greater risk of adverse effects. Comments noted that this variability is not an issue for synthetic or pure isolated ephedrine alkaloids.

Numerous comments, including those by traditional Asian medicine practitioners, also noted differences in how the products are used. Several comments stated that most traditional Asian uses of *Ephedra* are the same as the indications for OTC ephedrine and pseudoephedrine drugs (*e.g.*, short-term use to improve respiratory function) and that few if any adverse effects have been recorded. Several comments stated that use of *Ephedra* (ma huang) for weight control or for its stimulating effects, for more than a short period of time, in combination with caffeine and other botanical stimulants, and without the supervision of a health care provider, is irresponsible and dangerous. A number of traditional Asian medicine practitioners maintained that many

consumers experienced adverse effects because of this improper use, overdosage, or conflict with their illnesses.

Because of these differences, many practitioners of traditional Asian medicine commented that they support our June 1997 proposal except to the extent that it would restrict their use of *Ephedra* in traditional Asian medicine. Several comments asserted that since most serious adverse effects involve use of ephedrine alkaloids and not whole herb or whole herb extracts of *Ephedra*, any rule must exempt whole herb *Ephedra* or whole herb *Ephedra* extracts that contain no added ephedrine alkaloids. Furthermore, ephedrine alkaloid-free species of *Ephedra* should also be exempted.

Numerous comments asserted that because traditional Asian herbal products are prescribed by appropriate practitioners (licensed, certified, and registered acupuncturists, herbalists, and naturopathic physicians) and because these products are not associated with serious adverse effects, the products do not appear to constitute a public health risk and their use should not be prohibited. Many traditional Asian medicine practitioners stated that *Ephedra* is an essential medicine and requested an exemption from the final rule for use of *Ephedra* by traditional Asian medicine practitioners and acupuncturists. A few comments asserted that *Ephedra* should not be used commercially, but be restricted to professional use, to be dispensed by licensed health care professionals trained in the appropriate use of traditional Asian medicine.

(Response) This final rule does not affect the use of *Ephedra* preparations in traditional Asian medicine, although we considered the comments' views and information on the use of *Ephedra* in traditional Asian medicine in the context of their possible relevance to the risks of dietary supplements containing ephedrine alkaloids. This rule applies only to products regulated as dietary supplements (*See* 62 FR 30678 at 30691). Traditional Asian medicine practitioners do not typically use products marketed as dietary supplements.

With respect to the absence of adverse effects recorded with the use of traditional Asian medicine, as we stated in the June 1997 proposal, we are not aware of any systematic collection of data related to adverse effects occurring in individuals treated with *Ephedra* in traditional Asian medicine. The absence of recorded adverse events with the use of *Ephedra*, therefore, may be related to the lack of a mechanism for reporting. Under these circumstances, there are no data to evaluate. We note that the potential for adverse effects resulting from the traditional Asian use of *Ephedra* is implied in several reference texts that list precautions and contraindications for the use of the botanical *Ephedra* in traditional Asian medicine preparations (Refs. 3, 107, and 108). Moreover, even if we could say that the absence of recorded adverse events with the use of *Ephedra* in traditional Asian medicine was due to its safety for that use rather than due to a lack of mechanism for reporting, the history of use of *Ephedra* in traditional Asian medicine primarily for the treatment or mitigation of respiratory illness cannot provide assurance about the safety of dietary supplements containing ephedrine alkaloids for other uses.

6. Adverse Events

AERs involving drugs include those submitted to us voluntarily by consumers or healthcare professionals and those submitted by manufacturers who are required to report them to us. However, there is no required reporting of AERs to us for dietary supplements, including those containing ephedrine alkaloids. Depending on other information we may have about the event or about the suspect product, AERs can be hard to interpret. AERs may raise concerns about a product, as well as buttress a finding that a particular dietary supplement represents an unreasonable risk based on other types of evidence. Some AERs can be reasonably persuasive on their own. For example, individual cases of adverse events where dechallenge (discontinued use) and rechallenge (restarting use) have been linked to the abatement and recurrence of the events, strongly support the association between exposure to the product and occurrence of the adverse event. FDA, and others, have reviewed and analyzed the AERs in depth to add to the body of evidence and to ensure that all relevant evidence is considered (Refs. 109 through 115). Despite the limitations of such reports, a detailed review of the AERs submitted to us for dietary supplements containing ephedrine alkaloids and comparison of those AERs to scientific data about the pharmacology of these substances establishes that the AERs are consistent with the known and expected pharmacological effects of these products considered (Refs. 109, 115, and 116).

In the preamble to the June 1997 proposal, we stated that there were more than 800 reports of illnesses and injuries associated with the use of dietary supplements containing ephedrine alkaloids. Since that time, we have received more than 2,200 additional AERs submitted directly to us plus approximately 16,000 reports from call records submitted by Metabolife International, one of the largest distributors of dietary supplements containing ephedrine alkaloids. These records have been placed in the record for this rulemaking in redacted form.

A Congressional subcommittee minority report (Ref. 117), posted at *http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_dietary_ephedra_metabolife_rep.pdf* [4] noted that the call records from Metabolife International contain nearly 2,000 reports of significant AERs for its products, including 3 deaths, 20 heart attacks, 24 strokes, 40 seizures, 465 episodes of chest pain, and 966 reports of heart rhythm disturbances. In addition to these cardiac and neurological events, psychiatric symptoms were also reported. These reports include 46 reports of hospitalization following use of their products, and 82 additional reports of emergency room care. The report stated that in more than 90 percent of the most serious AERs— stroke, heart attack, seizure, and psychosis—where dosage information is documented in the call record, the consumer had followed the manufacturer's dosage recommendations. It also stated that among those most significant adverse event reports for which age was noted, 50 percent of the consumers were under 35 and many of the consumers were reported as being in good health with no prior medical problems. Despite the limited information provided in Metabolife International's call records, we note that these types of adverse events reported are consistent with the scientifically documented effects and potential risks of ephedrine alkaloids in those cases where appropriate information was available to make a medical evaluation of the reported event.

(Comment 45) Many comments criticized our system for collecting and evaluating adverse events and our use of AERs. A number of comments criticized the reporting system, stating that many of the received reports were insufficiently documented and lacked critical information necessary for appropriate evaluation. Other comments stated that the reports were anecdotal

[4] 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**.

and that no scientific standards were used in their evaluation.

Several comments stated that our attempt to rely on AERs for attributing adverse events to dietary supplements containing ephedrine alkaloids is in conflict with established scientific principles and FDA policy. The comments cited the criticism of our reliance on AER in the July 1999 GAO Report, our bases for regulation of Yellow No. 5 which included AERs and multiple clinical studies, and the opinion that our AER review system was biased and lacked scientific rigor.

Several comments stated that our methods of data collection might have affected the integrity of the data. The comments explained that we included in the database AERs that had not been verified. Many of these comments also stated that adverse events were frequently reported by family members and FDA officials rather than by physicians, health care facilities, and dietary supplement manufacturers. Some comments stated that certain products that did not contain ephedrine alkaloids were reported to be associated with adverse events. Several comments expressed the opinion that the AER database must be corrected to remove AERs that relate to products that do not contain ephedrine alkaloids prior to any rulemaking.

(Response) Because there is no mandatory requirement for submission of adverse event reports involving foods (including dietary supplements) to us, we rely on voluntary adverse event reporting from consumers, physicians and other health care professionals, product manufacturers, poison control centers, and State health agencies as a monitoring tool in our identification of potentially serious public health concerns that may be associated with a particular ingredient, product, or type of product. As with other passive surveillance systems, we acknowledge that voluntarily submitted adverse event reports do not always include adequate descriptions of the event and important elements of medical history, such as preexisting illness or other therapy. Our concerns about the risks of dietary supplements containing ephedrine alkaloids are based primarily on the known pharmacological effects of sympathomimetics and clinical studies using botanical and/or synthetic ephedrine alkaloids. Based on these pharmacological effects, we have identified a likelihood of potentially fatal arrhythmias, increased mortality in heart failure, and an increased rate of the consequences of elevated blood pressure, such as heart attack, stroke, and death. All of these events have been reported to be associated with consumption of dietary supplements containing ephedrine alkaloids. Because these events also occur spontaneously, specific occurrences of the events generally cannot be definitively attributed to dietary supplements containing ephedrine alkaloids, although they are compatible with the expected effects of these products. The AERs were, thus, only one component of our evaluation, which primarily relied on review of the best available scientific literature, such as peer-reviewed controlled clinical trials. The AERs are consistent with events expected from ephedrine alkaloids based on known pharmacological effects and other evidence in the scientific literature, and the AERs support our findings concerning the risks of dietary supplements containing ephedrine alkaloids.

a. *Definitional issues.*

(Comment 46) Some comments argued that only "life-threatening" adverse events should have been considered as the basis for the rulemaking. Another comment pointed out that a "serious event" is described in FDA's publication entitled "Clinical Impact of Adverse Event Reporting" (Ref. 32) as an event that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly, or requires intervention to prevent permanent impairment or damage. The comment stated that any event that fails to meet any of these criteria must then be nonserious, reasonable, or insignificant. The comment also pointed out that an "adverse effect" is an unwanted effect and does not necessarily imply "serious." The comment further stated that we should define key terms, including "serious," "unreasonable," "significant," "adverse effect," and "side effect."

Several comments also noted that the vast majority of complaints received by Metabolife International were mild and common. As such, one comment stated that some of the complaints were more accurately termed "side effects," not "adverse events." One Metabolife International consultant who reviewed the call records noted that there is no FDA guidance to define "significant effect."

(Response) We do not agree that we should consider only "serious" or "life-threatening" adverse events in our evaluation of AERs for dietary supplements containing ephedrine alkaloids. In considering reports of adverse effects of ephedra, we have focused on the reports themselves and their implications, not how they were designated. Thus, a report of tachycardia, not necessarily serious in itself, indicates a sympathomimetic response that in some patients could be dangerous. Marked increases in blood pressure would have similar implications and could suggest greater sensitivity to sympathomimetic effects in particular individuals. Reports of serious events like stroke, death or ventricular tachycardia are important, of course, but as noted earlier, can be difficult to interpret outside of a controlled trial or epidemiologic investigation. Concerns about ephedra arise principally because it has effects known to put particular individuals at risk (those with coronary artery disease or heart failure) or to pose a risk to any individual with continued use (increased blood pressure). Nonserious events that suggest sympathomimetic effects of ephedra are therefore important and need evaluation.

There is no real distinction between side effects and adverse effects. In either case, they are unwanted effects of the product. The description of the reported event is what is critical. Although we agree that the term "adverse effect" means there is an unwanted effect and does not necessarily imply that the event is serious, that does not mean it is insignificant. Such effects could be indicative of more serious cardiovascular risks if use of the product is continued. When considered with the scientific literature and other data, the less clinically significant effects may provide evidence that the use of a dietary supplement or dietary ingredient presents a significant or unreasonable risk of illness or injury.

In the case of dietary supplements containing ephedrine alkaloids, our evaluation indicates that serious adverse cardiovascular effects (*e.g.*, heart attack, stroke, worsened heart failure) can be expected to occur with the use of these products by the general population. Such events are relevant even if they may be expected to occur because they are known to be related to a substance, or combination of substances, contained in the product. Under section 402(f)(1)(A) of the act, a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury based on the conditions of use in its labeling (or under ordinary conditions of use if the labeling is silent). Therefore, if the labeled use of a dietary supplement containing ephedrine alkaloids would be expected to result in a risk of illness or injury, we must consider that risk in evaluating whether the dietary supplement is adulterated. For these reasons, we

considered all types of adverse events associated with the use of dietary supplements containing ephedrine alkaloids, even those that would not be considered "serious" or "life-threatening."

(Comment 47) Some comments stated that the AERs were anecdotal and by their nature do not allow for statistical evaluation. Other comments stated that AERs cannot establish a causal relationship between ephedra use and adverse events. Some comments cited the RAND report as support for the view that a causal relationship has not been shown.

Many comments stated that, without a control group, it is impossible to predict the number of persons who could experience the same type of adverse events that occur in the population not exposed to the product. Several comments argued that we may be detecting coincidental adverse events, which could have occurred whether or not consumers used an ephedrine alkaloid-containing dietary supplement. Many comments also stated, and pointed out that we have stated, that AERs cannot be used to calculate incidence rates of adverse events (i.e., the expected rate of adverse events occurring in the population using a product) because the actual number of persons exposed to the product is unknown, as is the actual number of adverse events that occur with use of these products.

(Response) As noted in the comments, the rate of occurrence of serious adverse events associated with a particular product or substance cannot be calculated based simply on the number of adverse events reported. Furthermore, we agree that the RAND report did not conclude that a causal relationship between ephedra and the reported adverse events had been shown. Despite the limitations of AERs, however, they can be of value in an evaluation of whether a dietary supplement presents a significant or unreasonable risk. Such reports can be important as signals of potential problems. Moreover, they can be more or less persuasive as to the strength of association between exposure to a product and occurrence of an event, depending, in part, on how likely the event is in the general population in the absence of the product. Thus, spontaneous reports have repeatedly signaled the ability of drugs to cause hepatic injury (*e.g.*, bromfenac, troglitizone) because the events seen were rarely witnessed in the absence of hepatotoxic drug or viral illness (which could be ruled out). Similarly, spontaneous reports have shown drug-caused torsade de pointes-type arrhythmias, which are also rare in the population. For more common events (*e.g.*, stroke, heart attack, headache), single reports may be harder to interpret. As previously discussed, the AERs for dietary supplements containing ephedrine alkaloids are consistent with events expected based on the scientific evidence, and the AERs support our findings.

(Comment 48) One comment urged us to disregard an e-mail memorandum from Dr. Paul Shekelle (Ref. 118) of the RAND Corp. that responds to our questions about the level of scientific proof that supports a causal relationship between the use of ephedrine-containing products and serious adverse events. The comment maintained that the opinions expressed in the e-mail are speculative, not objective, and not consistent with the peer-reviewed findings of the RAND report. The comment expressed concerns that we and others will interpret the e-mail as an extension or interpretation of the RAND report.

(Response) We are not treating the e-mail by Dr. Shekelle as an extension or interpretation of the RAND report. In seeking information from Dr. Shekelle, we were attempting to clarify the basis for RAND's conclusion regarding evidence of a causal relationship between dietary supplements containing ephedrine alkaloids and serious adverse events. We do not consider the Shekelle e-mail and Dr. Shekelle's subsequent publication (Ref. 119) as influencing the validity or interpretation of the RAND report, which is the document on which we rely.

(Comment 49) Several comments objected that we did not consider "denominator data" in our evaluation. Several comments stated that when the number of AERs we received is compared to the number of units sold and the population of users, the incidence of injury is insignificant or below the threshold for spontaneous illness (*e.g.*, the incidence of an adverse event in the general population) and that the level of risk is acceptable. Several related comments argued that if we made a statistical comparison of the number of AERs to the number of servings used, we could find the number of AERs to be statistically insignificant. Several comments made such a statistical comparison. For example, one comment estimated the annual number of servings of dietary supplements containing ephedrine alkaloids based on its own sales figures and an estimate of their share of the market, and concluded that the 800 AERs represent one adverse event occurring with every 8 million servings. The comments concluded that if the AER rate is statistically insignificant, the risk would be considered to be "insignificant" under the act.

Several comments requested that we consider industry evidence of the safe use of dietary supplements containing ephedrine alkaloids. Several of these comments were from manufacturers and distributors of dietary supplements containing ephedrine alkaloids that discussed the AERs their companies had received. One comment stated that the number of serious adverse events that the company received was statistically insignificant. Other manufacturers and distributors claimed that they had not received reports of adverse events related to the use of their dietary supplements containing ephedrine alkaloids when the products were used according to labeled directions or that lawsuits had not been filed against them. Comments from several dietary supplement trade groups or industry committees submitted survey information about the number of users of particular products or the number of units sold for particular products and the number of adverse events that were reported during the survey. These comments indicated that there were no or few adverse events (and these were mostly of a minor nature) in contrast to the millions of doses sold.

Many comments noted the experience of firms with respect to the number of complaints or lawsuits they had received on products containing particular amounts of ephedrine alkaloids, sometimes in conjunction with particular amounts of caffeine, and labeled for use for various levels of time. Some of these comments included information on the amount of product sold or the number of people consuming the product in a specified time period.

Several comments suggested that the number of adverse events estimated from the AERs is inconsistent with international data. For example, one comment noted that the Committee on Safety of Medicine (U.K.) indicated that there were only 22 reported adverse events on a product sold in the U.K. that contains a mixture of ephedrine alkaloids and caffeine in the 40 years or more that the product has been available. Similarly, some comments noted that Danish investigators estimated that 9.6 million doses of a product containing a combination of ephedrine and caffeine had been sold in Denmark in 1991 and 1992 and that only 86 reportable adverse events, defined as reactions which necessitated stopping the therapy, had been reported to the authorities during that time, despite relatively "high dosage levels".

(Response) We are not persuaded that the lack, or limited numbers, of adverse events reported to a limited subset of dietary supplement manufacturers and distributors demonstrates that the use of dietary supplements containing ephedrine alkaloids is safe. In contrast to the absence or low number of AERs described in some of the comments, we have received a total of more than 18,000 AERs directly, through dietary supplement firms, and from other sources. The AERs and international data discussed by the manufacturers and distributors in their comments are consistent with other adverse event reports we have received. We note that the Danish product referred to by some comments has been withdrawn from the market for safety reasons, including serious adverse event reports documenting cardiovascular and nervous system effects (Refs. 120 and 121).

There is little doubt that dietary supplement adverse events are underreported (Ref. 20). There is no requirement that manufacturers of dietary supplements report such events to FDA. Moreover, the usual reporters of AERs, physicians, are often unaware of the events themselves or the person's history of dietary supplement use. We therefore agree with the comments that the number of AERs reported to us cannot be used to calculate incidence rates. To calculate the incidence rate of an adverse event in the general population or in a subgroup of the general population, both numerator (i.e., the number of times a specific adverse event occurred with the use of a particular product over a given time period) and denominator (i.e., the total number of persons using the product over the same time period) data are needed. For reasons described previously, the adverse events that are actually reported are likely only a small fraction of the actual number of adverse events that occur with the use of these products. In addition, we have no reliable data on the use of these products by the general population or subgroups of the population. We could not evaluate the information from industry surveys on the number of people who use dietary supplements containing ephedrine alkaloids or the number of units of these products sold because this information was in summary form only (*e.g.*, the raw data were not submitted). Therefore, we do not know the actual number of persons who have used the product. In addition, because we do not have reliable information on the actual number of adverse events occurring with these products and on the size of the population exposed to dietary supplements containing ephedrine alkaloids, we cannot calculate the rate of adverse events occurring in the population using these products (i.e., incidence rate). Although we have done rough estimates for the purpose of calculating a potential economic impact, these estimates cannot be used to determine the precise incidence rates of adverse events for dietary supplements containing ephedrine alkaloids. However, we do not believe it is necessary to calculate the incidence rate to determine that dietary supplements containing ephedrine alkaloids present an unreasonable risk. Such a determination does not require us to find actual harm, only that a product's risk of illness or injury outweighs its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use.

b. *Reporting issues, including underreporting.*

(Comment 50) Although many comments agreed that the adverse events for dietary supplements containing ephedrine alkaloids were underreported, a number of comments disagreed with our estimates in the June 1997 proposal. Some comments believed that adverse events were less underreported than we estimated, while others thought they were more underreported. One manufacturer stated that it does not report the complaints it receives to us but rather keeps them for its own records.

(Response) As discussed in the response to comment 49 of this document, we continue to believe that adverse events are underreported due to the voluntary nature of the adverse event reporting system for dietary supplements and other factors. The manufacturer comment confirms that at least some firms in the dietary supplement industry receive AERs that they do not share with us. We commissioned a study that estimated that adverse events reported to us represent less than 1 percent of all of the adverse events associated with dietary supplements (Ref. 122). Our preliminary evaluation of data purchased from the American Association of Poison Control Centers, covering the years 1997 through 1999, indicated more adverse events than we had received for the same years (Ref. 123). In addition, the Office of the Inspector General of HHS determined that the number of dietary supplement adverse event reports we received was significantly less than the number of dietary supplement adverse event reports received by Poison Control Centers (Ref. 20 at p. 9).

In section VIII.A.5.a.i, we discuss in detail how we estimated rates of adverse event reporting for purposes of our impact analysis for this final rule.

(Comment 51) One comment stated that, despite underreporting, incomplete reports, and inadequate staff, there is no credible evidence that our reporting system makes errors in detection of adverse event signals. The comment asserted the validity of an association between AERs and risks presented by ephedrine alkaloids. The comment argued that this conclusion is confirmed by the known pharmacology of ephedrine alkaloids and the types of reports seen in ephedrine clinical trials and with drugs that have a similar pharmacological action. The comment noted that 26 percent of the reports over a four-year period documented dechallenge and 4 percent documented positive rechallenge, providing additional evidence supporting causation.

(Response) We agree that our spontaneous reporting system detected the potential health risks associated with dietary supplement products containing ephedrine alkaloids and that these health risks are consistent with those documented in the scientific literature and with the known pharmacology of these products. As stated in the July 1999 GAO report entitled "Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids" (Ref. 124), AERs surveillance can be important as an early alert to potential problems.

In considering the comments that disputed our estimates of adverse event reporting rates, it is important to note that we are not relying on the number of AERs for dietary supplements containing ephedrine alkaloids to demonstrate quantitatively that these products present an unreasonable risk. Rather, we are relying on the AERs as supportive evidence of the risks. Although the fact that we received many AERs for these products is relevant, an exact count of the number of AERs associated with consumption of dietary supplements containing ephedrine alkaloids is not necessary to our determination that these products present an unreasonable risk.

c. *Interpretation of AERs as supporting the existence of public health risks.*

(Comment 52) Several comments stated that the number of AERs does not raise a public health concern. One comment asserted that AERs with appropriate use of ephedra are rare. Other comments stated that there is no

association between the use of dietary supplements containing ephedrine alkaloids and serious adverse events when used with appropriate dosages, including the American Herbal Products Association (AHPA) trade recommendations. One comment noted that some of the AERs appear to be related to high amounts of ephedrine (i.e., in excess of 500 mg/day) and that the relationship of intake to adverse events with the use of lower amounts consumed is unknown.

(Response) We disagree with these comments. Public health concerns were initially raised by the number of AERs following consumption of dietary supplements containing, or suspected to contain, ephedrine alkaloids in comparison to the number of AERs for all other dietary supplements; the type of adverse event (*e.g.* cardiovascular system and nervous system effects); and the severity of the adverse events associated with the use of these products. The type, severity, and number of adverse events reported to us prompted us to investigate further. In many of these AERs, including those designated as "most significant" in the Congressional minority report (Ref. 117), the dietary supplement products were consumed as directed on the manufacturer's label. Although we do not endorse any current trade recommendations for the use of dietary supplements containing ephedrine alkaloids, we note that in many of the AERs, the amounts of ephedrine alkaloids consumed were within the ranges listed in trade recommendations or in product labeling. In addition, we note that the ephedrine alkaloid daily dose limit recommended by AHPA (Ref. 101) is higher than the dose administered to the treatment group in Boozer *et al.* (2002), which resulted in significantly higher blood pressure measured by ABPM when compared to the placebo group.

(Comment 53) Several comments cited the 1999 GAO report (Ref. 124) to support their criticisms of our the June 1997 proposal. These comments state that GAO criticized the validity of serious AERs reported for ephedra, particularly when used according to trade recommendations.

(Response) We do not agree that the July 1999 GAO report found the serious AERs reported for ephedra to be invalid (Ref. 124). Although the July 1999 GAO report criticized our use of adverse event reports to support the serving size and duration of use limits in the June 1997 proposal, it also emphasized that the adverse events reported to us were serious enough to warrant FDA's further investigation of the safety of dietary supplements containing ephedrine alkaloids. In addition, the report concluded that scientific information indicates that ephedrine alkaloids can affect the cardiovascular and nervous systems, citing (among others) published case reports that suggest ephedrine alkaloids can increase blood pressure in persons with normal and high blood pressure; predispose certain individuals to tachycardia (rapid heart rate), and cause cardiomyopathy (disease of the heart muscle), stroke, or myocardial necrosis (death of cells in the heart). The 1999 GAO report also noted that adverse events associated with dietary supplements containing ephedrine alkaloids include effects on the central nervous system, such as mania, paranoid psychoses, and seizures.

GAO's 2003 testimony before the Subcommittee on Oversight and Investigation of the House Committee on Energy and Commerce discussed and updated some of GAO's findings from its 1999 report on dietary supplements containing ephedrine alkaloids and provided new information, including an evaluation of Metabolife International's records of health-related calls from consumers of Metabolife 356 (Refs. 23 and 24). The 2003 GAO testimony noted that the types of adverse events identified in the health-related call records from Metabolife International were consistent with the types of adverse events reported to us, as well as with the scientifically documented pharmacological and physiological effects of ephedrine alkaloids. The 2003 GAO testimony noted that despite the limited information contained in most of the call records, approximately 14,684 call records contained reports of at least one adverse event among consumers of Metabolife 356. The 2003 GAO testimony identified 92 serious events that included heart attacks, strokes, seizures, and deaths and emphasized that these findings were similar to other reviews of the call records, including those done by Metabolife International and its consultants. The 2003 GAO testimony noted that, in those call records where age was documented, many of the serious adverse events occurred in relatively young consumers, with more than one-third of such adverse event occurring in individuals under the age of 30. Furthermore, for those call records in which quantity of use and/or frequency and duration of use were noted, most of the serious adverse events occurred among Metabolife 356 users who used the product within the recommended guidelines, i.e., they did not take more of the product nor consume it for a longer period of time than the product label recommended. These findings are consistent with our evaluations of AERs that we have received regarding dietary supplements containing ephedrine alkaloids (Refs. 27 and 109).

The 2003 GAO testimony noted that the adverse event reports are important sources of information concerning health risks of dietary supplements containing ephedrine alkaloids because the regulatory framework for dietary supplements is basically one of postmarketing surveillance and does not require premarket approval. The testimony stressed that despite the limited information obtained from the Metabolife International call records, the types of adverse events reviewed were consistent with the known risks of ephedrine alkaloids, including serious adverse events such as five reports of death. Finally, the testimony noted that several years earlier, we had concluded that dietary supplements containing ephedrine alkaloids present a "significant public health hazard" based upon the adverse event reports received and the consistency of those reports with the known pharmacological effects of ephedrine alkaloids.

C. What Are the Known and Reasonably Likely Benefits of Dietary Supplements Containing Ephedrine Alkaloids?

1. Weight Loss

(Comment 54) Numerous comments, including those from manufacturers and industry trade groups, stated that the results of the RAND report and other evidence, including the CANTOX review and the Boozer *et al.* clinical studies (Refs. 49 and 125), support or establish the safety and efficacy of dietary supplements containing ephedrine alkaloids for weight loss. Several comments stated that RAND concludes that dietary supplements containing ephedrine alkaloids have proven benefits for weight loss purposes. Several comments stated that RAND shows that dietary supplements containing ephedrine alkaloids provide a statistically significant increase in short-term weight loss compared to placebo of about 2 pounds per month for up to 6 months.

(Response) We agree that the RAND report found evidence that supported an association between short-term use of ephedrine, ephedrine plus caffeine, or dietary supplements containing ephedrine alkaloids with or without botanicals containing caffeine and a statistically significant increase in short-term weight loss compared to placebo. RAND found that combinations of

botanical ephedrine alkaloids plus botanical sources of caffeine, or synthetic ephedrine plus caffeine, were more effective in promoting short-term weight loss than ephedra or ephedrine alone. The RAND report concluded that ephedrine alkaloid containing products, in combination with caffeine, resulted in a modest weight loss of approximately two pounds per month greater than that with placebo over a period of 4 to 6 months.

We also agree that this modest weight loss effect may be perceived as a benefit by consumers who seek to lose weight for nonhealth related purposes (*e.g.*, to look slimmer). We do not agree, however, that these studies demonstrate the long-term weight loss necessary to provide health benefits. While the improvements in obesity/overweight and the accompanying risk factors may be demonstrated in as few as 1 to 2 months, the improvements must be maintained for years to achieve a reduction in risk (Refs. 66, 126, 127, and 128). We note that dietary supplements cannot be lawfully marketed for the treatment of obesity, a disease with serious health consequences. From a health perspective, the goal of weight loss is to prevent the substantial morbidity and mortality associated with overweight and obesity (Refs. 66, 129, and 130). Obesity itself adversely impacts multiple cardiovascular risk factors, or comorbidities, including hypertension, dyslipidemia (high cholesterol), and insulin resistance with glucose intolerance. Clinical studies have demonstrated improvements in these risk markers with even modest sustained weight loss (i.e., approximately 5 to 10 percent of initial body weight). Clinical studies have also demonstrated that both the weight loss and the improvements in the comorbidities take time to accrue (i.e., months) and that, as a rule, weight is regained and the comorbidities worsened when the intervention, pharmacological or behavioral, is discontinued. Thus, interventions necessary for successful weight maintenance must be long term. As discussed in greater detail below in the response to comment 56 of this document, the reasonably well-documented moderate, short-term weight loss from use of ephedrine alkaloids, with or without caffeine, does not prevent or decrease substantial, obesity-related irreversible morbidity and mortality. We have not found evidence that demonstrates long-term weight loss with these products.

We note that, to the extent these comments raise the issue of safety, we address those issues in section V.B of this document.

(Comment 55) A number of comments from manufacturers, distributors, industry experts, and trade groups were critical of the methodology used for the RAND report or the conclusions of this review. One comment stated that RAND does not take a sufficiently quantitative approach in its review of the data in contrast to the review performed by CANTOX. The comment also objected that RAND did not perform an efficacy comparison for ephedra-caffeine and that its dose-response assessment excludes the medium dosage range (40 to 90 mg), which includes the 6-month Boozer *et al.* (2002) study. Consequently, the comment argued that these omissions preclude any assessment of the degree of agreement or disagreement between RAND and CANTOX.

Other comments objected to RAND's criteria for study inclusion in the evaluation process, stating that RAND failed to consider all relevant and applicable trials. In particular, one comment criticized RAND's decision to consider only human weight loss trials that lasted at least 8 weeks, noting that 20 of 46 identified studies were excluded for this reason, and an additional six studies for other "alleged" reasons. Several comments objected to RAND's conclusions that weight loss research on ephedra, ephedrine, and caffeine (6-month data) is "short-term" only and not sufficient to demonstrate long-term weight loss, and cited additional studies to support this view. One comment stated that 6 months is longer than the period of time recommended by FDA's Advisory Review Panel on OTC Miscellaneous Internal Drug Products with respect to evaluating weight loss ingredients used in OTC drugs. The comment stated that, by these standards, RAND's 6-month weight loss efficacy data "exceeds the scientific requirement for evaluating OTC weight loss drugs recommended by FDA's advisory panel by 3 months." Other comments stated that, from a scientific perspective, there is no reason to believe the weight loss from dietary supplements containing ephedrine alkaloids would cease after a 6-month period (Refs. 70, 79, and 131).

(Response) RAND, using the principles of evidence-based medicine, established the scope of the review and methodology used in its assessment of the currently available data. The RAND reviewers limited their evaluation to those randomized or controlled clinical trials of a minimum study duration (8 weeks) that provided adequate information, including sufficient protocol design and safety information on the basis that shorter treatment durations were insufficient to assess long-term weight loss. We believe that RAND's study selection criteria were appropriate. Further, we note that in the absence of statutory requirements for dietary supplement manufacturers to submit well-designed, long-term, placebo-controlled studies to us, the available body of well-controlled clinical data is limited. We believe that RAND appropriately screened the available data and reviewed all relevant studies and adverse event reports meeting their stated minimum standard criteria, and thus we consider the results and conclusions of this assessment valid. Exclusion of studies not directed toward weight loss or obesity was appropriate for this evaluation in that these studies were designed to examine the efficacy of these agents for asthma and related pulmonary indications, rather than their safety.

We have reviewed the additional studies cited in the comments to support the effectiveness of dietary supplements containing ephedrine alkaloids for long-term weight loss (Refs. 68, 79, and 131). The results of the Filozof study have been presented only in abstract form and, therefore, neither details of the protocol nor data were available for review. The Daly *et al.* study enrolled only 24 subjects for 8 weeks in a placebo-controlled trial. After that period, 8 subjects were followed in an open label study for varying durations (1 subject was followed for 26 months). These additional studies were not evaluated in the RAND assessment because they did not meet RAND's screening criteria, and we find these studies to be either irrelevant or inadequate to change the conclusions stated in the RAND report. Therefore, we find that the Boozer 2002 study remains the longest (6-month) placebo-controlled study using ephedrine alkaloids. Consequently, we agree with RAND's conclusion that there are no studies showing an effect of dietary supplements containing ephedrine alkaloids on weight loss for more than 6 months.

Concerning the comment that referenced the Advisory Review Panel on OTC Miscellaneous Internal Drug Products with respect to evaluating weight loss ingredients used in OTC drugs, we note that the 1979 report of this panel was discussed in an advance notice of proposed rulemaking published in the **Federal Register** on February 26, 1982 (47 FR 8466). Based on the standard of practice at that time, the Advisory Review Panel

recommended that non-monograph weight loss ingredients (i.e., those not classified as GRASE) be studied for a period of 12 weeks to demonstrate effectiveness.

The treatment of obesity has evolved over the past 50 or so years (Refs. 127 and 128). In the 1960s, the mainstay of obesity treatment was behavioral modification and drugs were approved for short-term treatment to "jump start" patients' weight loss. There was a paradigm shift in the 1990s, with the realization that obesity is a chronic disease requiring long-term treatment, both with behavior modification and long-term drug therapy, when appropriate, in addition to diet and exercise. This shift is reflected in our draft guidance published in 1996 recommending the performance of clinical trials with a minimum 12-month treatment duration (*see* FDA Draft Guidance for The Clinical Evaluation of Weight-Control Drugs, Division of Metabolic and Endocrine Drug Products, issued on September 24, 1996) (Ref. 129). Therefore, because the treatment of obesity has evolved over time, the 1982 OTC Advisory Panel recommendations do not reflect current scientific understanding of effective treatment of obesity. There are currently no GRASE OTC drug products for weight loss or management.

(Comment 56) Many comments stated that obesity is a disease with serious health consequences. Numerous comments from consumers and physicians contained personal testimonials regarding the efficacy of dietary supplements containing ephedrine alkaloids for weight loss. Several physicians noted that patients who used these products were able to achieve long-term weight loss with an overall improvement of health, including improved cholesterol levels and lower blood pressure. No data were submitted, however, to support these statements. Several comments stated that ephedrine alkaloids are an effective tool to fight obesity. Several comments expressed the view that there are health benefits from short-term weight loss. Several other comments stated that dietary supplements containing ephedrine alkaloids are as—or more—effective for weight loss than some prescription drugs (*e.g.*, amphetamine, phentermine, sibutramine, phendimetrazine). Another comment stated that the evidence suggested that ephedra/ephedrine-caffeine supplements are as effective as OTC drugs for weight management. One comment stated that other modalities used to promote weight loss are very difficult, very dangerous, or very unsuccessful.

A comment by an industry trade group stated that the amount of weight loss identified by RAND for dietary supplements containing ephedrine alkaloids (approximately 2 pounds per month greater than placebo) is similar to that reported for approved obesity drugs (citing Ref. 128). Further, the comment asserted that "similar to ephedra-containing supplements, there is no long-term information [on weight loss] for any but the two most recently approved drugs [sibutramine and orlistat]" and that few studies of drugs approved for weight loss have extended to 6 months or beyond. One comment stated that double-blind placebo-controlled studies, including Boozer *et al.* (2002) (Ref. 49) have addressed the safety and efficacy of the dietary supplements containing ephedrine alkaloids, and further stated that the low cost of these products is beneficial, especially for low income groups where maintenance of a good diet is a challenge.

In contrast, other comments from physicians and medical societies, while acknowledging the results of the RAND report showing modest, but statistically significant short-term weight loss, questioned such a weight loss effect in light of the risks of these products. One comment indicated that this modest degree of "drug-induced weight loss" has never been shown to reduce the increased morbidity observed in obese patients. Several comments stated that there is no evidence for efficacy or safety of chronic treatment with ephedra. One medical association stated that the very modest benefits of ephedra combined with caffeine on short-term weight loss are far outweighed by the adverse effects observed in the clinical trials and the serious risks reported with the use of dietary supplements containing ephedrine alkaloids.

Several other comments, including those from an herbalist association and an herbal product manufacturer, stated that the use of these supplements, although effective, is not a sensible or healthy approach to long-term, sustainable weight management. The comment from the herbalist association also stated that obesity, with its higher risk for cardiovascular disease, is more likely to be a contraindication rather than an indication for the use of ephedra. A comment from a medical association said that NIH guidelines for the pharmacological treatment of adult obesity state that herbal preparations, including ephedra-containing products, are not recommended as part of a weight-loss program (Ref. 66).

Several comments, including one by a trade association and a medical society, while acknowledging the conclusions of the RAND report with regard to ephedrine alkaloids and weight loss, said that this effect should not be construed to imply that dietary supplements containing ephedrine alkaloids can treat diseases. One comment expressed the view that we should consistently state that obesity is a disease and, therefore, should only be treated with drugs that have been approved as safe and effective for that disease. These comments stated that use of dietary supplements to "treat" obesity is inappropriate.

(Response) As stated previously, we agree that obesity is a disease with serious health consequences; however, as some comments noted, treatment of a disease is outside the scope of the uses authorized for dietary supplements under DSHEA. Consequently, although dietary supplements containing ephedrine alkaloids could, if they did not present an unreasonable risk of illness or injury, be labeled for ordinary weight loss, they are subject to regulation as drugs if promoted for the treatment of obesity (65 FR 1000 at 1026 and 1027, January 6, 2000). We agree with the comments stating that obesity should be treated only with drugs that have been approved as safe and effective for that use.

We do not agree with the comments comparing the effectiveness of dietary supplements containing ephedrine alkaloids for weight loss to approved prescription drugs. The drugs mentioned by the comments are approved for the treatment of obesity, which is a use for which dietary supplements cannot be marketed. Furthermore, we are unaware of any data that have made direct comparisons between dietary supplements containing ephedrine alkaloids for weight loss and drugs approved for the treatment of obesity. As discussed previously, prescription drugs for the treatment of obesity are no longer approved on the basis of short-term data or for short-term use. Of note, the few prescription drugs that were approved for short-term use to "jump-start" weight loss are all stimulants and are controlled substances, the first group being approved in 1939 (amphetamine) and the last being approved in 1979 (phendimetrazine). The use of the majority of these drugs has fallen out of favor or the drugs have been withdrawn from the U.S. market. Whether the remainder of these drugs with indications for short-term use should be withdrawn is beyond the scope of this rulemaking. The rationale for requiring

long-term studies (1 to 2 years) to evaluate drugs intended to treat obesity was thoroughly discussed in the 1995 FDA/Center for Drug Evaluation and Research (CDER) Endocrinologic and Metabolic Drugs Advisory Committee Meeting. In that meeting, the panel discussed the duration of trials for evaluating both efficacy and safety of drugs for the treatment of obesity and used the example of Fluoxetine as a drug that demonstrated efficacy for weight loss at 6 months but did not promote additional weight loss or maintain previous weight loss in longer term (1-year) studies, although the risk for experiencing adverse effects still persisted.

Alleged economic benefits of these products are not considered as a component of our evaluation of their risks and benefits. Therefore, comments suggesting an economic benefit from using dietary supplements containing ephedrine alkaloids as an alternative to drugs for weight loss are not relevant to whether dietary supplements containing ephedrine alkaloids present an unreasonable risk. We also note that there are currently no stimulant-containing OTC drugs (including those with phenylpropanolamine) legally marketed for weight management and that amphetamine is no longer labeled for weight loss. There are no existing final OTC drug monographs for any weight control drug products, although one nonstimulant ingredient (benzocaine) remains to be evaluated for this use as part of FDA's OTC drug review and can continue to be marketed pending the outcome of that review.

The comments that mentioned health benefits from short-term weight loss submitted no data to support this contention, and we are not aware of any studies that indicate any meaningful health benefit from short-term weight loss. In the longest controlled study to date on the effect of ephedrine alkaloid containing products on weight loss by Boozer *et al.* (2002) (Ref. 49), subjects treated with placebo, plus diet and exercise recommendations, lost an average of approximately 6 pounds over a period of 6 months (Ref. 49). Subjects treated with a proprietary blend of herbal ephedra and kola nut (a source of caffeine), plus diet and exercise recommendations, lost an average of approximately 12 pounds during the same time period. As described previously in the response to comment 22 of this document, on balance this trial did not show a favorable effect on cardiovascular risk factors. To the contrary, there was a statistically significant increase in heart rate in the ephedra/kola nut (i.e., herbal ephedrine alkaloids/caffeine) treated subjects compared to the control group. Moreover, 24-hour measurements of blood pressure measured by ABPM at 1 month showed that the ephedrine alkaloid/caffeine treated subjects had blood pressure that was approximately 4 mm Hg higher than the placebo-treated subjects for both systolic and diastolic blood pressure.

While the authors report small but statistically significant decreases in total cholesterol and low density lipoproteins (LDL) cholesterol, the clinical significance of the net 3 mg/dl and 8 mg/dl decreases, respectively, cannot be determined from this study. In studies designed to assess modifications in cardiovascular risk factors, cholesterol changes are reported as percentage change from baseline. These data are not available from the Boozer *et al.* (2002) study (Ref. 49).

(Comment 57) A number of comments stated that the Danish experience using ephedrine/caffeine in a prescription drug for the treatment of obesity supported the use of dietary supplements containing ephedrine alkaloids for weight loss. One comment from a manufacturer of dietary supplements containing ephedrine alkaloids shared the opinion that the effectiveness of ephedrine alkaloids "to support one's diet" has been demonstrated in numerous studies, involving hundreds of patients in well-controlled environments, and that efficacy has also been demonstrated by extensive use data in the United States and Denmark. A comment from a medical association stated that, in Denmark, ephedrine is available to treat obesity, but only by prescription. Another comment stated that the Danish ephedrine-caffeine product (Letigen) has been banned and withdrawn from the market because of safety issues.

(Response) We agree with the comments that the product used in Denmark, Letigen, was a prescription drug and that this drug has been withdrawn from the market for safety reasons, including serious adverse event reports documenting cardiovascular and nervous system effects (Refs. 120 and 121). We note that certain studies from Denmark using the ephedrine-caffeine combination found in Letigen were considered as part of the RAND report. We do not agree with the comment that numerous studies have demonstrated the effectiveness of ephedrine alkaloids to support weight loss for the treatment of obesity, as discussed previously. The use of dietary supplements containing ephedrine alkaloids has been shown to produce a small, short-term weight loss, but no studies showing long-term weight loss with accompanying benefits to health have been conducted. In any case, if botanical ephedrine alkaloid products could be shown effective in long-term treatment of obesity or for long-term weight loss in people who are not obese, they would need to be marketed as prescription drugs and meet the standards of safety and effectiveness legally mandated for such products because physician supervision would be necessary to adequately mitigate the risks of using these products continuously in the long term.

2. Enhancement of Athletic Performance

(Comment 58) Several comments discussed the effects of ephedrine alkaloids on athletic performance. One comment noted that, while RAND states that ephedrine is a good surrogate for evaluation of dietary supplements containing ephedrine alkaloids, RAND does not make this extrapolation for athletic performance. Many other comments stated that there are few data to support the use of synthetic ephedrine alkaloids, and no data to support the use of dietary supplements containing ephedrine alkaloids to enhance athletic performance. Therefore, these comments do not consider the enhancement of athletic performance to be an appropriate use for dietary supplements containing ephedrine alkaloids. According to some comments, RAND concluded that there are insufficient data to support use for enhancement of athletic performance. One comment asserted that any effect on athletic performance is more likely due to the caffeine in ephedrine-caffeine dietary supplements. According to another comment, the few studies that have assessed the effect of ephedrine for this use support a modest effect of ephedrine plus caffeine on very short-term (1 to 2 hours after a single dose) athletic performance in a highly selected, physically fit population, but no studies have assessed the effect of dietary supplements containing ephedrine alkaloids.

(Response) We generally agree with these comments. The RAND report provides the most comprehensive, currently available review of efficacy studies for ephedrine alkaloid containing products, focusing on two popular uses of these products—athletic performance and weight loss (*see* section V.C.1 of this document). (Note that the RAND report did not consider the effectiveness data for ephedrine alkaloid containing products marketed as drugs for other uses, such as to treat asthma, or for other dietary supplement uses of such products). The effect of synthetic ephedrine on athletic

performance was assessed in seven studies that were reviewed in the RAND report. The RAND report noted that the effects of ephedrine on exercise performance were most often studied acutely (*e.g.*, 1 to 2 hours after a single dose) (Refs. 21 and 22). The RAND report could identify no studies that assessed the effect of dietary supplements containing ephedrine alkaloids on athletic performance. While the RAND report found that existing data supported a modest effect of synthetic ephedrine alkaloid containing products plus caffeine on athletic performance enhancement in healthy males in the very short term, no data support a sustained improvement in athletic performance over any significant time period. In these studies, the performance enhancement effect was demonstrated only with a combination of synthetic ephedrine and caffeine, not with ephedrine alone. Therefore, since the available evidence does not indicate that ephedrine itself enhances athletic performance, there is no need to address the issue as to whether ephedrine is a good surrogate for ephedra in evaluating athletic performance enhancement with the use of dietary supplements containing ephedrine alkaloids.

We determined that certain labeling claims made by manufacturers of dietary supplements containing ephedrine alkaloids for athletic performance enhancement were unsubstantiated in light of the findings in the RAND report. These claims were the subject of warning letters sent to various manufacturers in February and March 2003 (available at *http://www.fda.gov/bbs/topics/NEWS/ephedra/letterslist.html* (list of firms) and *http://www.fda.gov/bbs/topics/NEWS/ephedra/warning.html* (sample letter).

3. Eased Breathing

We are aware that there are teas and other types of dietary supplements containing ephedrine alkaloids marketed with claims such as "eased breathing" or "better breathing." There are no data that support a benefit to breathing from dietary supplements containing ephedrine alkaloids in healthy people. Moreover, because healthy people are able to breathe without difficulty, we do not believe there is any respiratory benefit in the absence of a disease state (*e.g.*, asthma or a respiratory infection). We note that claims to treat or mitigate a disease, or the effects of a disease, subject a product to regulation as a drug under the act.

4. Other Uses

We are also aware that dietary supplements containing ephedrine alkaloids are promoted for other uses, such as to "feel better," "feel more alert," and "energized." Effects such as "feel better" are subjective in nature and difficult to quantify. The agency is unaware of any data substantiating these types of subjective effects. Effects such as "alertness" and "energy" are consistent with the pharmacological properties of ephedrine alkaloids, although we are not aware of any studies evaluating ephedrine alkaloid products for these uses. Effects like alertness and energy may be of modest benefit to the individual (if they occur), but such effects are temporary and do not improve health. Any such temporary benefits must be weighed against the health risks discussed in section V.B of this document, which can result in long-term or permanent, serious adverse health effects.

D. Do Dietary Supplements Containing Ephedrine Alkaloids Present an Unreasonable Risk?

1. What Does "Unreasonable Risk" Mean?

A threshold issue is the legal standard of "significant or unreasonable risk of illness or injury" (section 402(f)(1)(A) of the act). By its plain language, this standard requires evidence of "significant or unreasonable risk of illness or injury" (emphasis added)." There is no requirement that there be evidence conclusively demonstrating causation of actual harm in specific individuals. In our evaluation of "significant or unreasonable risk," we can consider any relevant evidence, including scientific data about the toxicological properties of a dietary ingredient or its mechanisms of action; scientific information about the well-known effects of pharmacologically-related compounds, including those regulated as drugs; the results of clinical studies, including observational studies; and adverse event reports that have been subject to sound scientific analysis. The Government's burden of proof for "significant or unreasonable risk" can be met with any science-based evidence of risk, without the need to prove that the substance has actually caused harm in particular cases.

Thus, a dietary supplement that caused a sustained rise in blood pressure across the population would increase the risk of cardiovascular events including stroke, heart attack, or death to that population. Even risks that may not be detectable in small studies or studies of short duration could, over time, and on a population-wide basis, result in hundreds or thousands of adverse events. The Government's burden of proof for "unreasonable risk" is met when a product's risks outweigh its benefits in light of the claims and directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use.

(Comment 59) Most comments that articulated a view agreed with the general notion that we must consider a risk-benefit calculus to determine whether dietary supplements containing ephedrine alkaloids present an unreasonable risk, although the comments differed as to how to perform such a calculus and as to the conclusion about whether the risks of these products outweigh their benefits. Several comments agreed with our interpretation, as published in (Ref. 132), that a "significant or unreasonable risk" exists when a product's risks outweigh its benefits, based on the available scientific evidence, in light of the claims the product makes and in light of the products being directly sold to consumers without medical supervision. One comment from a public interest group stated that this interpretation represents a reasonable and practical interpretation of the act that offers some protection to consumers. One comment argued that this interpretation is not permissible under *Chevron U.S.A., Inc.* because we have never adopted a risk-benefit calculus in assessing the safety of foods and because the legislative history of DSHEA does not indicate any Congressional intent to establish a risk-benefit analysis for dietary supplements. The comment stated that we should determine whether risks are "unreasonable" without resorting to an assessment of the benefits of the product.

(Response) We agree with the comments stating that a risk-benefit calculus is appropriate to determine whether dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use. The relevant analysis for evaluating an agency's interpretation of a statute is set forth in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984). Under *Chevron*, the first question is whether Congress has directly spoken to the precise question at issue (Step 1). If so, the agency must implement the unambiguous intent of Congress *Id.* at 842–843. If Congress has

not directly spoken to the precise question at issue, our interpretation will be upheld as long as it is based on a "permissible construction" of the statute (Step 2) *Id.* at 843–844.

In determining whether Congress has specifically addressed the question at issue, "courts must exhaust the traditional tools of statutory construction, including looking at the statute's text, structure, and legislative history." *Chevron* v. *Federal Energy Regulatory Commission*, 193 F.Supp.2d 54, 67 (D.D.C. Cir. 2002). Section 402(f)(1)(A) of the act states that a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or, if the labeling is silent, under ordinary conditions of use. The plain meaning of the statute is the starting point of statutory interpretation. (*See* 2A SUTHERLAND STATUTORY CONSTRUCTION 81 (5th ed. 1992).) The words "significant" and "unreasonable" have two different meanings. "Significant" involves an evaluation of risk alone. The plain meaning of "unreasonable," on the other hand, connotes comparison of the risks and benefits of the product. A risk could be significant but reasonable if the benefits were great enough to outweigh the risks. That "unreasonable risk" entails a balancing test in which the benefits of the product or activity are weighed against its dangers is well-established in tort law (*See* PROSSER AND KEETON ON THE LAW OF TORTS, § 31, at 173 (5th ed. 1984).)

In assessing whether Congress has clearly spoken to the question at issue, a court "should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme" (*FDA* v. *Brown and Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000)). The term "unreasonable risk" is used in other provisions of the act, *e.g.*, in the provisions related to medical devices. In the medical device classification provisions, Class III devices are distinguished from Class I and Class II devices in part because they present a "potential unreasonable risk of injury or illness." The legislative history of the device provisions provides some indication of how Congress intended FDA to interpret the term "unreasonable risk in this context. The House Committee Report states: "the requirement that a risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against the benefits of use" (H. Rept. 853, 94th Cong., 2d Sess. 19 (1976)). Therefore, "unreasonable risk" in the context of classification of medical devices is properly interpreted to require a risk-benefit calculus. There is nothing in the provisions of the act dealing with dietary with dietary supplements, or the legislative history thereof, that would suggest that FDA should interpret the term "unreasonable risk" in the context of dietary supplements differently than it does in the context of medical devices.

An interpretation of unreasonable risk as entailing a balancing of the risks and benefits of the product is also consistent with the interpretation of other similar statutory provisions outside the act. The Toxic Substances Control Act contains an "unreasonable risk" standard, and legislative history indicates that Congress intended that this standard be evaluated through a balancing test (*e.g.*, H. Rept. 94–1341, 94th Cong.. 2d Sess. 32 (1976)). Indeed, it is difficult to construct an alternative formulation for the phrase "unreasonable risk."

Based upon the plain meaning of "unreasonable risk," the judicial interpretation of that phrase, and legislative history interpreting "unreasonable risk" in other contexts, including the device provisions of the act and other statutes, we conclude that Congress unambiguously intended that an assessment of "unreasonable risk" in the dietary supplement context should entail a risk-benefit analysis.

In the alternative, if a court were to find that Congress has not directly spoken to the issue of whether "unreasonable risk" in the dietary supplement context is demonstrated by balancing risks and benefits, our interpretation of an ambiguous provision should receive deference so long as it is "permissible" (*Chevron* Step 2). In interpreting ambiguous statutory language, we are guided by the same criteria we evaluated in Step 1 of the *Chevron* analysis, i.e., the statute's text, structure, history, and purpose (*See Bell Atlantic Telephone Cos.* v. *FCC*, 131 F.3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC*, 193 F. Supp. 2d at 68). Our interpretation of the "unreasonable risk" standard for dietary supplements as requiring a comparison of the risks and benefits of use is consistent with the purpose of the act, as amended by DSHEA, to promote public health and safety. This interpretation is also consistent with the legislative history of the medical device classification provisions. Therefore, our interpretation that "unreasonable risk" implies a weighing of the risks and benefits of use is, at a minimum, a "permissible construction."

In the absence of explicit standards for the evaluation of "unreasonable risk," one comment urged us to be guided by precedent from other agencies. The comment highlighted the Consumer Product Safety Act (CPSA), its implementing regulations, and related case law. The comment stated that any assessment of "unreasonable risk" must include a balancing of risks and benefits. a stringent burden on us to demonstrate that the product poses an unreasonable risk of injury, evidence other than consumer complaints, and valid scientific data sufficient to predict how likely an injury is to occur. (Citing *Gulf South Insulation* v. *CPSC*, 701 F.2d 1137, 1143 (5th Cir. 1983)), (citing *Aqua Slide 'N' Dive* v. *CPSC*, 569 F.2d 831, 838 (5th Cir. 1978)), the comment stated, "[T]he ultimate question in assessing unreasonable risk is whether the record contains 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" The comment acknowledged differences in the statutes, including the explicit statutory requirement in CPSA that the regulation impose the least burdensome requirement that prevents or adequately reduces the risk injury for which the rule is being issued (15 U.S.C. 2058(f)(3)(F)). The comment also cited Consumer Product Safety Commission (CPSC) case law stating that reliable evidence of the likely number of injuries is necessary to determine whether a risk is unreasonable (*Southland Mowor Co.* v. *CPSC*, 619 F.2d 499, 510 (5th Cir. 1980)).

(Response) We do not agree that our interpretation of "unreasonable risk" must be confined to the view reflected in the CPSC case law cited by the comment. We have concluded, based on a *Chevron* analysis, that Congress expressly intended "unreasonable risk" to entail a risk-benefit analysis (*see* the response to comment 59 of this document). In the alternative, if the term "unreasonable risk" is ambiguous, we. may interpret its meaning under *Chevron*. As the comment noted, CPSA contains an extensive list of findings that the CPSC must make, based on substantial evidence, before concluding that a consumer product poses an unreasonable risk, including, for example: (1) The degree and nature of the risk of injury the rule is designed to eliminate or reduce; (2) the approximate number of consumer products, or types or classes thereof, subject to such rule; and (3) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of

manufacturing and other commercial practices (15 U.S.C. 2058(f)(1) and (f)(3)). The requirements imposed on CPSC in the cases that the comment cited are based on the explicit requirements of CPSA. In contrast, the adulteration provision in section 402(f)(1)(A) of the act does not require that we make any such findings. Like section 402(f)(1)(A) of the act, other parts of the act that require an evaluation of unreasonable risk, such as the device classification and banning provisions, also do not require that we make the findings set forth in CPSA. Had Congress intended that FDA make specific findings such as the degree of risk of injury, it could have so directed in the act; however, it did not. Our conclusion that dietary supplements containing ephedrine alkaloids present an unreasonable risk is based upon our finding that the risks of heart attack, stroke, and death outweigh the minimal benefits conferred by the supplements. Our conclusion is consistent with Congress's express intent in section 402(f)(1)(A) of the act.

(Comment 60) One comment by a health professional group stated that unreasonable risk likely exists when there is no information that substantiates a clear therapeutic benefit or describes a predictable relationship between exposure (dose) and response, and when the appropriate product dose is not known or achievable.

(Response) We agree that unreasonable risk exists when a dietary supplement presents a risk to health, and there is no information substantiating a benefit sufficient to outweigh that risk. In this rulemaking, we base our determination that dietary supplements containing ephedrine alkaloids present an unreasonable risk under section 402(f)(1)(A) of the act on a risk-benefit analysis, finding that the risks of heart attack, stroke, and death outweigh the benefits that may result from such products. In the absence of a use that results in a benefit that outweighs the risks of these products, we conclude that all such products pose an unreasonable risk. We therefore need not determine whether an unreasonable risk exists when the precise relationship between exposure and response is not predictable or when the appropriate product dose is not known or achievable.

(Comment 61) Several comments stated that proof of causation is required to establish unreasonable risk.

(Response) We do not agree that proof of causation is required to establish unreasonable risk under section 402(f)(1)(A) of the act, and conclude that the plain meaning of the standard precludes such an interpretation. In determining whether Congress has specifically addressed the question at issue, "courts must exhaust the traditional tools of statutory construction, including looking at the statute's text, structure, and legislative history" (*Chevron U.S.A., Inc.* v. *FERC*, 193 F.Supp. 2d at 67). The plain meaning of the statute is the starting point for an analysis of legislative intent. The most applicable definition of the word "risk" in Merriam Webster's Collegiate Dictionary is "possibility of loss or injury" (Merriam Webster's Collegiate Dictionary, 10th ed. 1008 (2002)) (emphasis added). Black's Law Dictionary defines "risk," in part, as follows: "In general, the element of uncertainty in an undertaking; the possibility that actual future returns will deviate from expected returns. Risk may be moral, physical, or economic." Black's Law Dictionary, 6th ed. 1328 (1990) (emphasis added). The words "possibility" and "uncertainty" in these definitions indicates that proof of a definitive causal relationship between the product and illness or injury is not required under section 402(f)(1)(A) of the act. If Congress had intended that definitive proof that a dietary supplement causes harm be a requirement for a showing of adulteration, it would not have used the word "risk" in the statute, and would have instead provided that a dietary supplement is adulterated if it "causes" illness or injury. This interpretation is consistent with other parts of the act, as interpreted in legislative history and case law. For instance, the legislative history of the medical device banning provisions, which require a showing of "substantial deception or an unreasonable and substantial risk of illness or injury" states that "[A]ctual proof of deception or injury to an individual is [not] required" (Section 516 of the act (21 U.S.C. 360f), H. Rept. 853, 94th Cong., 2d Sess. 19 (1976)). Case law on medical device classification also supports that we need not have causal evidence of harm (*See Lake* v. *FDA*, 1989 WL 71554 (E.D. Pa.)) (upholding FDA's finding of unreasonable risk where the risks were unknown and the benefits unproven)). Therefore, we conclude that Congress has spoken clearly and unambiguously that proof of causation is not required to show that a dietary supplement presents an "unreasonable risk" under section 402(f)(1)(A) of the act.

Our interpretation is also consistent with other statutes that regulate public health risks, most notably TSCA (15 U.S.C. 2601 *et seq.* (1976)). TSCA authorizes the EPA to place restrictions on chemical substances if it finds that "* * * there is a reasonable basis to conclude that the [chemical substance] presents or will present an unreasonable risk of injury to health or the environment" (*Id.* § 2605(a)). The legislative history of this provision states:

> This standard for taking action recognizes that factual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible and the bill does not require it. Further, regulatory action may be taken even though there are uncertainties as to the threshold levels of causation.

(H. Rept. 94–1341, 94th Cong., 2d Sess. 25 (1976)).

(Comment 62) Several comments stated that any FDA regulatory approach to dietary supplements containing ephedrine alkaloids must consider both risks and benefits, and moreover, that we should determine, based on scientific evidence, a risk-benefit ratio for assessing their safety. These comments suggested that, if we were to set a break-even point, a decision matrix should be established along the following lines: (1) A benefit-to-risk ratio below the break-even point would mean that the risks outweigh the benefits and this would justify either a decision to (a) ban dietary supplement products containing ephedrine alkaloids or (b) restrict access to a case-by-case-basis, i.e., prescription; (2) a benefit-to-risk ratio in excess of the break-even point would mean that the benefits outweigh the risks and this would justify continued availability, with appropriate warning labels, dosage instructions, etc.; and (3) a benefit-to-risk ratio equal to the break-even point would mean that the risks equaled the benefits and this would justify either (a) continued availability under the present regulatory framework with appropriate labeling or (b) prescription-only access, whereby a medical professional would make the decision as to whether or not the product was appropriate for an individual consumer on a case-by-case basis.

One comment by a medical association stated that, because dietary supplements are classified as foods, and therefore are assumed to be safe, it is imperative that such products have no risks and provide some benefit to consumers. More specifically, the comment stated that dietary supplements containing ephedrine alkaloids should be safer than drugs and should have a much higher overall benefit/risk ratio when compared to drugs.

(Response) We agree that in regulating dietary supplements, we should

consider both risks and benefits. As discussed previously in this document, we also agree that we should weigh risks and benefits when evaluating the safety of dietary supplements under the adulteration standard in section 402(f)(1)(A) of the act. With regard to the comment from the medical association, we agree in part and disagree in part. Although the comment is correct that dietary supplements are classified as foods, we do not agree that they are required to have no risks at all. Section 402(f)(1)(A) of the act provides that a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury" (emphasis added) as labeled, not if it presents any risk at all. Accordingly, risks that are insignificant and reasonable in light of the benefits from the supplement would not render a dietary supplement adulterated. Further, we note that conventional foods are not always risk-free. With regard to the comment's statements that dietary supplements should be safer than drugs and have a higher overall benefit/risk ratio than drugs, we do not believe it is necessary to reach these issues. For purposes of this rulemaking, we are considering whether the known and reasonably likely risks of dietary supplements containing ephedrine alkaloids outweigh their known and reasonably likely benefits. It is not necessary to determine generally how the risk/benefit ratio of dietary supplements should compare to that of drugs.

2. Do Dietary Supplements Containing Ephedrine Alkaloids Present an Unreasonable Risk Under Labeled or Ordinary Conditions of Use?

(Comment 63) Several comments stated there is enough evidence, both scientific and anecdotal, to conclude that the risks of taking dietary supplements containing ephedrine alkaloids are so severe and reported adverse events sufficiently numerous to conclude that the risks clearly exceed the benefits because either there are no benefits or the benefits are unsubstantiated or modest for both efficacy and duration. These comments included references to support their conclusions. Some cited the RAND report's conclusions regarding the very modest benefit for short-term weight loss and the questionable benefit for other uses; according to the comments, these limited or questionable benefits are far outweighed by adverse events observed in clinical trials. Other references submitted by these comments included (Refs. 19, 34, 42, and 133 through 136).

Several comments argued that the harm caused by certain medical conditions—for example, obesity—is so severe as to render the unsubstantiated (in the commenter's view) risks of taking dietary supplements containing ephedrine alkaloids insignificant relative to the benefits that would accrue from use of these products. In this view, the weight loss benefit would exceed any potential risk from taking the product and the risk is not unreasonable when compared to the harm caused by obesity. Several comments cited the prevalence of obesity and an increase in obesity over time, and urged us not to take away one important tool for consumers to address the problem. Two comments cited statistics showing that 54 percent of adults are obese in the United States, that the prevalence of obesity increased by 30 percent from 1980 to 1994, and that in 1997 the Centers for Disease Control and Prevention (CDC) attributed 42 percent of deaths to conditions that typically result from obesity. One comment stated that the risks due to obesity are a greater danger than the rare incidences of stroke or heart attacks attributed to dietary supplements containing ephedrine alkaloids.

Other comments concluded that dietary supplements containing ephedrine alkaloids do not present an unreasonable risk because the risks do not outweigh the benefits. They argued that while the benefits of dietary supplements containing ephedrine alkaloids are substantiated, the adverse events reported are either mild, anecdotal, or unsubstantiated and not scientifically valid. Some comments cited the RAND report to support the benefit of ephedrine alkaloids for short-term weight loss and the lack of adverse effects in clinical trials. The comments assert that only a speculative risk for serious adverse events exists and that RAND concluded that an assessment of case reports is insufficient to reach conclusions regarding causality.

(Response) We have carefully reviewed the preceding comments, and note that many of these issues have been addressed in more detail in the scientific evaluation sections V.B and C of this document. Based on the scientific data and information discussed in those sections, we have concluded that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in their labeling, or, if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use. As discussed in the responses to comments 34 and 35 of this document, even if we were to extrapolate from data demonstrating effectiveness of certain ephedrine drug products when considering the reasonably likely benefits of dietary supplements containing ephedrine alkaloids, we conclude that the known and reasonably likely risks would outweigh even such extrapolated benefits. A summary of our rationale for reaching this conclusion is presented in our analysis below.

a. *Summary of risks for dietary supplements with ephedrine alkaloids.* People who use dietary supplements containing ephedrine alkaloids are at increased risk for serious adverse events, including heart attack, stroke, and death. Susceptible individuals (*e.g.*, those with coronary artery disease or heart failure), many of whom may not know they have underlying illnesses, are at increased risk for adverse events because these products can cause abnormal heart rhythms (pro-arrhythmic effect), even when the product is ingested at recommended doses over a short course (one or a few doses). Over longer periods of use, the risk for adverse health effects to the general population, including susceptible individuals, increases further due to a sustained elevation in blood pressure. This is a characteristic effect of the sympathomimetic class of pharmacological compounds. Moreover, the results of Boozer, *et al.* (2002) demonstrate that weight loss achieved with botanical ephedrine alkaloids does not produce the expected decrease in blood pressure (Ref. 49). The risk of experiencing harmful effects from elevated blood pressure increases the longer the blood pressure remains high, and such adverse effects are likely to occur sooner in individuals with hypertension, many of whom are unaware of their illness.

b. *Summary of known and reasonably likely benefits for dietary supplements containing ephedrine alkaloids.* As discussed in the following paragraphs, we conclude, based on all available information and data reviewed in this rulemaking, that these products do not provide a meaningful health benefit. The best clinical evidence for a benefit is for weight loss, but even there the evidence supports only a modest short-term weight loss insufficient to positively affect cardiovascular risk factors or health conditions associated with being overweight or obese. Other possible benefits, such as enhanced athletic performance, enhanced energy, or a feeling of alertness, lack scientific support and/or they would provide only temporary benefits that are trivial in comparison to the risks of serious long-

term or permanent consequences like heart attack, stroke, and death.

i. *Weight loss.* As discussed previously, the RAND report provides the most comprehensive review of efficacy studies for ephedrine alkaloid containing products. The RAND report found evidence that supported an association between short-term use of ephedrine, ephedrine plus caffeine, or dietary supplements that contain ephedrine alkaloids with or without herbs containing caffeine, and a statistically significant increase in short-term weight loss compared to placebo. The RAND report concluded that products containing ephedrine alkaloids in combination with caffeine resulted in a modest weight loss of approximately 2 pounds per month more than placebo over a period of 4 to 6 months. RAND concluded that the use of ephedrine without caffeine was associated with a statistically significant increase in weight loss (1.3 pounds of weight loss per month) compared with that of placebo for up to 4 months of use. RAND identified a single trial of 3 months duration that assessed the effect of herbal ephedra versus placebo. Those in the ephedra arm lost 1.8 pounds more per month than did those in the placebo arm. We are unaware of any appropriate, well-designed studies showing an effect of dietary supplements containing ephedrine alkaloids on weight loss for more than 6 months. Such a long-term effect would be necessary to translate into health outcome improvements.

Even if there were adequate substantiation that dietary supplements containing ephedrine alkaloids produce long-term, sustained weight loss in the overweight or obese population, the long-term risks posed by these products, particularly in obese patients who may already have underlying illnesses that can be aggravated by these products (such as hypertension), remain a serious concern. We believe that physician supervision is necessary to mitigate the risks associated with the use of sympathomimetic products in the long term for weight loss and the treatment of obesity, or for any other long-term use. This is achieved in part by monitoring patients who use these products and discontinuing product use if the patient develops hypertension, experiences other adverse health effects, or fails to achieve weight loss that would justify continued exposure to the risks associated with use of the product.

People might choose to use a dietary supplement containing ephedrine alkaloids to lose weight for purposes other than to improve health (*e.g.*, to look slimmer or fit into an outfit for a special occasion), and we do not dismiss this use as without value to the individual. To achieve the result of modest weight loss, however, these products must be used over a period of months. Individuals who use these dietary supplements over a period of months for weight loss are at risk for the adverse events that can occur with both short- and long-term use of these products. These risks are greater than the modest benefits described in the RAND report.

In the case of both short-term and long-term use, any benefits of dietary supplements containing ephedrine alkaloids for weight loss are outweighed by their risks. Therefore, we conclude that dietary supplements containing ephedrine alkaloids labeled or used for weight loss present an unreasonable risk.

ii. *Enhancement of athletic performance.* The effects of synthetic ephedrine on athletic performance were assessed in seven studies that were reviewed in the RAND report. Despite the widespread marketing of products containing ephedrine alkaloids as performance-enhancers, the RAND report found no studies involving botanical ephedrine alkaloids, and very limited evidence involving synthetic ephedrine, to support the claims. Furthermore, the RAND report concluded that, "to show even a short-term effect of ephedrine, combination with caffeine was required." Therefore, there is no evidence to indicate that ephedrine alone enhances athletic performance. People who use dietary supplements containing ephedrine alkaloids for athletic performance are at risk for the same serious adverse events as individuals who use these products for other indications. As discussed previously in section V.C.2, the available evidence regarding a possible benefit from these products for enhancing athletic performance is further limited: the supporting evidence all comes from studies in which synthetic ephedrine and caffeine in combination were administered to healthy males, and the modest effects shown were in the very short term only. Even if one could disregard all the gaps in the scientific evidence and assume that ephedra has the same effect on athletic performance as synthetic ephedrine in combination with caffeine, we do not consider a modest, temporary enhancement of certain aspects of athletic performance to be a benefit sufficient to outweigh the risks of dietary supplements containing ephedrine alkaloids. Therefore, we conclude that the use of dietary supplements containing ephedrine alkaloids to enhance athletic performance for any duration of use present an unreasonable risk.

iii. *Eased breathing and other uses.* We have long recognized the legitimate short-term oral use of sympathomimetics, such as ephedrine, in OTC bronchodilator drug products. These products are marketed for those who have been diagnosed with asthma by a physician. The products are GRASE when formulated and labeled in accordance with the requirements of the final monograph for OTC bronchodilators (21 CFR part 341). Mandatory warnings include advising the consumer not to use the product unless diagnosed as having asthma by a doctor and not to use the product if suffering from heart disease or high blood pressure.

We are aware that there are dietary supplements containing ephedrine alkaloids that are marketed for uses other than weight loss or athletic performance enhancement, such as "eased breathing," "better breathing," "feel better," "feel more alert," "energized." By contrast to the monograph-compliant OTC bronchodilators, and as discussed in section V.B.3 of this document, we have seen no data that support any benefit relating to eased breathing in healthy people from dietary supplements containing ephedrine alkaloids. Moreover, as also discussed in that section, because healthy people are able to breathe without difficulty, we do not believe there is any respiratory benefit in the absence of a disease state, such as asthma or a respiratory infection. At the same time, however, there are data that establish the risks of these products. We note that claims to treat or mitigate the effects of a disease subject a product to regulation as a drug under the act.

With regard to other claims such as "feel better," "feel more alert," and "energized," effects of this nature may be of modest benefit to the individual (if they occur), but they are temporary and do not improve health. Therefore, such effects would not be sufficient to outweigh the risks of dietary supplements containing ephedrine alkaloids.

There are also dietary supplements containing ephedrine alkaloids that do not make any specific claims or otherwise suggest or recommend conditions of use in their labeling. The use of such products presents the same risks and can lead to the same serious adverse events as discussed previously for weight loss and athletic performance, even if the product is

taken under ordinary conditions of use (i.e., not abused).

A dietary supplement labeled for a very temporary, episodic use might not present an unreasonable risk if there were adequate evidence that the use resulted in a health benefit sufficient to outweigh the health risks. Any new indication would still be subject to our post-market risk evaluation as to whether it could be legally marketed. Conclusions regarding the benefit of dietary supplements containing ephedrine alkaloids for nondisease claims cannot be drawn solely from studies using synthetic ephedrine for specific diseases. Although we could require labeling for dietary supplements containing ephedrine alkaloids to limit the duration of use, among other things, currently there are no data that demonstrate that dietary supplements containing ephedrine alkaloids provide a benefit to a particular population when used temporarily or episodically (in contrast to OTC ephedrine and pseudoephedrine products for disease uses).

3. Conclusion

Multiple studies demonstrate that dietary supplements containing ephedrine alkaloids, like other sympathomimetics, raise blood pressure and increase heart rate. These products expose users to several risks, including the consequences of a sustained increase in blood pressure (*e.g.* serious illnesses or injuries that include stroke and heart attack that can result in death) and increased morbidity and mortality from worsened heart failure and pro-arrhythmic effects. Although the pro-arrhythmic effects of these products typically occur only in susceptible individuals, the long-term risks from elevated blood pressure can occur even in nonsusceptible, healthy individuals. These risks are neither outweighed by any known or reasonably likely benefits when dietary supplements containing ephedrine alkaloids are used under conditions suggested or recommended in their labeling, such as for weight loss, athletic performance, increased energy or alertness, or eased breathing. Nor do the benefits outweigh the risks under ordinary conditions of use, in the absence of suggested or recommended conditions of use in product labeling. As discussed above in section V.C of this document, the best scientific evidence of benefit is for modest short-term weight loss; however, such benefit would be insufficient to bring about an improvement in health that would outweigh the concomitant health risks. The other possible benefits discussed in section V.C if this document, have less scientific support. Even assuming that these possible benefits in fact occur, such temporary benefits are also insufficient to outweigh health risks that can lead to serious long-term or permanent consequences like heart attack, stroke, and death. On the other hand, we have determined that there are benefits from the use of OTC and prescription drug products containing ephedrine alkaloids in certain populations for certain disease indications that outweigh their risks.

As with other sympathomimetics, the risks posed by dietary supplements containing ephedrine alkaloids for continuous, long-term use cannot be adequately mitigated without physician supervision. Temporary, episodic use can be justified only if a known or reasonably likely benefit outweighs the known and reasonably likely risks. Similar to OTC single ingredient ephedrine products, dietary supplements containing ephedrine alkaloids could theoretically be marketed without physician supervision for a very temporary, episodic use if there were adequate evidence that the use resulted in a benefit sufficient to outweigh the risks of these products. However, we are currently unaware of any such use, and our experience with ephedrine and pseudoephedrine OTC drug products suggests that such benefits will be demonstrable only for disease uses. Therefore, we conclude that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling or under ordinary conditions of use, if the labeling does not suggest or recommend conditions of use.

VI. Why We Conclude that Other Restrictions Would Not Adequately Protect Consumers from the Risks Presented by Dietary Supplements Containing Ephedrine Alkaloids

We considered several regulatory alternatives to this final rule. As discussed in section I.C of this document, we issued a proposed rule in 1997 that would have placed various restrictions on dietary supplements containing ephedrine alkaloids. Most of the proposed restrictions were withdrawn in 2000; only the proposed prohibition on combining ephedrine alkaloids with other stimulant ingredients and the proposed warning statement (as modified in FDA's March 2003 notice) remain. As discussed in the following paragraphs, we have reached the conclusion that those restrictions are inadequate to protect public health. In addition, we considered other regulatory alternatives presented in the comments received.

A. Warning Statement Alone

We first proposed a warning statement in the June 1997 proposal. At that time, we tentatively concluded that a warning statement was necessary to disclose material facts about the consequences of using these products, and that it would help to reduce the risk of an adverse event after use of dietary supplements containing ephedrine alkaloids (62 FR 30670 at 30703). In our March 2003 notice, we reopened the comment period to seek, among other things, comments on a revised warning statement that we were considering at that time for dietary supplements containing ephedrine alkaloids.

We received a number of comments on the proposed labeling requirements in the June 1997 proposal and on the revised warning statement in our March 2003 notice. Because we have decided to proceed under the adulteration provision in section 402(f)(1)(A) of the act rather than to require labeling for dietary supplements containing ephedrine alkaloids, these comments are moot to the extent that they discuss the substance or format of the warning statement. Nevertheless, comments regarding the sufficiency of a warning are relevant to this rulemaking.

(Comment 64) Many comments supported the use of a warning label as an effective way to protect public health, although they differed on the specific language and format of the warning. Many comments urged us to mandate strict warning labels to inform users about the potential health risks that have been reported to be associated with the use of dietary supplements containing ephedrine alkaloids. One comment stated that product labeling does influence user behavior and strongly urged us to take action in the form of issuing a mandatory warning label for all dietary supplements containing ephedrine alkaloids. Several comments stated that there was a significant decrease in the number of AERs in certain States after their respective departments of health mandated label restrictions and strong cautionary statements. A number of comments stated that the warning labels voluntarily adopted and already used by industry are sufficient to protect the public from any risks. A number of comments proposed different labels to be adopted by the entire industry.

In contrast, many comments maintained that warnings are insufficient and recommended a ban of these products. Several comments pointed out that serious adverse events

continue to occur even though most dietary supplements containing ephedrine alkaloids already carry warning statements, such as those recommended by industry trade groups. For several years, warning labels have also been mandated in several states by law or regulation. Many comments noted that, in at least 90 percent of the adverse event reports submitted to us, consumers reported taking dietary supplements containing ephedrine alkaloids as directed on the label.

A few other comments asserted that warning labels are ineffective because serious adverse events have occurred after the initial use or after very short-term use of dietary supplements containing ephedrine alkaloids. As pointed out in the June 1997 proposal, about 40 percent of the 600 AERs reported between 1993 and 1996 occurred with the first use or within 1 week of first use, providing little or no warning to consumers of risk. Many of the adverse events occurred in individuals who had no apparent risk factors, or who were unaware that they were at risk.

Several comments stated that warning labels on ephedrine alkaloid-containing dietary supplements are not sufficient to protect the public health because many people are not aware they have medical conditions or individual sensitivities that put them at greater risk for experiencing serious adverse effects.

(Response) We agree that warning statements cannot adequately protect consumers from the risks associated with dietary supplements containing ephedrine alkaloids. Even if all consumers read the warnings and the warnings thoroughly describe the risks, many using these products may not be aware they have medical conditions or individual sensitivities that put them at greater risk for experiencing serious adverse effects. A full discussion of the risks to sensitive populations appears previously in the response to comment 22 of this document.

Warning labels may be beneficial when people are able themselves to identify the risk factors they have, or when evaluation by a physician prior to use can identify whether they have the risk factors and further supervision by a physician is not necessary for safe use of the product. The purpose of the physician's evaluation is to identify individuals with underlying conditions (such as heart failure or coronary artery disease) that place them at risk for serious adverse events (such as death) due to pro-arrhythmic effects. Such warnings can reduce but not eliminate the risks from episodic use of dietary supplements containing ephedrine alkaloids because not all susceptible individuals can be identified by a physician's evaluation. For example, people can have asymptomatic coronary artery disease or early heart failure that a physician would not recognize without performing tests that would usually be reserved for patients with signs or symptoms of a disease. We are not aware of a nondisease claim for which the known and reasonably likely benefits of dietary supplements containing ephedrine alkaloids would outweigh their known and reasonably likely risks when used episodically.

A warning to consult your physician before use provides even less risk mitigation for dietary supplements containing ephedrine alkaloids that are used continuously because even healthy people would experience a rise in blood pressure and, therefore, be at increased risk for heart attack, stroke, and death. At a minimum, continued physician supervision would be a necessary risk management tool. Thus, even if consumers were to heed warning labels and consult their physician, the known and reasonably likely risks of dietary supplements containing ephedrine alkaloids when used episodically or continuously would still outweigh their known and reasonably likely benefits.

The conclusion that warning statements are not adequate to protect public health is consistent with the fact that, since 1993, we have received more than 18,000 AERs (including both adverse events reported directly to FDA and the Metabolife call records). The majority of the products associated with these AERs contained directions for use and warning statements. The warning statements varied from general precautions, suggesting that consumers check with a health care professional before beginning any diet or exercise program, to more specific warning statements, including cautions that consumers not use the product if they have certain diseases or health conditions or are using certain drugs, and to stop the use of the product if they develop certain symptoms. Despite these warning statements in the product labeling of dietary supplements containing ephedrine alkaloids, we continue to receive reports of serious adverse events.

(Comment 65) Several comments compared sensitivity to ephedrine alkaloids in dietary supplements to sensitivity to food allergens. One comment expressed the opinion that the number of individuals sensitive to ephedrine alkaloids in dietary supplements is either less than, or comparable with, those individuals who suffer from food allergies. One comment argued that warning statements are effective for people who know they are sensitive to a substance, such as peanuts. The comment suggested that if warning labels are considered sufficient in this context, they should also be considered sufficient in the context of dietary supplements containing ephedrine alkaloids. Another comment stated that, with respect to those individuals who are unaware that they may have one of the conditions that is contraindicated on the label, some misuse due to ignorance is unavoidable and occurs no matter what regulations are put in place.

(Response) We do not agree that individuals sensitive to ephedrine alkaloids in dietary supplements are comparable to individuals who suffer from food allergies. In the case of food allergies, individuals learn that they are allergic to certain foods (*e.g.*, shellfish and nuts) and, because we require that the presence of the food ingredients be declared on the food label (*see* 21 CFR 101.4), these individuals can then avoid the problem ingredient by reading the food label. The physical manifestations of the allergic reaction are usually readily recognized by the consumer. In the case of the ephedrine alkaloids, as discussed previously in the responses to comments 22 and 27 of this document, many individuals are not aware that they are sensitive to sympathomimetic agents, such as the ephedrine alkaloids, and may not recognize early signs of risk, such as elevated blood pressure or the adverse cardiovascular and nervous system effects related to the use of ephedrine alkaloids. In most instances, patients with nascent food allergies experience classic allergy symptoms, such as tingling lips, scratchy throat, wheezing, and shortness of breath, that alert them to the development of a particular food allergy, whereas with ephedrine alkaloids, severe, life-threatening reactions, may occur at any time, even with the first exposure. Therefore, an ingredient declaration or a warning label statement cannot assist these consumers in adequately reducing their risk of adverse events.

B. Multiple Restrictions

(Comment 66) Addressing the inadequacy of a warning statement alone, many comments supported multiple restrictions (*e.g.*, dosage limits, ingredient combination restrictions, duration of use restrictions, label claim restrictions, good manufacturing practices (GMP) requirements, and warning label statements) to reduce the risk of adverse events. One comment pointed out that the frequency, severity, and the broad cross section of the

population for which there are documented adverse events support at least this level of regulation. Some comments contended that we should establish more stringent regulations. Several of these comments recommended that we ban the use of ephedrine alkaloids in dietary supplements because of the serious health hazards associated with their use and the potential for abuse and misuse of these products.

(Response) We do not agree that the restrictions recommended in these comments will eliminate the risks imposed by dietary supplements containing ephedrine alkaloids. As discussed in the response to comment 26 of this document, we are not aware of any evidence that establishes a safe dose of ephedrine alkaloids in dietary supplements. Therefore, dose limitations cannot change the unfavorable risk-benefit ratio of these products. Similarly, a requirement for a label statement recommending that consumers limit the duration of product use will not provide adequate protection because adverse events sometimes occur after the first use or in the first few days. We also do not agree that dietary ingredient restrictions, such as limiting the presence of other stimulant ingredients, will eliminate the unreasonable risk associated with the use of dietary supplements containing ephedrine alkaloids. As explained in section V.B.1 of this document, ephedrine alkaloids given alone can be expected to cause significant increases in blood pressure, although the presence of other stimulants combined with ephedrine alkaloids may increase the risks associated with use of these products. Finally, while GMP requirements may ensure consistent quality across dietary supplement products containing ephedrine alkaloids, the risks attributed to ephedrine alkaloids are due to their inherent pharmacological and physiological effects rather than the quality of their manufacture, although poor manufacturing could lead to additional risks, such as from the introduction of toxic impurities into the product.

C. Self-Regulation

(Comment 67) Other comments objected to the June 1997 proposal, arguing that no FDA action is necessary. Several of these comments recommended that we take no action but instead continue to monitor adverse events. A number of comments stated that the dietary supplement industry will self-regulate. These comments argued that several dietary supplement trade associations have reacted responsibly to the public concerns about the AERs by setting standards for the use of ephedrine alkaloids in dietary supplements for their members (Ref. 101).

(Response) We disagree with the comments that state that no FDA action is necessary because the industry will self-regulate. It is incumbent upon us to respond to the serious adverse events associated with the use of dietary supplements containing ephedrine alkaloids and other information about the risks of these products. We have been aware for several years that a number of trade associations have policies concerning the formulation and labeling of dietary supplements containing ephedrine alkaloids. These voluntary industry standards are insufficient to alter the risk-benefit ratio for these products. Despite the fact that these industry standards are in place, we continue to receive reports of clinically significant adverse events following the consumption of dietary supplements containing ephedrine alkaloids. Some of these adverse events may be due to noncompliance with those voluntary standards; however, for the reasons stated in the response to comment 39 of this document, these types of standards, even if adhered to, would be insufficient to protect consumers from the risks posed by dietary supplements containing ephedrine alkaloids.

D. More Education

(Comment 68) One comment recommended that we provide better education to the public on the public health concerns about dietary supplements containing ephedrine alkaloids.

(Response) We do not agree that educating consumers about the public health concerns related to the use of dietary supplements containing ephedrine alkaloids is an appropriate substitute for this regulation. Although we have been active in, and support, consumer education activities about these supplements, consumer education will not adequately address the risks they present. For example, many individuals who are sensitive to sympathomimetic agents, such as the ephedrine alkaloids, and are therefore at an increased risk of experiencing an adverse event, are not aware that they are at risk. Therefore, consumer education would not be expected to greatly reduce the risk of adverse events.

E. Nonbinding Guidance

(Comment 69) Several other comments recommended the issuance of nonbinding guidance providing notice to marketers as to which dietary supplements containing ephedrine alkaloids would most likely be the subject of FDA enforcement. One comment argued that a guidance document would conform to our good guidance practices (21 CFR 10.115) and provide guidance to the dietary supplement industry as to a level of ephedrine alkaloids that can be used in their products with some confidence that such products will not be subject to regulatory action. In arguing for a guidance document and against a regulation, the comment said that a Federal regulation is only appropriate and necessary to protect the public health when safe use of a product cannot be ensured absent such a regulation; the comment maintained that we have not made this showing. One comment stated that the major dietary supplement industry trade associations could exhort industry compliance to guidelines issued by us or by the trade associations.

(Response) We disagree that nonbinding guidance would be an effective substitute for this rulemaking. As stated previously in this document, several industry trade associations have established policies concerning the formulation and labeling of dietary supplements containing ephedrine alkaloids. These policies are non-binding and manufacturers and distributors are under no obligation to comply. Moreover, as discussed previously in the responses to comments 39 and 67 of this document, guidance on labeling or product formulation, even if adhered to, would be insufficient to protect consumers from the risks posed by dietary supplements containing ephedrine alkaloids.

F. Targeted Enforcement Actions

(Comment 70) Other comments stated that enforcement actions against products containing extremely high levels of ephedrine alkaloids should be sufficient to address the problem.

(Response) We find that individual enforcement actions against products containing high levels of ephedrine alkaloids are inadequate to protect the public health. Data from the scientific literature and AERs indicate that clinically significant adverse effects are not limited to the use of products containing high levels of ephedrine alkaloids (Refs. 109 and 134). Therefore, enforcement actions against products containing only high levels of ephedrine alkaloids would not be expected to eliminate the unreasonable risk presented by these products. We also

note that rulemaking is a more efficient regulatory mechanism than individual enforcement actions in cases where hundreds of different products on the market contain the same ingredient that presents a risk to the public health, as is the case here. Without a regulation, we would be required to establish our case de novo with witnesses in every enforcement proceeding. Multiple proceedings would require multiple witnesses and extensive discovery, and would be extremely time-consuming and burdensome for both the courts and us. However, we point out that a regulation is not necessary to find that a dietary ingredient or a dietary supplement presents an unreasonable risk.

VII. Miscellaneous Issues

A. Freedom of Choice/FDA Bias

(Comment 71) Many comments stated that our attempt to regulate dietary supplements containing ephedrine alkaloids would erode personal freedom and the public's freedom of choice, values that the comments maintained were established through the passage of DSHEA. Several comments stated that DSHEA gives the public a right to access affordable, natural, and effective dietary supplements. A number of comments alleged that we issued the June 1997 proposal because we are biased against dietary supplements. One industry comment accused us of selectively including information in the docket. Several of these comments alleged that our purpose for issuing the June 1997 proposal was to protect the business interests of the pharmaceutical industry. Several comments explained that, if access to dietary supplements for weight loss is restricted, consumers will have little choice but to use prescription drugs. Many comments from consumers stated that use of prescription drugs for weight loss is both more costly and associated with more adverse effects than use of products containing natural herbs. Many of these comments stated that dietary supplements containing ephedrine alkaloids from natural sources are safe and have no side effects. Conversely, several comments stated that the perception that supplements are natural and, therefore, safe and acceptable alternatives to prescribed medications is erroneous and that there are serious concerns about the safety and efficacy of these products.

(Response) We deny these allegations of bias against the marketing and use of dietary supplements and any allegations of protecting or favoring the pharmaceutical industry. We support access to dietary supplements that are safe, properly labeled, and in compliance with Federal law. However, we are also obligated under DSHEA to protect the public against dietary supplements that are unsafe or otherwise adulterated. Contrary to one comment's assertion, we did not base our decision on selectively chosen information; instead, we considered all information that was submitted to the relevant dockets, including more than 48,000 comments and hundreds of studies submitted by the dietary supplement industry, trade associations, academics, health professionals, scientists, public health groups, and consumer groups. Given the scientific information about the pharmacology of ephedrine alkaloids, clinical studies examining their effects, and AERs, we found that there are serious and well-documented public health risks associated with the use of dietary supplements containing ephedrine alkaloids. Therefore, our obligation under DSHEA is to take action to address such risks, particularly in light of the products' lack of health benefits.

Additionally, comments concerning the pharmaceutical industry's business interests and possible consumer use of prescription drugs are not relevant to our determination as to whether dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the act. Section 402(f)(1)(A) of the act focuses exclusively on whether the dietary supplement or dietary ingredient presents a significant or unreasonable risk; consequently, arguments pertaining to other industries or other products have no bearing on whether dietary supplements containing ephedrine alkaloids are adulterated under the act.

B. Conduct of the Advisory Committee Meetings

(Comment 72) Several comments stated that we conducted the October 1995 meeting of the Working Group and the 1996 meeting of the Food Advisory Committee (the Committees) in a manner that improperly influenced their deliberations and recommendations. These comments argued that we instructed the Committee members not to consider certain data (*e.g.*, data concerning the use of ephedrine-containing OTC drug products for the treatment of asthma); misrepresented certain data (*e.g.*, data concerning the AERs and data from clinical trials on the use of ephedrine in the treatment of obesity); failed to present data that industry believed to be relevant to the evaluation (*e.g.*, number of units of products sold during the period of time the AERs were received, data regarding whether a cause and effect relationship existed between dietary supplements containing ephedrine alkaloids and the adverse events reported to us); instructed the Committee to evaluate safety using an interpretation of "significant harm" (i.e., either a large number of adverse events or a serious adverse event in one individual) that is not specified in DSHEA; and improperly asked the Committee to recommend action to reduce the risks associated with the use of these products.

Other comments argued that the procedures we followed at the Committees' meetings were unfair. The comments cited several reasons, including the following: FDA materials were not made available to dietary supplement industry groups and other interested persons prior to the meetings; we were given unlimited time to "influence" the Committee, and the time others were given to present comments was limited; and interested persons were not allowed to question FDA officials. For these reasons, several of these comments stated that we must reconvene the Committee.

(Response) We disagree with the comments. The comments concerning the data and information we presented or did not present during the meetings are without merit because the essence of these comments is that they disagreed with our interpretation of the data or preliminary conclusions. Presenting our interpretation of the data and our preliminary conclusions is entirely appropriate and does not constitute undue influence over the Committees (Ref. 137). Interested persons, including the dietary supplement industry, were provided with ample opportunity to express their views and present data they believed relevant to the evaluation during the public hearing portions of the meetings or in written comments to the Committees. To the extent that specific comments on the data, our interpretation of the data, and our preliminary conclusions are relevant to this rulemaking, they are addressed in other sections of this document.

Regarding the conduct of the Committees' meetings, those meetings were conducted in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2), FDA's implementing regulations (21 CFR part 14), and FDA guidance entitled "Policy and Guidance Handbook for FDA Advisory Committees" (1994) (Ref. 137). We also note that the procedures followed during these meetings were no different from the procedures used in conducting the numerous advisory committee

meetings we have held on a variety of other issues.

We convened the Committees as a means to acquire independent scientific and technical advice on the public health concerns surrounding the use of dietary supplements containing ephedrine alkaloids and on specific ways to address these public health concerns. During the meetings, we implemented several safeguards to ensure the Committees' independence and fairness to all interested parties.

First, it was made entirely clear during the meetings that the Committees' members were invited to express a view different than ours, so that our tentative conclusions could be revised, if necessary. During these meetings, we presented a critical and fair evaluation and interpretation of the available data. We also expressed our tentative conclusions and our concern for the public health. Again, it is entirely appropriate for us to state our views and interpretation of the data. Furthermore, individual members of the Committees took advantage of the many opportunities during the meetings to discuss their views and to question FDA officials about the available data, our interpretation of the data, and our tentative position.

Second, the Committees included consumer and industry representatives, including two representatives from associations representing the dietary supplement industry. The consumer and industry representatives represented the views of consumers and industry throughout the meeting and made recommendations to us. All FDA-prepared materials to be considered by the Committees were sent to all members of the Committees, including the dietary supplement industry representatives, prior to the meeting.

Third, the Committees' meetings provided a forum for public discussion. Interested persons, including the dietary supplement industry, were provided with ample opportunity to express their views and present data they believed relevant to the evaluation during the public hearing portions of the meetings or in written comments to the Committees. During the Committees' meetings, we provided over 2 hours of public hearing time, which is twice the time required by our regulations (21 CFR 14.29(a)).

Thus, contrary to the comments' assertions, we provided ample opportunity for public participation in the meetings. The public hearings were conducted prior to the Committees' deliberations so that comments made by interested parties could be considered by the Committees in making their recommendations.

VIII. Analysis of Impacts

A. Benefit-Cost Analysis

1. Introduction

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulatory action as a significant regulatory action if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also classifies a regulatory action as significant if it raises novel legal or policy issues. We have determined that this final rule is a significant regulatory action as defined by Executive Order 12866 because the benefits of the rule could exceed $100 million per year and because the rule raises novel legal and policy issues.

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, the OMB has determined that this final rule will be a major rule for the purpose of congressional review because the benefits may exceed $100 million annually.

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 $113 million per year. We have estimated that the total cost of this final rule would be no more than $90 million per year. Therefore, we have determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

2. Regulatory Options

We discussed the following seven regulatory options in the benefit-cost analysis of the June 1997 proposal: (1) Take no action; (2) take no new regulatory action, but generate additional information on which to base a future regulatory action; (3) take the actions in the June 1997 proposal; (4) take the proposed action, but with a higher potency limit; (5) remove dietary supplements that contain ephedrine alkaloids from the market; (6) take the proposed action, but do not require a warning statement; and 7) require a warning statement only (62 FR 30678 at 30705). We later withdrew all elements of the proposed action except the warning statement and prohibition of dietary supplements that combine ephedrine alkaloids with other stimulants (65 FR 17474). In 2003, we issued a March 2003 notice seeking comment on, among other things, a revised warning statement consisting of a short warning on the PDP and a more detailed warning elsewhere in the product labeling. We did not perform any economic evaluation of the revised warning statement at that time. We received additional comments on the revised warning statement. In addition, the comments on the June 1997 proposal suggested some additional options. Considering the options from these sources, we address the following options in this analysis: (1) Take no new regulatory action; (2) remove dietary supplements containing ephedrine alkaloids from the market; (3) require the proposed warning statement, as revised in 2003; (4) require a warning statement, but modify it or require it only on certain products; and (5) generate additional information or take some action other than removing dietary supplements containing ephedrine alkaloids from the market or requiring warning statements. Executive Order 12866 requires us to analyze regulatory options but recognizes that there are practical limits to the number of options that we can analyze. The options listed above encompass all or most of the significant suggestions raised in the comments.

3. Summary of Conclusions

We have decided to remove dietary supplements containing ephedrine

alkaloids from the market, identified as option 2 in the previous paragraph. We estimate net effects would be between -$47 million and $125 million per year from this option, if consumer behavior does not already incorporate the health risks posed by these products, and between -$90 million and -$7 million per year, if consumer behavior already incorporates the health risks. A detailed discussion of all the options is provided in the following paragraphs.

4. Option One—Take No New Regulatory Action

We use this option as the baseline for determining the costs and benefits of the other options. Therefore, we do not associate costs or benefits with this option. Instead, we discuss the costs and benefits of taking no action in the context of the costs and benefits of the other options. As we discuss more fully under the other options, the expected number of adverse events from these products will probably decline, over time, even if we take no regulatory action, for two reasons. First, many firms are moving away from the use of ephedrine alkaloids because of media coverage of adverse events associated with these products, the high cost of liability insurance, and the potential for legal actions by consumers. Second, some State and local governments have either banned the sale of these products or placed various requirements or restrictions on sales of these products.

5. Option Two—Remove Dietary Supplements Containing Ephedrine Alkaloids from the Market

a. *Benefits of removing dietary supplements containing ephedrine alkaloids from the market.* The benefits of this final rule stem from the reduction of risks brought about by removing dietary supplements containing ephedrine alkaloids from the market. We measure the risk reduction, for the purpose of estimating benefits, as the number of illnesses and deaths averted. Because OMB's guidance to Executive Order 12866 calls for quantification of risk reduction, we place special emphasis in this part of the document on those AERs that lend themselves more readily to quantification.

As shown earlier in this document, dietary supplements containing ephedrine alkaloids would be expected to increase heart rate/rhythm and blood pressure. Increasing blood pressure in any population is associated with increased probabilities of heart attack, stroke, and death, which are the serious adverse events most commonly associated with ephedrine alkaloids. The known pharmacological effects of ephedrine alkaloids lead us to conclude that removing these dietary supplements from the market will reduce the incidence of these adverse events. Estimating the likely reduction, however, presents challenges. One method used in similar situations is to combine data on exposure with a dose-response function to generate estimates of adverse events prevented as exposure declines. We cannot use that method here, however, because we do not have sufficient data on exposure to ephedrine alkaloids from dietary supplements, and we do not know the associated dose-response function. Therefore, the best available approach, and the method we apply here, is to use AERs to generate estimates of the number of adverse events associated with dietary supplements containing ephedrine alkaloids.

It is important to note that the AERs are not the principal scientific basis for the regulatory action we selected. Instead, the AERs are consistent with the known pharmacological and physiological effects of ephedrine alkaloids, as well as the results of clinical studies and, therefore, support, our finding of unreasonable risk. As we explain in more detail later in this document, we use a high barrier before admitting an AER as evidence of adverse events associated with ephedrine alkaloids. We also use conservative methods to infer the total number of adverse events from the reports.

i. *Use of AERs in estimating benefits and baseline number of AERs.* In the analysis of the June 1997 proposal, we based our estimate of the impact of removing dietary supplements containing ephedrine alkaloids from the market on the estimated annual number of adverse events caused by dietary supplements containing ephedrine alkaloids (62 FR 30678 at 30705). We based the latter estimate on the average annual number of AERs that we received between January 1993 and June 1996, that we suspected of having been caused by these supplements, which we characterized as the "baseline number of AERs." We then adjusted this number of AERs by a series of assumptions designed to reflect various sources of uncertainty over whether these supplements actually caused those AERs and the uncertainty over the relationship between the AERs and the actual number of adverse events associated with the use of dietary supplements containing ephedrine alkaloids (including both reported and unreported adverse events).

(Comment 73) A number of comments on the June 1997 proposal addressed the issue of the baseline number of AERs. Some comments objected to adjusting the number of AERs with assumptions designed to reflect uncertainty over the relevance of those AERs. One comment said we should have used only those AERs that we were certain had been caused by dietary supplements containing ephedrine alkaloids. Other comments simply pointed out that some adverse events might not have been caused by dietary supplements containing ephedrine alkaloids.

Some comments suggested that our estimate of the number of adverse events based on the number of AERs was inconsistent with the results of various studies on the safety of ephedrine alkaloids, herbal ephedra, or particular dietary supplements containing ephedrine alkaloids. One comment noted that the estimated number of adverse events, particularly the estimated number of deaths, was inconsistent with data collected by the Drug Abuse Warning Network program, which is administered by the Office of Applied Studies in the Substance Abuse and Mental Health Services Administration of HHS. Some comments made similar points with respect to the inconsistency of our estimated adverse events with the lower number of adverse events reported for ephedrine alkaloid-containing products marketed in foreign countries.

Several comments suggested that our estimate of the number of adverse events was inconsistent with their personal experience. Many comments included information on the amount of the product sold or estimates of the number of people who consumed the relevant product.

A number of comments discussed adverse events that purportedly would have occurred without consumption of dietary supplements containing ephedrine alkaloids. These comments argued that we probably generated a large number of irrelevant AERs by asking consumers to report ubiquitous symptoms as adverse events that may have been caused by these products.

Some comments criticized the report that RAND prepared for HHS on the safety and effectiveness of dietary supplements containing ephedrine alkaloids because of its attention to AERs (Ref. 21). One comment argued that RAND's approach was inappropriate because GAO had previously criticized our use of the AERs in the analysis of the June 1997 proposal. Other comments supported RAND's attention to AERs. One comment argued that RAND did not

adequately account for preexisting health conditions when classifying events in the AERs as "sentinel" or "possibly sentinel" events. Other comments criticized RAND's review of the clinical studies involving ephedrine alkaloids. One comment argued that the method RAND used to determine which clinical studies to review was biased. Some comments argued that the results of RAND's review of the AERs were inconsistent with the results of RAND's review of the clinical studies because the clinical studies enrolled enough patients to uncover the types of adverse events that appear in the AERs, if ephedrine alkaloids could cause those types of events. Other comments suggested that sources other than the RAND report provide better assessments of the risks associated with dietary supplements containing ephedrine alkaloids.

Other comments addressed one or more of the other articles that we listed in the March 2003 reopening of the comment period. Many comments criticized one or more of those studies on various bases. Other comments supported one or more of those studies. One comment argued that we presented a biased list of studies because we ignored four other articles that were published at about the same time as the articles that we listed. Some comments noted that RAND said that clinical trials that they reviewed had enrolled enough patients to detect serious adverse events at rates of 1 per 1,000 or higher.

Finally, some comments addressed trends that might affect the estimated number of adverse events. Some comments addressed the apparent upward trend in the rate at which we received AERs as of 1997, which we mentioned in the proposed rule. Some comments suggested that the perceived upward trend in AERs at that time may have been caused by changes in publicity or in the methods we used to collect adverse events, rather than by changes in the number of adverse events. One comment noted that many firms had stopped making dietary supplements containing ephedrine alkaloids.

(Response) Although uncertainty remains over the exact number of adverse events that are caused by dietary supplements containing ephedrine alkaloids, we disagree that, when estimating the number of adverse events, we should use only those AERs that we or others have proven to have been caused by dietary supplements containing ephedrine alkaloids. The comments appear to suggest that we should adopt a standard of absolute proof that a dietary supplement caused an individual adverse event. However, establishing absolute proof for individual cases is very difficult for dietary supplements or most other substances other than direct poisons. It is appropriate in the case of dietary supplements containing ephedrine alkaloids to estimate the number of adverse events prevented by this rule based upon scientifically established pharmacological effects of ephedrine alkaloids and the clinical and epidemiological evidence. The RAND report used the term "sentinel events" to describe adverse events that involved ephedrine alkaloids and for which RAND could exclude alternative explanations for the event with "reasonable certainty." If other possible causes could not be excluded, then the report classified the cases as possible sentinel events. This level of certainty is unusually high in the context of identifying a public health risk.

We also disagree that we should use only clinical studies when estimating the number of adverse events. In addition, we disagree with the comments that stated that because clinical studies find baseline rates for stroke and major cardiac events in excess of 1 per 1,000, the existing clinical evidence is sufficient to detect adverse events associated with ephedrine alkaloids. The clinical studies reviewed by RAND were not large enough to distinguish between effects of ephedrine alkaloids and the ordinary variance around the baseline. We, therefore, do not agree that existing clinical studies are sufficiently large to detect additional adverse events associated with ephedra or ephedrine. As discussed in section V.B of this document, the scientific evidence identifies the risks presented by dietary supplements containing ephedrine alkaloids. For example, a 6-month clinical study examining the efficacy and safety of ephedrine alkaloids for the treatment of obesity found a statistically significant association between treatment with ephedrine alkaloids and higher blood pressure compared to placebo (Ref. 49). Higher blood pressure tends to increase the likelihood of cardiovascular disease. Thus, the clinical evidence establishes a potential mechanism leading from the use of dietary supplements containing ephedrine alkaloids to the occurrence of serious adverse effects.

We link the findings from this clinical study and the well-known pharmacological effects of ephedrine alkaloids to adverse events to establish the likelihood that at least some adverse events reported to be associated with the use of dietary supplements containing ephedrine alkaloids were in fact caused by these products. Although not as rigorous as an epidemiological case control study, this evidence is the best available to estimate the benefits of this rule.

We agree that we should reduce the uncertainty associated with the AERs as much as possible and accurately express any remaining uncertainty. Therefore, we have replaced the baseline number of AERs that we used in the analysis of the proposed rule with the number of AERs that RAND identified as sentinel and possibly sentinel events involving herbal ephedra. RAND identified 20 sentinel events over a period of approximately 9 years from 1992 to 2001, which corresponds to an average of about 2 such events per year. RAND also identified 42 possible sentinel events in this time period, which corresponds to an average of about five such events per year.

We have based our revised estimate on the RAND report because it is the most comprehensive review of the information that is currently available on the safety and efficacy of dietary supplements containing ephedrine alkaloids. However, we acknowledge that considerable uncertainty continues to exist with respect to the number of adverse events that have been caused by ephedrine alkaloids. We have attempted to reflect the continuing uncertainty by updating the assumptions we used in the analysis of the June 1997 proposal, as we discuss in the following paragraphs.

We did not attempt to forecast trends in the number of adverse events in the analysis of the June 1997 proposal, and we have not done so in this analysis. Forecasting trends in the number of adverse events would be difficult, and any such forecasts would be associated with large uncertainty ranges. Although we recognize that some firms may have recently discontinued the use of ephedrine alkaloids in some or all of their products, we have insufficient information to revise the results of the RAND report on that basis.

Assumptions used in analysis of the final rule

First assumption

Ninety percent to 100 percent of the sentinel events and 50 percent to 100 percent of the possible sentinel events identified in the RAND report were caused by dietary supplements that we suspect contained ephedrine alkaloids.

(Comment 74) A number of comments addressed the first assumption. One comment suggested that we should have set the lower bound of the first assumption to zero because it was possible that none of the AERs had been

caused by dietary supplements containing ephedrine alkaloids. Some comments provided their own estimates of the number of AERs that had been caused by those supplements.

(Response) We have revised our estimate of the baseline number of AERs using the number of sentinel and possible sentinel cases identified in the RAND report in order to address the concerns that these comments raised about causation and the presence of ephedrine alkaloids with respect to some of the AERs that we used as a basis for our benefit estimates in the analysis of the June 1997 proposed rule. Although RAND stressed that it could not conclude that these events were definitely caused by ephedrine alkaloids and declined to make any probabilistic statements about causality, the definitions that it used for sentinel and possible sentinel events suggest that those AERs have a relatively high probability of having been caused by ephedrine alkaloids. Therefore, we have revised the assumption concerning the proportion of the AERs that were caused by dietary supplements from 80 percent to a range of 90 percent to 100 percent for sentinel events and 50 percent to 100 percent for possible sentinel events.

Second assumption

One hundred percent of the sentinel and possible sentinel events that were caused by dietary supplements that we suspect contained ephedrine alkaloids involved dietary supplements that did, in fact, contain ephedrine alkaloids.

(Comment 75) Other comments addressed the second assumption. One comment reported that an industry review of the 920 AERs in the docket found that more than 123, or 13 percent, involved products for which there was no indication that the product contained ephedrine alkaloids. One comment was from a firm that claimed it had informed us during FAC meetings that nearly 25 percent of the AERs that involved their products involved products that did not, in fact, contain ephedrine alkaloids.

(Response) One of the criteria that RAND used to identify sentinel and possible sentinel events was documentation that the person that suffered the adverse event had consumed a dietary supplement containing ephedra within 24 hours prior to the adverse event. The assumption in the proposed rule that 80 percent of the AERs involved products that contained ephedrine alkaloids applied to the set of AERs used in that analysis. RAND has documented that all of the sentinel and possible sentinel events it reviewed involved products containing ephedrine alkaloids. Documentation of the presence of ephedrine alkaloids varied from case to case, and included blood tests of the person who suffered the adverse event, chemical analysis of capsules, and labeling of the products consumed. RAND did not consider self-reports alone to be sufficient documentation for sentinel and possible sentinel events. Because we use the RAND study as the basis for the analysis of this final rule, the 80 percent assumption is no longer relevant. In the analysis of this final rule, we assume that 100 percent of the AERs involved products that contained ephedrine alkaloids.

Third assumption

AERs represented 10 percent of the actual number of adverse events.

(Comment 76) Some comments argued that our assumption of a 10 percent reporting rate was too low. Some comments argued that people are more likely to overreport than underreport adverse events involving dietary supplements containing ephedrine alkaloids for various reasons, including FDA's public statements and media coverage of this issue. One comment argued that people are more likely to overreport than underreport serious adverse events such as heart attack, stroke, seizure, psychotic events, and death, because people tend to consider any temporal connection equivalent to a causal connection. However, this comment suggested that people probably underreport minor adverse events. Some comments noted that the AERs that we discussed in the June 1997 proposal appeared to arrive in discrete groups as though in response to inciting events, such as FDA press releases. One comment noted that, of the 22 AERs in the docket that involved their products, we received two-thirds of those AERs within 1 week of our April 1996 press release, and we received the other one-third over a much longer period of 30 months. Some comments suggested that the 10 percent assumption might be appropriate for passive reporting systems, but argued that the reporting system that we used to generate the AERs was not passive because both the Texas Department of Health and FDA took various steps to solicit AERs. Two comments discussed estimates of reporting rates for a passive adverse event reporting system in Britain. One comment estimated the reporting rate for serious adverse events at 50 percent. Another comment estimated the same rate at 10 percent. Both comments estimated that the system had a much smaller reporting rate of 2 percent to 4 percent for nonserious adverse events. Some comments noted that we assumed a 50 percent reporting rate in our report on Eosinophilia-Myalgia Syndrome, which was an outbreak level event (Ref. 138). These comments noted that this report referred to adverse events related to a dietary supplement, L-tryptophan, which had also received significant media publicity. These comments argued that it was, therefore, a reasonable model to use for the ephedrine alkaloid situation. Some comments suggested that we revise our reporting rate assumption from 10 percent to a range of 10 percent to 50 percent.

Other comments argued that our assumption of a 10 percent reporting rate was too high. Some comments argued that people are more likely to underreport than overreport adverse events involving dietary supplements containing ephedrine alkaloids for various reasons, such as not wanting to acknowledge using the product. One comment noted that a 2001 report from the Office of the Inspector General of HHS concluded that current surveillance systems for identifying adverse reactions from dietary supplements probably detect less than 1 percent of adverse reactions (Ref. 20). However, another comment claimed that most researchers consider a reporting rate of less than 1 percent to reflect a worst-case scenario. One comment noted that the report that suggested a reporting rate of less than 1 percent did not differentiate between serious and nonserious adverse events. This comment argued that the reporting rate for serious adverse events is probably higher than for nonserious adverse events.

(Response) In order to express the continuing uncertainty over the reporting rate, we have calculated benefits based on reporting rates of 10 percent, 50 percent, and 100 percent of sentinel and possible sentinel events. Although the reporting rate could be lower than 10 percent, the severity of the adverse events under consideration and the level of media coverage suggest that the reporting rate may be 10 percent or higher. The assumed 100 percent reporting rate generates a lower bound number of adverse events. We selected 50 percent as an intermediate number. We used a 10 percent reporting rate in our summary statements to simplify the presentation of the results and because 10 percent reporting appears to be a reasonable point estimate, taking into account the seriousness and media coverage of these adverse events and the estimated reporting rates of 1 percent or lower for adverse events involving drugs (Refs. 32 and 139). The 10 percent reporting rate applies to serious events only, and incorporates the fact that a

report of a serious adverse event had to fulfill the RAND criteria in order to be included as a sentinel or possible sentinel event. We did not consider nonsentinel events in the analysis, as explained in the following paragraphs.

ii. *Valuing reductions in adverse events.*

(Comment 77) Some comments addressed the values that we placed on eliminating various types of adverse events in the analysis of the proposed rule. One comment objected to the value of $5 million that we placed on one fewer fatality per year across the affected population, which is sometimes called the value of a statistical life. This comment described this value as the value of an average life and argued that this figure is unrealistic because the average person does not have $5 million.

(Response) In its guidelines on performing economic analysis of federal regulations under Executive Order 12866, OMB noted that the term "statistical life" can lead to some confusion. It pointed out that this term refers to the sum of risk reductions expected in a population, as expressed in the following example: If the annual risk of death is reduced by one in a million for each of two million people, that represents two "statistical lives" saved per year (two million x one in one million = two). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives saved (Ref. 140). Similarly, the estimated value of a statistical life (VSL) is based on the willingness to pay for relatively small reductions in the risk of premature death for many people summed across a population. The individual risk management decisions on which we base estimates of the VSL must reflect the budget constraints of those individuals making those decisions. However, the resulting VSL need not reflect the budget constraints of the average person. We have revised the VSL in this analysis to a range of $5 million to $6.5 million to reflect the latest estimates of this figure (68 FR 41433 through 41506, July 11, 2003).

In addition, we have revised our method of estimating the values of avoiding the other health endpoints. For nonfatal myocardial infarction (MI), we used the same procedure that we used in our analysis of the proposed rule on trans fatty acids (64 FR 62772, November 17, 1999). That method was based on estimating the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. This method assumes that someone suffering a nonfatal MI will have functional disability or pain and suffering or both in every year after the year following the MI. We estimated the loss per year to be 0.2 quality adjusted life years (QALYs) every year of life following the MI. We did not include any reduction in life expectancy due to the MI. For this rule, we based the years of disability or pain and suffering on the ages of those suffering nonfatal myocardial infarction in the RAND report (Ref. 141). RAND reported summary information on age by type of adverse event using three age categories (13 to 30, 31 to 50, and 51 to 70). We took the midpoints of the three age categories and constructed a weighted average based on the proportion of people suffering that adverse event in those categories. We then compared that age to an average life expectancy in the United States in 2001 of 77.2 years to determine the years of disability or pain and suffering or both (Ref. 142).

We used a similar procedure to estimate new values for strokes. To estimate combined functional disability and pain and suffering we used a 0.2 quality adjusted life year (QALY) loss per year after a stroke (Ref. 143). We used the same QALY losses for "other cardiovascular" events that we used for nonfatal MI. We were unable to find information on chronic QALY losses for acute cases of "other neurological," "seizure," or "psychiatric" adverse events. For medical costs, we used 2001 National Statistics from HCUPnet (Ref. 144). We provide summary information on these values in table 1 of this document.

(Comment 78) Some comments that discussed the background rates of expected but unexplained adverse events argued that many AERs involved people with underlying health conditions and that dietary supplements containing ephedrine alkaloids might have simply precipitated adverse events that would have occurred within a short time anyway.

(Response) As we indicated previously in this document, we have revised our estimate of the number of relevant AERs to reflect the RAND report. The definition that RAND used for sentinel events involved investigating alternative explanations and excluding them with reasonable certainty. However, the definition that RAND used for possible sentinel events included cases where another condition by itself could have caused the adverse event, but for which the known pharmacology of ephedrine made it possible that ephedra or ephedrine may have helped precipitate the event. We have reflected the uncertainty over causality in the first of the three assumptions that we discussed above. We assume that dietary supplements containing ephedrine alkaloids caused 90 percent to 100 percent of sentinel events and 50 percent to 100 percent of possible sentinel events.

iii. *Serious versus minor adverse events.*

(Comment 79) Some comments suggested that some AERs that we used in the analysis of the June 1997 proposal involved events that we should not have classified as adverse events. These comments argued that these events involved expected side effects of ephedrine alkaloids that are both minor and transient.

(Response) We discussed adverse events that we classified as "less serious" in the analysis of the proposed rule (62 FR 30678 at 30708). However, we indicated that the value of eliminating those adverse events contributed very little to total estimated benefits. RAND did not include these types of more minor adverse events in its sentinel and possible sentinel event cases. Although it did find evidence that products that contained both ephedrine alkaloids and caffeine increased the risk of certain minor adverse events, it noted that it was unable to distinguish the effects of the ephedrine alkaloids and the caffeine. Based on these considerations, we have not attempted to address adverse events beyond those that RAND identified as sentinel and possible sentinel events.

iv. *Risks of substitutes and weight regain.*

(Comment 80) Some comments argued that consumers would face similar or greater health risks if they switched from dietary supplements containing ephedrine alkaloids to alternative weight loss solutions, such as prescription weight-loss drugs, other dietary supplements, or weight loss surgery.

Some comments discussed what would happen if consumers stopped using dietary supplements containing ephedrine alkaloids and did not switch to equally effective alternative weight loss methods. Some comments discussed the extent and rising trend of obesity in the United States. Some comments noted that obesity increases the risk for heart attack, stroke, diabetes, and cancer. However, other comments argued that any countervailing health costs that would result if people stopped using dietary supplements containing ephedrine alkaloids to lose weight would be small or nonexistent. Some comments suggested there were no clear health benefits from the amount of weight loss that the RAND report attributed to dietary supplements

containing ephedrine alkaloids. Other comments disagreed and argued that there were clear health benefits from the amount of weight loss that the RAND report attributed to dietary supplements containing ephedrine alkaloids. One comment argued that, although people often regain weight that they lose during a diet program, people who have participated in diet programs nevertheless generally maintain lower weights than those who have not.

(Response) Subtracting the value of countervailing health effects posed by substitute products and activities from the value of the health benefits from removing dietary supplements containing ephedrine alkaloids from the market to obtain the net health benefits is consistent with our approach for estimating benefits. (For purposes of this economic impact analysis, "health benefits" refers to an improvement to health and is not synonymous to the "benefits" that we mention in our risk-benefit analysis for purposes of determining that these products present an unreasonable risk of illness or injury; "health benefits" are a type of "benefit" we consider when making an unreasonable risk determination.) Our full conceptual model of benefits is as follows: (net change in risk from the reduction in intake of ephedrine alkaloids x value per unit change in risk) + (net change in risk from substitute products and activity x value per unit change in risk) + (net change in risk from weight gain x value per unit change in risk) + (any net change in risk from the small impact on wealth from the cost of substitute products or activity x value per unit change in risk).

However, we do not have sufficient information to estimate all elements of this model. In the analysis of the June 1997 proposal , we noted one article that found that a product a firm had reformulated to remove ephedrine alkaloids had lost approximately 33 percent of its previous sales (Ref. 145). Since that time, a media report discussed another reformulated product that had greater sales than the original product (Ref. 146). Therefore, we estimate that from two-thirds to all of the consumers of these supplements would probably switch to other dietary supplements that firms market for the same purposes as dietary supplements containing ephedrine alkaloids. This implies that between one-third and none of the consumers of these products would switch to entirely different types of weight loss or performance enhancing substitutes.

Some manufacturers have already reformulated dietary supplements so that products that had contained ephedrine alkaloids now contain alternative ingredients. Some of these reformulated products contain *Citrus aurantium* L., which is a source of synephrine, and caffeine, sometimes in the form of green tea extract. *Synephrine* is a sympathomimetic agent, and these agents are a class of compounds that also includes ephedrine alkaloids. A number of other potential herbal sources of sympathomimetics probably exist. These ingredients may pose risks that are similar to those of ephedra. If consumers switched to substitute products containing these ingredients, similar health risks might be expected as those with products containing ephedrine alkaloids. Some other ingredients that have been reported in reformulated products include cocoa beans, yerba mate, cinnamon twig, and galangal.

The estimated none to one-third of the consumers of dietary supplements containing ephedrine alkaloids who would switch to products other than other dietary supplements might switch to alternatives that carry either health risks or benefits. Some of those who consumed these supplements for weight loss may seek medical care to obtain prescription weight loss medications or for weight loss surgery. However, only some of these consumers would qualify for these medical treatments. These treatments would carry health risks that might be equal to, or greater than, the risks of ephedrine alkaloids. Only the risks that remain after accounting for the management of risk under physician supervision would be relevant in this context. In addition, these treatments may be more expensive than dietary supplements. The resulting relatively small reductions in the overall wealth of those who switch to more expensive alternatives could also generate small countervailing health risks because they have less disposable income to spend on other risk-reducing activities.

Other consumers interested in weight loss may switch to meal replacements or other diet products rather than seek medical treatment. Other consumers might choose to do nothing and simply forego the weight loss they may have obtained with ephedra products. This foregone weight loss could, in theory, generate health costs. The lack of health benefits from the weight loss associated with the use of these products, however, implies that these health costs, if any, would be negligible. Finally, some consumers might choose to reduce their caloric intake or increase their caloric output through additional exercise. These consumers would obtain additional health benefits beyond eliminating the risk of adverse events associated with dietary supplements containing ephedrine alkaloids. Those who consume supplements containing ephedrine alkaloids to enhance their athletic performance and who do not switch to other dietary supplements marketed for that purpose might switch to other stimulants, including black market products containing ephedrine alkaloids or methamphetamines. These products would pose health risks equal to or greater than those of currently marketed dietary supplements containing ephedrine alkaloids.

We have insufficient information to quantify the effects of switching to alternative weight loss or athletic performance enhancing products or activities, or to quantify the health costs associated with the absence of weight loss that might be achieved using dietary supplements containing ephedrine alkaloids.

v. *Risks of certain dietary supplements containing ephedrine alkaloids.*

(Comment 81) A number of comments suggested that certain dietary supplements containing ephedrine alkaloids do not pose any health risks. These comments addressed this point in the context of exempting certain products from the proposed warning statement. However, these comments are also relevant to the issue of exempting certain products from a regulation removing dietary supplements containing ephedrine alkaloids from the market. Therefore, we discuss these comments under this option.

Several comments argued that we should not treat ephedrine alkaloids in Chinese herbal formulas that are used in Chinese medicine treatment protocols the same as dietary supplement products containing ephedrine alkaloids that consumers use to lose weight or enhance athletic performance. One comment suggested that warning statements are unnecessary for herbal products that firms distribute to "healthcare professionals," including members of the American Herbalists Guild. Some comments suggested that we should set different regulatory requirements for different products or product types because risks vary by product or product type.

(Response) The RAND report found little scientific agreement on the dose-response relationship for ephedrine alkaloids (Refs. 21 and 22). Therefore, we are unable to estimate the impact of exempting products from this rule based on the level of ephedrine alkaloids that they contain. As we discussed earlier in the preamble, we have determined that botanical sources of ephedrine alkaloids

in traditional Asian herbal therapies are not covered by this rule. We do not have sufficient information to estimate the impact of exempting products based on the other considerations suggested in the comments, including type of product, label warnings, or directions for use.

b. *Revised benefit estimates.* Based on the preceding discussion, we have revised our estimate of the benefits of removing dietary supplements containing ephedrine alkaloids from the market. The social benefits of removing dietary supplements containing ephedrine alkaloids from the market consist of the increase in consumer utility that would be generated by any net health benefits resulting from removing dietary supplements containing ephedrine alkaloids from the market. The following table 1 of this document provides an estimate of the number of the various types of serious adverse events that we might eliminate by removing dietary supplements containing ephedrine alkaloids from the market, along with an estimate of the utility loss prevented by that reduction. As we discussed previously, benefits could be much lower and potentially zero if the health risks posed by substitute weight loss or sports performance products, such as other dietary supplements containing sources of sympathomimetics, were comparable to the health risks posed by ephedrine alkaloids.

We convert the number of deaths prevented into a monetary estimate by multiplying by the number of deaths by the VSL. We convert the number of nonfatal events prevented into a monetary estimate by multiplying the number of nonfatal events by the value of the appropriate change in quality QALYs. Acute events that do not have clear chronic effects will generate only minimal losses in terms of QALYs. We calculated the total benefits for each class of adverse events as: (Number of deaths prevented) x ($ per fatal case); and (number of nonfatal cases prevented) x (($ per QALY x QALY loss) + medical costs per case)). The benefits for the first year would be slightly different from the benefits in every subsequent year because the effective date is 60 days after the publication date of the final rule. By convention, we calculate benefits starting from the publication date of the final rule. Therefore, the benefits in the first year will be 5/6 (or 83 percent) of the benefits of every subsequent year. To simplify the discussion, we use the benefits for every year after the first year in all summary discussions.

TABLE 1.—ANNUAL NUMBER OF SENTINEL AND POSSIBLE SENTINEL EVENTS PREVENTED UNDER OPTION TWO (REMOVING DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET), WITH QALY AND MEDICAL COST PER CASE

Type	Annual Number Prevented	QALY Loss Per Case	Medical Costs per Case
Death	0.7 to 1.2	NA (used VSL)	$25,742
MI (heart attack)	0.6 to 1.0	0.29	$30,586
CVA (stroke)	1.5 to 2.1	0.2	$20,898
Other Cardiovascular (*e.g.* Cardiomyopathy, Ventricular Tachycardia)	0.1 to 0.2	0.29	$30,586
Other Neurological (*e.g.* Transient Ischemic Attack)	0.1	minimal	$13,212
Seizure	0.5 to 0.9	minimal	$11,812
Psychiatric	0.9 to 1.3	minimal	$6,927

Note. All dollar values in this document represent 2003 prices.

TABLE 2.—ANNUAL BENEFITS OF OPTION TWO (REMOVING DIETARY SUPPLEMENT CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET) BASED ON ALTERNATIVE ASSUMPTIONS OF REPORTING RATES AND VALUES OF PREVENTING ADVERSE EVENTS, ROUNDED TO $ MILLIONS

Value of Avoiding Fatal Cases and QALY Losses	Adverse Event Reporting Rate ($ in millions)		
	10 percent	50 percent	100 percent
$ per fatal case = $5 million $ per QALY = $100,000	$43 to $73	$9 to $15	$4 to $7
$ per fatal case = $6.5 million $ per QALY = $100,000	$53 to $91	$11 to $18	$5 to $9
$ per fatal case = $5 million $ per QALY = $300,000	$56 to $93	$11 to $19	$6 to $9

TABLE 2.—ANNUAL BENEFITS OF OPTION TWO (REMOVING DIETARY SUPPLEMENT CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET) BASED ON ALTERNATIVE ASSUMPTIONS OF REPORTING RATES AND VALUES OF PREVENTING ADVERSE EVENTS, ROUNDED TO $ MILLIONS—Continued

Value of Avoiding Fatal Cases and QALY Losses	Adverse Event Reporting Rate ($ in millions)		
	10 percent	50 percent	100 percent
$ per fatal case = $6.5 million $ per QALY = $300,000	$66 to $112	$13 to $22	$7 to $11
$ per fatal case = $6.5 million $ per QALY = $500,000	$80 to $132	$16 to $26	$8 to $13

c. *Costs of removing dietary supplements containing ephedrine alkaloids from the market.* In the analysis of the proposed rule, we identified the costs that would be generated by removing dietary supplements containing ephedrine alkaloids from the market as the one-time cost of reformulating and relabeling products that currently contain ephedrine alkaloids, plus the utility loss for those consumers who would need to switch from their preferred option (consuming these products) to their next most preferred option (consuming an alternative product or taking some other type of action) (62 FR 30678 at 30709). In that analysis we did not estimate utility losses for consumers. A number of comments stressed this cost but did not provide estimates of it. Nevertheless, we have revised the analysis by attempting to quantify this cost.

Theoretically, we could measure the utility loss for consumers by looking at the difference between their willingness to pay for products containing ephedrine alkaloids and their willingness to pay for alternative supplements or other substitute products or activities. However, we do not have sufficient information to implement this approach, and may never have a direct measure of the utility loss in this market. Instead, we attempt to measure indirectly the utility loss for consumers of these products. We assume that the premium that these consumers are willing to pay to consume dietary supplements containing ephedrine alkaloids rather than whatever they perceive to be the next closest alternative is between 1

percent and 10 percent of the sales price of the dietary supplements containing ephedrine alkaloids. This range is based on the fact that some premium must exist if consumers prefer these products to alternatives. We selected 1 percent as a lower bound because we did not find any large price differences between products containing ephedrine alkaloids and those that did not contain ephedrine alkaloids. Of course, it is possible that current consumers place a much higher premium on products containing ephedrine alkaloids than consumers who have already switched to alternatives. To allow for that possibility, we selected 10 percent (a substantial premium) as the upper bound of the range. Current market prices do not provide sufficient information for a more precise estimate. This estimate of the utility loss assumes that consumers do not incorporate the expected utility losses from potential adverse events in their willingness to pay for dietary supplements containing ephedrine alkaloids. If consumers already incorporate this information in their purchasing decisions, then it would be inappropriate to compare the value of the health benefits to the estimated utility losses for consumers using willingness to pay because the willingness to pay would already account for any adverse health effects. In that case, the estimated utility loss from the removal of these products from the market would represent the full net loss of utility.

A recent article estimated that the sales of "herbal products" containing ephedra accounted for between 4.3 percent and 13.5 percent of the sales for all herbal products (Ref. 135). The article did not define "herbal products," but it noted that their use of the phrase "herbal products" included products that a natural products information company had classified as "vitamins/supplements" and "grocery" items rather than as "herbal products" (Ref. 147). Therefore, these estimates may have included products other than dietary supplements. Another source argued that the estimates presented in the article that we discussed previously in this paragraph did not include all relevant products. The source claimed that more comprehensive data from the Nutrition Business Journal showed that the sales of products containing herbal ephedra accounted for 33 percent of the total sales of all herbal products and 7.5 percent of the total sales of dietary supplements (Ref. 148). Both of these articles apparently dealt only with products that contained herbal ephedra. Ephedrine alkaloids are also contained in a number of different plants, including *Sida cordifolia* L., and *Pinellia ternata* (Thunb.) Makino. Therefore, these articles may have underestimated the number of products that contained ephedrine alkaloids. These articles did not present actual sales figures for herbal products, dietary supplements, or products containing ephedra. However, the Nutritional Business Journal estimated that the sales of all dietary supplements and all herbal dietary supplements in 2002 were $18 billion and $4.3 billion, respectively (Ref. 149). If one assumes that "herbal dietary supplements" corresponds to "herbal products," then total sales of dietary supplements containing ephedrine alkaloids would be $185 million to $1,419 million.

In an effort to reduce this range, we estimated the sales of these products based on a recent survey that showed that 2 million consumers used these products at some point during a given week (Ref. 150). We assumed that consumers who used these products at some point during a given week probably used the products every day during that week, because most of the labels we have examined say that the product should be taken daily, or several times per day. We also assumed that the particular week under study was comparable to any other week. Therefore, we assumed that 2 million consumers use these supplements per day. We then multiplied this number of consumers by the average daily cost of these supplements, which we estimated from a sample of 30 dietary supplements containing ephedrine-alkaloids that we found on the Internet. Based on the recommended intake levels appearing on the labels of these products, the corresponding estimated total sales per year is $559 million to $806 million. The costs in the first year after publication of the rule would be slightly different from the cost in every subsequent year because the effective date is 60 days after the publication date of the final rule. Therefore, the utility losses in the first year will be 5/6 (or 83 percent) of the losses of every subsequent year. To simplify the discussion, we use the benefits for every year after the first year in all summary discussions.

Earlier, we assumed that the consumer utility loss from switching from an ephedra-based product to the next closest substitute would be from 1 percent to 10 percent of the sales price at the current level of consumption. Under this assumption and our estimate of total sales, the consumer utility loss associated with removing dietary supplements containing ephedrine alkaloids from the market would be $6 million to $81 million per year. The loss of consumer utility would probably decline over time as consumers find more substitute products and as producers develop new, more acceptable substitute products. Eventually, consumer substitutions and product development could drive this cost to zero. We have insufficient information to estimate the rate at which this cost would decline over time.

In the analysis of the June 1997 proposal, we estimated relabeling costs of $3 million to $60 million and product reformulation costs of $0 million to $25 million, for a total cost for these two activities of $3 million to $85 million (62 FR 30678 at 30709). We did not receive any comments on these estimates. We have, however, revised the analysis to incorporate a new model for estimating reformulation costs that we developed after publication of the proposed rule (Ref. 151). According to that model, reformulation costs with a 12-month reformulation period would be $7 million to $78 million. In deriving that figure, we assume that reformulating dietary supplements would not be as complicated as reformulating most other types of food and cosmetics. In particular, we assume that reformulating dietary supplements would include the following cost generating activities: Idea generation, product research, analytic testing, packaging development, plant trials, startup, and lost inventory. We assume that reformulating dietary supplements would not include the following types of cost generating activities: Process development, coordinating activities, consumer tests, shelf life studies, any type of safety studies, and market tests. If all of these other steps were involved, then estimated reformulation costs for a 12-month reformulation period would be $22 million to $142 million. We assume that 6 months is the most likely time period for reformulation if dietary supplements containing ephedrine alkaloids are removed from the market. Although the effective date of this rule is 60 days after the publication date, we do not expect that many firms will try to condense the reformulation process into a 60-day period. Some firms may have already done some of the preliminary work for reformulation. Other firms might need to withdraw their product from the market in the period between the effective date and the date at which they complete their reformulation. FDA's reformulation cost model does not address costs for a reformulation time of 6 months, so we

extrapolated the costs based on the proportionate change in cost that would result from halving the reformulation time from 24 months to 12 months. Under that extrapolation, we estimate that reformulation costs for a 6-month reformulation period would be $10 million to $100 million. We annualize these estimated costs over 20 years at an interest rate of 3 percent to convert these one-time costs to a yearly cost of $1 million to $7 million. Annualizing these costs over 20 years at an interest rate of 7 percent gives an annual cost of $1 million to $9 million.

We summarize the annual costs of this option in table 3 of this document. We compare the benefits and costs of this option in table 4 of this document. To obtain the higher bound estimate of net benefits, we start with the higher bound estimate of benefits and subtract the lower bound estimates of costs. To obtain the lower bound estimate of net benefits, we start with the lower bound estimate of costs and subtract the higher bound estimate of costs. If consumer behavior already incorporates health risks, then utility costs would already be net of health benefits. In that case, the net impact of this rule is simply the total costs.

TABLE 3.—ANNUAL COSTS OF OPTION TWO (REMOVING DIETARY SUPPLEMENT CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET) ROUNDED TO $ MILLIONS

Type of Cost	Cost (rounded to $ millions)
Utility Losses for Consumers	$6 to $81
Product Reformulation	$1 to $9

TABLE 4.—ANNUAL SOCIAL BENEFITS AND COSTS OF OPTION TWO (REMOVING DIETARY SUPPLEMENT CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET) ROUNDED TO $ MILLIONS

Type of Benefit or Cost	Benefit or Cost (rounded to $ millions)
Health Benefits (for 10 percent reporting rate)	$43 to $132
Cost of Utility Losses for Consumers	$6 to $81
Cost of Product Reformulation	$1 to $9
Net Effect (if consumer behavior does not already incorporate health risks)	-$47 to $125

TABLE 4.—ANNUAL SOCIAL BENEFITS AND COSTS OF OPTION TWO (REMOVING DIETARY SUPPLEMENT CONTAINING EPHEDRINE ALKALOIDS FROM THE MARKET) ROUNDED TO $ MILLIONS—Continued

Type of Benefit or Cost	Benefit or Cost (rounded to $ millions)
Net Effect (if consumer behavior already incorporates health risks)	-$90 to -$7

d. *Distributional issues and impact on industry.* In the analysis of the June 1997 proposal, we estimated that removing dietary supplements containing ephedrine alkaloids from the market would reduce the sales of dietary supplements containing ephedrine alkaloids by between $200 million and $230 million per year (62 FR 30678 at 30710). We discussed reduced sales because, in that analysis, we characterized a reformulated product as the same product as before reformulation for purposes of describing the impact of the proposed action (although the reformulated products would obviously not be the same as the products they replaced). We did not receive comments that would require us to change those estimates. However, we have revised the analysis to reflect the fact that the effect on accounting profit is a more appropriate way to conceptualize the potential distributional impact than reduced sales. We can use the same information that we used to estimate consumer utility losses to consider the likely effect on the profits of firms that currently produce dietary supplements containing ephedrine alkaloids. In 2001, the average accounting profit for all Fortune 500 companies was about 5 percent of revenue, and some pharmaceutical firms had profit rates as high as 19 percent of revenue (Ref. 150). Profit rates for firms in the dietary supplement industry are probably toward the low end of this scale because of the low barriers to entry for this industry. Therefore, we assume that the profit rate for dietary supplement manufacturers is about 5 percent of total sales. As we discussed previously, press accounts suggest that manufacturers that have reformulated their dietary supplements to eliminate ephedrine alkaloids have experienced declines in sales ranging from about one-third to no decline in sales. We previously estimated total sales to be $559 million to $806 million. Therefore, we estimate that sales may decrease by $0 to $269 million per year. Assuming that the profit rate is 5 percent of sales, removing dietary supplements containing ephedrine alkaloids from the market would generate accounting profit losses of $0 to $13 million per year. We classify this impact as a transfer and not a social cost because removing dietary supplements containing ephedrine alkaloids from the market would increase the profits of firms that produce and distribute substitute products. If these other firms also have an average profit rate of 5 percent of sales, then the profit gained by these companies would also equal $0 to $13 million per year.

In addition to causing a potential reduction in profits for firms currently producing dietary supplements containing ephedrine alkaloids, removing dietary supplements containing ephedrine alkaloids from the market might also generate some countervailing transfers through the elimination of insurance costs and lawsuits associated with products containing ephedrine alkaloids. Eliminating legal fees and court costs would also generate social benefits. Of course, if reformulated products were eventually found to pose health risks comparable to those found for ephedra-based products, then these effects (i.e., the elimination of insurance and legal costs) would eventually decrease to zero. A recent press report found that ephedra manufacturers or distributors have settled 33 cases since 1994 and that an additional 42 cases were pending (Ref. 152). This represents 75 cases over 9 years, or about 8 cases per year. Recent awards for cases that have gone to court have ranged from $2.5 million to $13 million (Refs. 152 and 153). The figures reported in the media for cases that were settled out of court were considerably lower. One such case was settled out of court for $25,000 (Ref. 152). If removing dietary supplements containing ephedrine alkaloids from the market eliminated 8 cases per year, then it would decrease transfer payments from firms to consumers by between $0.2 million per year, if all cases were settled out of court, and $104 million per year, if all cases were lost in court at the high end of the range of legal penalties.

One company noted in 2002 that its product-liability insurance increased by $2.1 million from 2001 to 2002 (Ref. 146). If all 30 manufacturers saw this increase in insurance premiums, then the total increase in insurance premiums would be $60 million. Some of the independent distributors might also face higher insurance rates, but we have insufficient information to estimate those costs. Insurance rates

would not necessarily increase at this same rate in the future, and they could decrease. Therefore, we will assume that this adjustment in insurance rates reflects a one-time adjustment in the perceived liability risks associated with these products. If these higher premiums were unnecessary for reformulated products, then removing dietary supplements containing ephedrine alkaloids from the market would generate a one-time reduction in private costs of $60 million. However, if reformulated products were eventually shown to pose risks comparable to those for ephedra-based products, then insurance rates might increase to a comparable level for these products.

The uncertainty ranges associated with the potential transfers of accounting profits make it impossible to estimate the impact of removing dietary supplements containing ephedrine alkaloids from the market on the firms that currently produce and distribute dietary supplements containing ephedrine alkaloids. Firms that are unable or unwilling to produce or sell substitute products would suffer losses, and firms that are able and willing to produce or sell substitutes might not suffer decreases in profits. Indeed, media reports suggest that many firms have already voluntarily withdrawn their ephedra-based products and replaced them with reformulated products to avoid the high legal and insurance costs associated with dietary supplements containing ephedrine alkaloids (Ref. 146).

6. Option Three—Require the 2003 Proposed Warning Statement

a. *Benefits of requiring the 2003 proposed warning statement comparison to removing dietary supplements.*

i. *Containing ephedrine alkaloids from the market.* In the analysis of the June 1997 proposal, we noted that estimating the benefit of limiting our regulatory action to requiring the 1997 proposed warning statement involved a potentially controversial value judgment about how one evaluates risks that consumers voluntarily accept in the presence of adequate warning statements (62 FR 30678 at 30711). Our analysis of a mandatory warning statement is further complicated by the fact that the labels of most dietary supplements containing ephedrine alkaloids already bear warning statements.

(Comment 82) One perspective that we discussed in the analysis of the June 1997 proposal was that adverse events that occur despite the presence of adequate warning statements are not social costs but are instead private costs that reflect informed decisions about the private benefits and costs of using these products. A number of comments agreed with this perspective. One comment argued that consumers have a responsibility to read and follow warnings and instructions for use on products that they consume. Some comments suggested that we should expect consumers to read and follow warning statements, and we should not hold manufacturers liable if consumers fail to do so. One comment argued that we have adopted that viewpoint in other cases involving products that can produce severe adverse effects. Some comments from consumers argued that we should take no regulatory action other than requiring a warning statement because that approach would allow consumers to decide whether or not to assume the risks associated with these products. One comment pointed out that a recent report on the safety of ephedrine alkaloids that was sponsored by industry endorsed this perspective, as expressed in the following quote: "As the law appropriately suggests, the FDA cannot assume responsibility for protecting the public from themselves, if they choose to use this or any other product at higher than recommended levels or otherwise misuse properly labeled products."

The other perspective on warning statements that we discussed in the analysis of the June 1997 proposal was that adverse events that occur despite the presence of adequate warning statements represent social costs. Under this perspective, requiring a warning statement would not be a sufficient regulatory action unless it actually caused consumers to change their behavior so as to eliminate any adverse events associated with these products. Some comments supported this perspective by arguing that warning statements are inappropriate or inadequate because they probably would not significantly reduce the number of adverse events among all or some subset of consumers.

(Response) In the analysis of removing dietary supplements containing ephedrine alkaloids from the market, we concluded that removing dietary supplements containing ephedrine alkaloids from the market would generate net social benefits if consumers fail to incorporate the probability of adverse events into their demand for those products. Our assessment of the effects of a warning statement hinges on the same uncertainty. If consumers do not fully incorporate the risk of adverse events into their demand for products containing ephedrine alkaloids, and if the proposed warning label would cause at least some consumers to change their demand so as to incorporate the risk, then the warning label could reduce adverse events and generate net social benefits. The likelihood of that outcome depends on the effectiveness of current warning statements and of warning statements in general. One consideration that suggests that consumers fail to incorporate, at least in part, the probability of adverse events into their market behavior is that some consumers do not know they have the underlying conditions discussed in warning statements.

ii. *Comparison to existing warning statements.* In economic terms, the benefit of changing a warning statement is the value that consumers place on the change in the information available on product labels. If we had information on how consumers value different warning statements, then we would not need to consider the impact of changing the warning statements on adverse events. Without that information, we must infer the value from the adverse health effects that changing the warning statement would eliminate. This value represents the minimum value of changing the warning statements: Consumers who change their behavior in response to the change in warning statements would presumably be willing to pay the amount that they saved in health costs and lost utility because of that change in warning statements, but some consumers might value the information even though they do not change their behavior. Because the information value for consumers who do not change their behavior is likely to be small, the value of the eliminated adverse events is probably a close approximation to the value of changing the warning statements. Therefore, we have based our analysis on estimating the impact on adverse events of changing the warning statements from the existing voluntary industry warning statements to the proposed mandatory warning statement.

iii. *Effectiveness of warning statements in eliminating adverse events.* In the analysis of the June 1997 proposal, we estimated that the warning statement that we proposed in 1997 would reduce the estimated number of annual adverse events caused by dietary supplements containing ephedrine alkaloids by 0 to 15 percent (62 FR 30678 at 30712).

(Comment 83) A number of comments addressed this estimate. One comment suggested that the estimated impact was too low and noted that a recent study showed that almost 70 percent of adults read product labels every time they use

a product. However, another comment argued that warning statements would probably be ineffective because most consumers do not read product labels. This comment noted that there is no evidence that warning labels on alcohol and tobacco products reduced consumption of those products. Other comments simply pointed out that warning statements might not eliminate all adverse events, because some consumers might not read or follow them. One comment provided a number of reasons why warning statements might be ineffective at reducing adverse events (*e.g.* many consumers do not read labels for OTC drugs and would be even less likely to do so for dietary supplements, many consumers base their usage patterns on suggestions read in magazines rather than on label information, many consumers believe consuming more of a dietary supplement makes it more effective). Another comment noted that we appeared to infer the ostensible benefit of warning statements rather than demonstrating their effectiveness through carefully conducted clinical trials. This comment also argued that warning statements would not be useful for consumers with unrecognized medical conditions that might predispose them to adverse reactions caused by ephedrine alkaloids, such as hypertension, hyperthyroidism, vascular malformations of the brain, and subclinical cardiac arrhythmias. One comment suggested that the proposed warning statement was too long to be effective. This comment claimed that the necessary print size and spacing would discourage some consumers from reading the warning statement.

(Response) These comments did not provide sufficient information to allow us to change our estimate of the effectiveness of the warning statement that we originally proposed in 1997 and revised in 2003. The comments that noted that warning statements might not eliminate all adverse events are consistent with the assumption that warning statements would eliminate 0 to 15 percent of the adverse events. The comment that noted a study that showed 70 percent of consumers read product labels every time they purchase a product did not provide a reference for that study, but the reported results are consistent with other studies. The FDA 2002 Health and Diet Survey found that 80 percent of nonvitamin/mineral supplement users reported that they used product labels to find out if there were side effects or drug interactions associated with a product or if anyone should avoid the product. A survey of consumer use of dietary supplements by Prevention Magazine found that the following percentages of herbal remedy shoppers reported looking for the following types of information: 72 percent for possible side effects; 70 percent for warnings for people not to take the supplement, *e.g.* pregnant women; 65 percent for warnings about possible interactions with prescription medicines; and 59 percent for warnings about possible interactions with OTC products (Ref. 154). However, consumers who read warning statements will not necessarily change their behavior. A 2002 recent survey of consumers who have recently taken OTC pain medications found that 84 percent read at least some of the label the first time they took a product but that 44 percent said they took more than the recommended dosage, despite the warnings on the label (Ref. 155). In general, most of the literature on warning statements has not focused on product purchase or use pattern decisions but on issues such as comprehension, awareness, and believability (Ref. 156). Some articles have found that alcohol warning statements have had little or no impact on behavior (Ref. 157). However, these results do not necessarily hold for the proposed warning statement because the effectiveness of warning statements varies with a number of considerations, including the content and format of the warning and the characteristics of the consumers reading the warning. Thus, this literature does not provide a basis for revising our assumption that the proposed warning statement will reduce adverse events by 0 to 15 percent. However, the fact that most dietary supplements already bear extensive warning statements suggests that 15 percent is probably an upper bound and that a value closer to 0 percent is probably more likely.

(Comment 84) Some comments argued that the proposed warning statement would probably have little effect on the number of adverse events because many dietary supplements that contain ephedrine alkaloids already bear warning statements. One comment argued that some existing warning statements fully and accurately describe the potential for adverse effects and thereby satisfy the objectives of the proposed warning statement. One comment argued that some existing warning statements are more complete than the proposed warning statement. However, one comment said that the proposed warning statement would probably be more effective than existing warning statements because existing warnings do not alert consumers to avoid taking multiple products containing ephedrine alkaloids at the same time.

(Response) To address these comments, we reviewed and compared the labels of forty dietary supplements containing ephedrine alkaloids that we collected between March 20 and May 30, 2001, and also compared the number of adverse reports received during the period January 2000 to January 2004 as warning labels appeared on certain dietary supplements. (Ref. 158) All of the product labels bore some sort of warning statement. Most warning statements had many of the same basic elements as the proposed warning statement. For example, most existing warnings listed various conditions under which consumers should not take the product, various conditions under which consumers should see a health care provider before taking the product, and side effects or symptoms that should lead consumers to consult with a health care provider. However, the specific content of the various elements varied quite a bit both among existing warning statements and between existing warning statements and the proposed warning statement. Some elements of the proposed warning statement were common in existing warning statements; other elements were less common. For example, none of the existing product labels carried a PDP warning statement. In contrast, most product labels carried some sort of warning for people who had previously experienced heart problems. In addition, parts of some existing warnings were more strongly worded than the corresponding parts of the proposed warning. In other cases, parts of the proposed warning were more strongly worded than the corresponding parts of existing labels. Our label comparison did not support the notion that the proposed warning statement would have no effect because it was identical to existing warning statements. The comparison did suggest that the proposed warning statement is similar in many respects to existing warning statements, and that the proposed warning statement might not reduce adverse events very much. This result is consistent with the assumption that the proposed warning statement might eliminate between 0 and 15 percent of adverse events.

(Comment 85) Some comments argued that the proposed warning statement would be ineffective because some States already require warning statements, and the presence of multiple warning statements would confuse consumers.

(Response) Multiple warning statements might reduce the impact of the proposed warning statement. However, many different warning statements might be more effective than one or a few. The comments did not provide sufficient information to enable us to revise our estimate of the effectiveness of the proposed warning statement based on the possibility that some products might face multiple labeling requirements.

b. *Revised benefit estimates.* When we revise the analysis as described previously, we obtain the estimated benefits shown in table 5 of this document. The assumption underlying the table is that the proposed warning statement would cause some proportion of consumers to incorporate the risks from dietary supplements containing ephedrine alkaloids into their demand for these products. Some proportion of those consumers (0 to 15 percent) would cease using those products, which would reduce the number of adverse events by a like percentage. The benefits would therefore be some percentage (between 0 and 15 percent) of the benefits of removing dietary supplements containing ephedrine alkaloids from the market. The results presented in table 5 of this document apply to every year after the first year. Benefits for the first year would be lower because our proposed rule would have allowed firms up to 6 months to comply with the warning statement requirements. We do not know the actual rate at which firms would come into compliance during the initial 6 months after publication of a rule finalizing the proposed warning statement requirements. To simplify the analysis, we assume that it would take all firms 6 months to comply with such a rule. Under this assumption, the benefits in the first year would be half those of every year after the first year. In the summary of regulating options and table 8 of this document, we use the range $0 to $20 million for annual benefits (excluding the first year) because it is inconsistent with the presentation of the other options.

TABLE 5.—ANNUAL BENEFITS OF OPTION THREE (REQUIRE THE 2003 PROPOSED WARNING STATEMENT) BASED ON ELIMINATING 0 TO 15 PERCENT OF THE SENTINEL AND POSSIBLE SENTINEL EVENTS

Type	Number	QALY Loss Per Case	Medical Costs Per Case
Death	0.0 to 0.2	NA (used VSL)	$25,742
MI (heart attack)	0.0 to 0.2	0.29	$30,586
CVA (stroke)	0.0 to 0.3	0.2	$20,898
Other Cardiovascular (*e.g.* Cardiomyopathy, Ventricular Tachycardia)	0.0	0.29	$30,586
Other Neurological (*e.g.* Transient Ischemic Attack)	0.0	minimal	$13,212
Seizure	0.0 to 0.1	minimal	$11,812
Psychiatric	0.0 to 0.2	minimal	$6,927

TABLE 6.—ANNUAL BENEFITS OF OPTION THREE (REQUIRE THE 2003 PROPOSED WARNING STATEMENT) BASED ON ALTERNATIVE ASSUMPTIONS OF REPORTING RATES, ROUNDED TO $ MILLIONS

Value of Avoiding Fatal Cases and QALY Losses	Adverse Event Reporting Rate		
	10 percent	50 percent	100 percent
$ per fatal case = $5 million $ per QALY = $100,000	$0 to $11	$0 to $2	$0 to $1
$ per fatal case = $6.5 million $ per QALY = $100,000	$0 to $14	$0 to $3	$0 to $1
$ per fatal case = $5 million $ per QALY = $300,000	$0 to $14	$0 to $3	$0 to $1
$ per fatal case = $6.5 million $ per QALY = $300,000	$0 to $17	$0 to $3	$0 to $2
$ per fatal case = $6.5 million $ per QALY = $500,000	$0 to $20	$0 to $4	$0 to $2

c. *Costs of requiring the 2003 proposed warning statement.*

i. *Label Costs.*

(Comment 86) Some comments said that the proposed PDP or nonPDP warning statements are too long to fit on the labels of most dietary supplement products. One comment noted that firms package many "traditional style extracts" in containers that have a maximum label size of 1.75 x 3.75 inches, or about 6.6 square inches. The comment argued that the proposed warning statements cannot fit on a label of this size. One comment argued that the proposed warning statement would take up so much space on the label that firms would be able to provide very little other information on the label. One comment argued that there is not enough room on package labels for multiple warning statements and suggested that we clarify that our proposed warning statement would preempt any state labeling requirements.

(Response) We reviewed the labels of the 40 dietary supplements containing ephedrine alkaloids that we collected between March 20 and May 30, 2001, to investigate label size. Most labels were wrap-around adhesive labels with a minimum label size of about 7.5 square inches and an average of about 22.8 inches. Nearly all labels already bore extensive warning statements, and most of the content of the existing warning statements was distinct from the additional warning material required by some States. Therefore, we conclude that the proposed warning statements would probably have fit on most product labels. However, some dietary supplements containing ephedrine alkaloids, possibly including traditional style extracts, might have significantly smaller labels than the products that we collected. If we had adopted this option, we would have addressed this possibility in a number of ways. Firms that cannot fit the proposed PDP warning statement on the PDP if they use the normal font size would be able to use a smaller font size. Firms that cannot fit the nonPDP warning statement on the product labels could place the warning statement on any product labeling that is an integral part of the outer product packaging such that consumers may read the warning statement at the point of purchase, including the rise backing, panel extension, and outsert. In some cases, firms may already use these packaging features. These firms would simply need to revise the content of existing

labeling. In other cases, firms might need to change the style of their packaging to utilize these types of labels. Rather than changing the style of their packaging, firms could also change the size of the package to increase the label space available for the warning statement. Changing the product packaging in one of these ways might require some firms to purchase new packaging machinery, which would be an additional cost beyond the cost of the label changes that we discussed in the analysis of the June 1997 proposal. We have insufficient information to estimate the number of products that might need to take these steps. Based on our review of existing product labels, we estimate that the number of such products is probably very small.

We have reestimated labeling costs because we have new information on the number of dietary supplements containing ephedrine alkaloids and we have updated the labeling cost model that we used to estimate labeling costs in the analysis of the June 1997 proposed rule. The cost of changing labels varies with the amount of time that we give firms to change the labels. We previously proposed setting the effective date for this option to be 180 days after the publication of the final rule. According to the revised label cost model, the one-time cost of adding or revising a PDP and a nonPDP warning statement to the labels of all dietary supplements under a 6-month compliance period would be approximately $140 million to $319 million. The labeling cost model does not differentiate dietary supplements that contain ephedrine alkaloids from other dietary supplements. However, a database of dietary supplements compiled by Research Triangle Institute (RTI) under contract to FDA listed a total of 3,000 dietary supplement products in 1999, and 49 of those products, or about 2 percent, listed ephedrine or one of the following sources of ephedrine alkaloids in their ingredient lists: Ephedra, ephedra extract, ephedra herb, *Ephedra sinica* Stapf., ma huang, ma huang extract, ma huang herb, ma huang concentrate, or ma huang herb extract (Ref. 159). In the absence of other information, we assume that the cost of changing the labels of these products would be about 2 percent of the cost of changing all dietary supplement product labels. Therefore, we estimate that the one-time cost of changing the labels of dietary supplements containing ephedrine alkaloids is $3 million to $6 million. Annualizing this cost over 20 years at 3 percent gives an annual cost that rounds to $0 million per year; that is, less than $500,000 per year. Annualizing this cost over 20 years at 7 percent gives an annual cost of $0 million to $1 million.

ii. *Risks of substitutes/absence of weight loss.*

(Comment 87) One comment noted that the proposed warning statement would instruct consumers not to take dietary supplements containing ephedrine alkaloids before or during strenuous exercise. This comment argued that this element of the warning statement could harm consumers by inhibiting weight loss because exercise is an essential component of a weight loss program.

(Response) As we discussed under Option Two of this section, we have insufficient information to estimate countervailing health effects such as the health risks generated by the use of substitute products or by the reduction or elimination of weight loss benefits. However, for this option, we have calculated benefits as a range of $0 to $20 million. This range is consistent with the existence of countervailing health risks from the source suggested by this comment.

d. *Effective date.*

(Comment 88) Some comments recommended that we revise the proposed effective date for the warning statement that we proposed in 1997 and revised in 2003. One comment suggested that we set the effective date to 12 months after publication of the final rule, rather than the proposed 180 days after publication of the final rule, to give industry more time to comply with the labeling requirements. Another comment suggested that we set the effective date to 60 days after publication of the final rule. Some comments suggested that we base the effective date on labeling at the manufacturing site. Under this approach, we would require products leaving the manufacturing site after the effective date to bear the warning statements, but firms could continue to sell existing inventory without the warning statement after that date.

(Response) Setting the effective date to 12 months after publication of a final rule requiring the warning statement would lead to one time labeling costs of between $2 million and $5 million. Annualizing this cost over 20 years at 3 percent and 7 percent gives an annual cost that rounds to $0 million per year (i.e., less than $500,000 per year). This would also reduce benefits in the first year to $0 under the simplifying assumption that all firms would take 12 months to comply with the required warning statement.

Eliminating all costs associated with unusable label or package inventory by allowing firms to continue to sell product without the warning statement after the effective date would lead to compliance costs of $2 million to $6 million under the proposed 180 day compliance period. Annualizing this cost over 20 years at 3 percent gives an annual cost that rounds to $0 million per year (i.e., less than $500,000 per year). Annualizing this cost over 20 years at 7 percent gives an annual cost of $0 million to $1 million per year. In our summary statements, we present the cost estimates under the 7 percent discount rate because that range includes the range of costs that we estimated under a 3 percent discount rate. However, this option would also generate additional enforcement costs because we would need some way of determining that the products that firms sell without the warning statement were actually labeled before the effective date. In addition, this revision would reduce benefits over a number of years according to the proportion of products sold during that time that did not bear warning statements. The period over which benefits would be reduced could be quite large because firms might produce as much product as possible prior to the effective date to avoid having to meet the labeling requirements. The comments did not provide information on this issue, and we are unable to estimate this reduction in benefits.

We compare costs of different effective dates for the proposed labeling option in table 7 of this document. We only consider first year net benefits because changing the effective date from 180 days to 365 days only affects benefits in the first year. After the first year, annual benefits would be the same for either effective date. To obtain the higher bound estimate of net benefits, we start with the higher bound estimate of benefits and subtract the lower bound estimates of costs. To obtain the lower bound estimate of net benefits, we start with the lower bound estimate of costs and subtract the higher bound estimate of costs. We do not have information suggesting that any of these options would lead to greater net benefits than the proposed enforcement period of 180 days.

TABLE 7.—COMPARISON OF EFFECTIVE DATE OPTIONS FOR OPTION THREE (REQUIRE THE PROPOSED WARNING STATEMENT), ROUNDED TO $ MILLIONS

Effective Date	Annualized Cost (millions)	First Year Benefits (millions)	First Year Net Benefits (millions)
180 days	$0 to $1	$0 to $10	-$1 to $10
365 days	$0	$0	$0
180 days at manufacturing site	$0 plus additional enforcement costs	NA	NA

e. *Conclusions on the benefits and costs of 2003 proposed warning statement.* We estimate costs to include the one-time cost of changing the labels of dietary supplements containing ephedrine alkaloids to be $3 million to $6 million, which rounds to approximately $0 million per year (i.e. less than $500,000 per year) when annualized over 20 years at 3 percent and approximately $0 million to $1 million per year when annualized over 20 years at 7 percent. We are unable to quantify potential recurring countervailing health costs. We estimate the recurring annual benefit to be $0 to $20 million, depending on the reporting rate for adverse events, and the method used to value those events. Therefore, we estimate the annual net benefit of this option to be -$1 million to $20 million. In the long run, this option would probably generate net benefits, for two reasons: First, the benefits recur annually and any non-zero level of benefits will eventually surpass the one-time labeling cost. Second, as we discussed above, the recurring countervailing health costs are unlikely to exceed the recurring health benefits.

7. Option Four—Require the Proposed Warning Statement, But Modify it or Require it Only on Certain Products.

a. *Require warning only for certain products.* We discussed a number of comments under Option Two that claimed that certain dietary supplements containing ephedrine alkaloids do not pose any health risks. That discussion is also relevant in the context of exempting certain products from the proposed warning statement. The summary of those comments and our response is the same as under Option Two in section VIII.A.5 of this document. For example, one comment suggested that warning statements are unnecessary for herbal products that firms distribute to "healthcare professionals," including members of the American Herbalists Guild. We do not have sufficient information to estimate the impact of exempting products based on patterns of distribution or other product characteristics.

b. *Placement and format of warning statement.*

(Comment 89) Some comments addressed the placement of the proposed warning statement on product packages. Some comments suggested that we allow firms to use inserts, stickers, or "peel away" labels. One comment said that we should allow firms to use alternative methods of disseminating warning information if they dispense products that are part of a bulk decoction formula that lacks standard labeling, such as products compounded and dispensed in Chinese herbal medicine pharmacies or by "qualified health professionals."

(Response) According to the March 2003 notice, we proposed to allow firms to use special labeling for the nonPDP warning statement as long as consumers could read the warning statement at the point of purchase.

(Comment 90) Some comments objected to the PDP warning statement that was part of the revised warning statement that we proposed in 2003. Other comments supported the 2003 proposed PDP warning statement. Some comments suggested that we require firms to use the PDP warning statement on both the product container and the outside container or wrapper of the retail package. One comment suggested that we require firms to include the PDP warning statement in any promotional literature and advertising.

(Response) Eliminating the PDP warning statement but retaining the nonPDP warning statement would probably significantly reduce the impact of the proposed warning statement. The PDP warning statement was one of the main elements of the proposed warning statement that differed from most existing warning statements. Reducing the impact of the warning statement by eliminating the proposed PDP warning statement would reduce both the benefits and the distributive impacts of the warning label option. However, eliminating the PDP warning statement would have little impact on the overall cost of changing labels to comply with the proposed warning statement because firms would still need to change labels even if we did not require a PDP warning statement. Requiring firms to place the warning statement on both the product container and the outside container or wrapper and requiring firms to include it in any promotional literature and advertising might increase the impact of the warning statement, but would also increase the costs. The comments did not provide sufficient information to establish that the benefits from these revisions would outweigh the costs.

(Comment 91) One comment argued that the PDP for mail order dietary supplements corresponds to the front page of any product literature that a firm uses to advertise its product. This comment said that the proposed regulation would, therefore, require some firms to change their pamphlets and other material. The comment argued that such a requirement would put mail order businesses at a competitive disadvantage relative to retail businesses. The comment suggested that we allow the warning statement to appear either above the mail order form that consumers use to order the product or above the toll free telephone number that consumers call to order the product. The comment argued that these locations would be more similar to the labeling requirements for OTC drugs.

(Response) The PDP for mail order dietary supplements is defined in the same way as the PDP for supplements sold in other ways: The label that appears on the front of the product package. It does not correspond to the front page of any product literature that a firm uses to advertise its product.

(Comment 92) Some comments objected to the requirement that firms set off the warning statement in a box graphic. One comment argued that the RAND report did not support the need for a black box type of warning statement. Some comments suggested that we give manufacturers greater leeway with respect to the format of the warning statement. Other comments supported the requirement that firms set off the warning statement in a box graphic. One comment suggested that we require firms to set off the warning

statement in a brightly colored or neon box instead of in a black box.

(Response) The proposed warning statement is consistent with current research on effective warning statements. Eliminating the box graphic would probably not significantly reduce relabeling costs. However, it might reduce the visibility of the warning statement, which would reduce the distributive impacts of the rule as well as the rule's potential health benefits. We have no information establishing that colored boxes are more effective than black boxes. Depending on the background color of the label, colored boxes may reduce the color contrast between the border and the background, which would decrease visibility of the warning statement. In addition, requiring colored boxes would increase labeling costs because some existing labels are not printed in colors.

c. *Content of PDP warning.*

(Comment 93) Some comments suggested that we revise the proposed PDP warning statement in various other ways. One comment argued that there was no evidence that "whole-herb products" containing ephedrine alkaloids have been associated with heart attack, stroke, seizure, or death, so that the proposed PDP warning statement would be inappropriate for those products. This comment suggested that we revise the PDP statement so that it simply informs consumers that a product contains ephedrine alkaloids and directs them to a warning statement elsewhere on the label. A number of comments argued that shortening the proposed PDP warning statement would make it more effective. One comment noted that the proposed approach is inconsistent with the "signal/refer/explain" format used for the labeling of other hazardous products. However, one comment suggested that we add material to the PDP warning statement, rather than shortening it.

(Response) Revising the PDP warning statement for some or all dietary supplements that contain ephedrine alkaloids would have little effect on labeling costs because firms would still need to revise their labels even if we did not require a PDP warning statement. The comments did not provide sufficient information to establish that revising the PDP warning statement would increase net benefits.

(Comment 94) A number of comments raised the issue of whom we instruct consumers to contact under various conditions. The proposed PDP and nonPDP warning statements suggest that consumers contact a "doctor" under various conditions. Some comments suggested we use a more general phrase such as "health care provider" in order to include nurse practitioners and pharmacists. One comment suggested that we change "doctor" to "licensed health care provider" to include acupuncturists who are trained in traditional Chinese medicine. The comment noted that at least half of the states that regulate the practice of acupuncture include the use of herbs in the authorized scope of practice of acupuncturists. The comment also noted that herbal ephedra is used by health care providers in other disciplines, such as naturopathy and herbalism. This comment argued that it was important to protect the ability of these groups to dispense dietary supplements containing ephedrine alkaloids.

(Response) Changing the specification of the person that the proposed warning label directs consumers to contact under various conditions would have little impact on labeling costs but would affect the benefits and distributional effects of this rule. Medical doctors are probably in the best position to advise consumers on the health implications of consuming ephedrine alkaloids under various conditions, but consumers might be able to get comparable advice from some other sources, including pharmacists and other health care providers, as well as some practitioners of acupuncture, herbalism, and naturopathy. On the other hand, obtaining advice from a medical doctor is probably more costly for many consumers than obtaining advice from other potential sources. In addition, some consumers may be unwilling to seek advice from medical doctors on the use of dietary supplements for reasons other than cost. These consumers may be less likely to follow directions to contact a medical doctor than they are to follow directions to contact a broader variety of health care providers. This component of the warning statement could also have distributional effects because directing consumers to contact a medical doctor increases the demand for the services of medical doctors and reduces the demand for the services of competing health care providers. The comments did not provide sufficient information to allow us to determine that changing the specification of the person that the label directs consumers to contact would increase net benefits. The comments also did not provide enough information for us to quantify the potential distributional impact of revising this component of the label.

(Comment 95) Some comments noted that the PDP warning statement inplied that ephedrine alkaloids cause heart attack, stroke, seizure, and death. These comments argued that this is misleading because no one has proven that ephedrine alkaloids cause these types of adverse events. One comment suggested that if we refer to these types of adverse events in the warning statement, then we should include a qualifying statement explaining that no one has established a causal link between these types of adverse events and ephedrine alkaloids. This comment also suggested that we indicate in the warning statement that reports of serious adverse events are extremely rare.

(Response) Although the information in the proposed warning statement is factually correct because some people have reported the specified adverse events after consuming ephedrine alkaloids, some consumers might interpret the phrase "have been reported" to mean that a proven causal relationship exists between the consumption of the ephedrine alkaloids and the reported adverse events. This perception could generate additional costs in terms of lost consumer utility because some consumers who would choose not to consume these products if a proven causal relationship existed might choose to continue to consume these products if a causal relationship were only possible or even likely. One way to reduce potential misperceptions would be to add a disclaimer to the label, explaining that the causal relationship between ephedrine alkaloids and these adverse events may be uncertain. This additional material might either decrease or increase the demand for these products, and consumers are generally less likely to respond to a longer, qualified warning statement, than to a shorter, non-qualified warning statement. The comments did not provide sufficient information to establish that adding this type of clarification to the warning would increase the benefits of the warning statement.

d. *Content of nonPDP warning statement.*

(Comment 96) A number of comments suggested that we revise the proposed nonPDP warning statement. Some comments suggested that we use the same warning statement that appears on OTC drug products containing ephedrine alkaloids. One comment suggested that we allow firms to use the OTC warning statement for dietary supplements that they sell directly to health professionals for subsequent sale to consumers. One comment argued that the warning statement should not instruct consumers to contact a doctor if they experience nausea because nausea is not likely to be a precursor symptom

of a potentially serious or life-threatening condition.

Some comments objected to the warning that the risk of serious side effects increases with duration of use. One comment suggested that the scientific data showed that adverse effects dramatically decline with continued use. Some comments argued that there was no persuasive evidence that ephedrine alkaloids had any cumulative effect on the cardiovascular or central nervous systems.

One comment suggested that we allow manufacturers to add contraindications beyond those listed on the required warning label. One comment suggested that we require a statement clarifying that we have not reviewed the product for safety or efficacy. Some comments argued that we should require warning statements to include the toll free telephone number and Web site address for our MedWatch program. Some comments recommended that we require firms to indicate the amount of ephedrine alkaloids present in a product on the product label.

(Response) These comments did not provide sufficient information to analyze the costs and benefits of revising the proposed nonPDP warning statement according to their recommendation.

e. *Conclusions on benefits and costs of modifying the proposed warning statement or requiring it only for certain products.* Requiring a warning statement for certain products only would reduce costs and distributional effects and might reduce benefits compared with Option 3 (all comparisons in this section are with Option 3). Eliminating the PDP warning statement or eliminating the box graphic would have little effect on costs but would reduce distributional effects and probably also reduce benefits. Requiring a colored box graphic instead of a black and white box graphic would increase costs and possibly increase distributional effects and benefits. Revising the content of the warning statements would have little effect on costs but might increase or decrease distributional effects and benefits, depending on the revision. We have insufficient information to quantify these possible impacts, so we are unable to provide a summary estimate of the costs and benefits of this option.

8. Option Five—Generate Additional Information or Take Some Action Other Than Removing Dietary Supplements Containing Ephedrine Alkaloids From the Market or Requiring Warning Statements

(Comment 97) One comment argued that we have no controlled epidemiological studies that support an association between ephedrine alkaloids and stroke, seizure, or myocardial infarction. Other comments noted that RAND said in its report that it was unable to establish that ephedrine alkaloids caused adverse events and that RAND recommended that someone perform a controlled clinical study to address the issue. Another comment noted that Haller and Benowitz (2000) said that their approach did not establish that ephedrine alkaloids caused adverse events and suggested that someone do a large scale case control study to quantitatively determine the risks associated with ephedrine alkaloids (Ref. 34). One comment noted that the NIH National Advisory Council for Complementary and Alternative Medicine Working Group on *Ephedra* suggested that someone perform a multi-site prospective case-control study to assess the risks associated with taking ephedra. This comment suggested that such a study would require 4 to 8 years to complete and cost $2 million to $4 million per year. Another comment argued that even if someone were to establish that ephedrine alkaloids increased cardiovascular risk by raising blood pressure, someone would still need to do a controlled research study to determine whether that effect outweighed the reduction in cardiovascular risk resulting from any weight loss generated by these products. One comment argued that a retrospective case control study is the correct study design for rare events. This comment argued that someone could do multiple studies of this type because they are quick, relatively inexpensive, and because the population exposure level is relatively high at 1 percent, according to a multistate survey on reported use of ephedra products from 1996 to 1998. Some comments suggested that we not take regulatory action until we determine that the adverse events that we suspect are caused by these supplements are due to ephedrine alkaloids rather than due to inconsistent and inaccurate formulations.

Some comments argued that we do not need to generate additional information because we already have sufficient information to remove dietary supplements containing ephedrine alkaloids from the market or require warning statements. Other comments argued that we do not need to generate additional information because we already have sufficient information to establish that these restrictions are unnecessary. Some of these comments argued that Morgenstern *et al.*, which was published after the RAND report, was just the type of case control study that the RAND report recommended (Ref. 136). These comments noted that this study found that ephedra did not raise the risk for hemorrhagic stroke. However, other comments argued that this study found that ephedra did raise the risk for hemorrhagic stroke. Some comments criticized various aspects of that study. A number of comments argued that the only additional studies that would be worthwhile to perform at this point would be unethical. These comments suggested that a human subjects committee would not allow a prospective study of the safety of ephedrine alkaloids without medical screening. They also suggested that a cohort study would be difficult because ephedrine alkaloids do not generate significant health benefits and also because of the ethical requirements to effectively inform participants of the risks.

(Response) Generating additional information might reduce the remaining uncertainty associated with the benefits of this rule or it might not. Generating additional information may be difficult, time consuming, and expensive. In addition, it is not clear that reducing the remaining uncertainty would change the outcome of this rulemaking. The comments did not provide sufficient information to allow us to estimate the costs and benefits of delaying rulemaking until we generate additional information.

(Comment 98) Other comments suggested that we should take some type of action other than issuing a regulation or generating additional information. A number of comments suggested that we address any problems with dietary supplements containing ephedrine alkaloids by using our existing authority to seize unsafe or adulterated dietary supplements. Other comments suggested that we address any problems by using our existing authority to investigate and prosecute unscrupulous multilevel marketing (MLM) distributors. Another comment suggested that we develop a level 1 guidance document rather than taking regulatory action.

(Response) The comments did not provide sufficient information to establish that spending additional

resources on enforcement of existing regulations or on promulgating a level 1 guidance document would generate greater net benefits than issuing this final rule. Following guidance documents is strictly voluntary. The fact that some manufacturers continue to produce dietary supplements containing ephedrine alkaloids despite ongoing and well-publicized concerns about the safety of such products suggests that voluntary guidance documents are unlikely to have a significant effect.

9. Benefit-Cost Analysis: Summary

Removing dietary supplements containing ephedrine alkaloids from the market (i.e. taking this final action) will generate estimated benefits of between $43 million and $132 million per year. We used the following assumptions to calculate this range of benefits: A 10 percent reporting rate for adverse events, no potentially countervailing health effects from the use of substitute products and other weight loss alternatives, no countervailing health effects from potentially foregone weight loss, and the fact that consumers do not already understand and incorporate the risks posed by these products in their consumption decisions. Including the impact of substitute products and activities could reduce the rule's health benefit considerably, possibly to $0 per year, although that is unlikely. These countervailing effects may occur because this rule will not affect the underlying demand for products having functional characteristics similar to ephedrine alkaloids, and it is likely that products having similar functional characteristics may contain similar types of ingredients that may pose similar types of health risks. The range of benefits includes alternative assumptions about the value of a statistical life ($5 million and $6.5 million) and the value of a statistical life year ($0.1 million, $0.3 million, and $0.5 million). We also considered a reporting rate of 50 percent, which leads to estimated annual benefits of $9 million to $26 million, and 100 percent, which leads to estimated annual benefits of $4 million to $13 million. More precise estimates of the health benefits would depend on choosing a particular combination of assumptions.

Removing these products from the market will generate one-time product reformulation costs of $10 million to $100 million, which amounts to a yearly cost of $1 million to $7 million when annualized over 20 years at an interest rate of 3 percent, and $1 million to $9 million at an interest rate of seven percent. These costs could be partly offset by reductions in fees associated with legal actions involving these products. In addition to the social costs, removing dietary supplements containing ephedrine alkaloids from the market could also generate distributional effects under which some firms manufacturing or distributing dietary supplements containing ephedrine alkaloids may experience reduced profits, while firms manufacturing or distributing other dietary supplements or other weight loss alternatives may experience increased profits. In addition, removing dietary supplements containing ephedrine alkaloids from the market would also generate costs in the form of lost consumer utility or satisfaction because of the removal of a product from the market. We estimated lost utility to be $6 million to $81 million per year.

Based on these estimates, the potential economic effects of this rule range from a net annual social cost of $90 million per year, if the rule's net health benefits are zero because of countervailing health effects or because consumers already understand and voluntarily accept the risks posed be these products, to an annual net social benefit of $125 million, if there are no countervailing health risks and consumers do not already understand and accept the known and potential risks.

TABLE 8.—SUMMARY OF OPTIONS, ROUNDED TO $ MILLIONS

Option	Annual Cost	Annual Benefit	Net
1. Take no new regulatory action (baseline)	$0	$0	$0
2a. Remove dietary supplements containing ephedrine alkaloids from the market (if consumer behavior does not already incorporate risk)	$7 to $90	$43 to $132	- $47 to $125
2b. Remove dietary supplements containing ephedrine alkaloids from the market (if consumer behavior already incorporates risk)	$7 to $90	$0	- $90 to - $7
3. Require 2003 warning atatement	$0 to $1	$0 to $20	- $1 to $20
4. Require warning statement, but modify it or require only on certain products	NA	NA	NA
5. Generate additional information or take some action other than removal or warning statements	unknown	unknown	unknown

B. Small Entity Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and in accordance with Executive Order 13272 (August 13, 2002). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule would have a significant economic impact on a substantial number of small entities.

(Comment 99) Some comments addressed our estimate of the number of small firms in the analysis of the proposed rule. Some comments argued that we had ignored a large number of independent small distributors in the analysis of the proposed rule. One comment suggested we revisit our analysis of the impact of the rule on small businesses. One comment

suggested we obtain information on the impact of the rule on small entities by opening a dialogue with industry associations.

(Response) We have revisited and revised our estimate of the number of firms based on a database of dietary supplement products that the Research Triangle Institute compiled under contract to FDA after publication of the proposed rule. This database listed 30 firms associated with 48 dietary supplement products containing ephedrine alkaloids (Ref. 159). To estimate the number of these firms that are small, we used a database of dietary supplement manufacturing practices that was also compiled by RTI under contract to FDA (Ref. 160). This database had size information for only a few of the 30 firms that we identified as relevant from the first database. Therefore, we estimated the number of small firms based on the percentage of all dietary supplement firms in the database that would qualify as small firms. The Small Business Administration (SBA) publishes definitions of small businesses by the North American Industry Classification System (NAICS) code. The firms in the database fell into the following NAICS codes: (1) 311222 Soybean Processing, (2) 311920 Coffee and Tea Manufacturing, (3) 325188 All Other Basic Inorganic Chemical Manufacturing, (4) 325199 All Other Basic Organic Chemical Manufacturing, (5) 325411 Medicinal and Botanical Manufacturing, and (6) 325412 Pharmaceutical Preparation Manufacturing. SBA defines small businesses in these NAICS codes based on a maximum number of employees, as follows: 311222 and 311920—no more than 500 employees; 325411 and 325412—no more than 750 employees; and 325188 and 325199—no more than 1000 employees. The database of firms listed 1,566 individual plants and 146 parent companies. Essentially all individual plants qualified as small businesses (98 percent under a maximum of 500 employees and 100 percent under a maximum of 1,000 employees). However, approximately 12 percent of the individual plants were associated with parent companies, and only about half of the parent companies qualified as small businesses (53 percent under a maximum of 500 employees and 58 percent under a maximum of 1,000 employees). Based on this information, we estimated that about 94 percent of the 30 firms associated with dietary supplement containing ephedrine alkaloids, or about 28 firms, would qualify as small businesses.

There may also be a number of independent distributors that are not captured in our database of dietary supplement firms. All or most of these firms would probably qualify as small businesses. However, we do not have sufficient information to estimate the number of distributors or to compare their characteristics to the SBA definition of a small business for that industry. As we noted in the previous paragraphs, this final rule will generate shifts in demand that might adversely affect these firms. However, the most likely substitutes for dietary supplements containing ephedrine alkaloids are other dietary supplements, and the same distributors that handle dietary supplements containing ephedrine alkaloids might also handle these other dietary supplements. Therefore, the net distributive impact on small distributors may be small or nonexistent. Although demand shifts generated by this final rule might also increase business for other small businesses, we do not consider countervailing positive effects on other small entities when assessing the impact of our rules on small entities.

In response to the request that we open a dialogue with industry associations, we note that small entities, and trade associations (with member small entities) submitted a number of comments regarding small business impact during the various comment periods for this rulemaking.

In the preceding cost-benefit analysis, we estimated that removing dietary supplements containing ephedrine alkaloids from the market would generate annualized cost of $1 million to $9 million over 20 years because of the need to reformulate products. This would correspond to a cost per firm across 30 firms of between $30,000 and $300,000 per year. In addition, we estimated that profits might be reduced by $0 to $13 million per year due to decreased sales. Profits may accrue to either manufacturers or distributors. If all profit losses affected manufacturers only, then the annual profit loss per firm across 30 firms would be between $0 and $ 430,000, which would give a total cost per firm of $30,000 to $730,000. Most of these firms are small, so even $30,000 per year (the lower bound) would be a significant additional burden. We previously estimated total sales to be $559 million to $806 million. If we assume that profits correspond to approximately 5 percent of sales, then annual profits would be $28 million to $40 million. If we assume that all profits accrue to manufacturers, then profits would be $0.9 million to $1.3 million per year per firm across 30 firms. In that case, reformulation costs would represent 2 percent to 33 percent of total profits, while total costs would represent 2 percent to 81 percent of total profits. The Regulatory Flexibility Act does not specify a threshold for costs to have a significant economic impact, but the 2 ranges we have calculated reach a high fraction of total profit; for some individual small firms the fraction of profit would be higher. If some of the profit losses accrued to distributors rather than manufacturers, then the potential cost per firm across all firms would be lower. However, we have insufficient information to estimate the number of distributors or the sales or profits per distributor.

(Comment 100) One comment argued that the PDP warning statement would have a significant economic impact on small businesses. This comment argued that the nonPDP warning statement would be adequate to protect consumers. This comment recommended that we eliminate the PDP warning statement.

(Response) A PDP warning statement might have a significant impact on small businesses. We have analyzed the costs of the proposed warning statement as a whole (including both PDP and nonPDP components) in our analysis of impacts under Executive Order 12866. However, the comment did not provide sufficient information to differentiate the impact on small businesses from the impact on other regulated entities, or to differentiate the impact of the PDP warning from the impact of the nonPDP warning.

(Comment 101) One comment recommended that we consider reasonable alternatives to the rule in order to reduce the burden on small businesses.

(Response) The discussion of regulatory options in the preceding benefit-cost analysis pertains primarily to small businesses because nearly all affected firms are small businesses under SBA size definitions. We could develop a definition of a very small business (different from the SBA definition of a small business) and develop additional regulatory options to reduce the burden on those firms, but those options would also be similar to those in the benefit-cost analysis. As we stated elsewhere in this analysis, any option that would reduce the regulatory burden on very small firms would also reduce benefits by increasing the risk to public health. We do not have sufficient information to compare the value of the

regulatory relief for very small firms to the associated reduction in benefits.

IX. Environmental Impact

Removing dietary supplements containing ephedrine alkaloids from the market will not have a significant impact on the human environment. Therefore, an environmental impact statement is not required.

X. Paperwork Reduction Act

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

XI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Section 402(f)(1)(A) of the act states that a dietary supplement or dietary ingredient shall be considered adulterated if it presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the product's labeling. If no conditions of use are suggested or recommended in the product's labeling, the dietary supplement or dietary ingredient is considered to be adulterated if it presents a significant or unreasonable risk of illness or injury under ordinary conditions of use. We have concluded that dietary supplements containing ephedrine alkaloids present an unreasonable risk and are therefore adulterated under section 402(f)(1)(A) of the act.

Section 402(f)(1)(A) of the act does not expressly preempt State or local laws. Therefore, under section 4(b) of Executive Order 13132, we are to construe our rulemaking authority as authorizing preemption of State law by rulemaking "only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that Congress intended the agency to have the authority to preempt State law."

We are aware that several States have laws concerning dietary supplements containing ephedrine alkaloids, such as required label statements, which clearly contemplate the continued marketing of such products. Section 301(a) of the act (in relevant part) prohibits the introduction or delivery for introduction into interstate commerce of any adulterated food. In this rule, the agency has declared dietary supplements containing ephedrine alkaloids to be adulterated. As a result, State laws establishing label requirements or other requirements that contemplate the continued marketing of these products conflict with this final rule and, consequently, are preempted.

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the "minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated." This action meets the preceding requirement because it only applies to State laws that contemplate the continued marketing of this class of products.

Section 4(d) of Executive Order 13132 states that when an agency foresees the possibility of a conflict between State law and federally protected interests within the agency's area of regulatory responsibility, the agency "shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict." Section 4(e) of Executive Order 13132 adds that, when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency "shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings."

In the present rulemaking, consultation with and notice to State officials under section 4(d) and (e) of Executive Order 13132 did not occur before we published the June 1997 proposal. Such consultation and notice was not possible because we published the proposed rule in the **Federal Register** of June 4, 1997, and Executive Order 13132 was not signed until August 4, 1999. OMB's guidance for implementing Executive Order 13132 states that, when a final rule may have been issued as a proposed rule before August 4, 1999, such that the intergovernmental consultation process had not occurred as called for by Executive Order 13132, the agency's certification "should so state" (*see* Memorandum for Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, dated October 28, 1999) (Ref. 161). Thus, we certify that the intergovernmental consultation process described in section 4(d) of Executive Order 13132 did not occur for the proposed rule, but we also believe that State and local governments had sufficient notice and an opportunity to participate in this rulemaking process. We note that the proposed rule was subject to a previous Executive Order, Executive Order 12612, which was also entitled, "Federalism," and had a similar consultation and notification obligation for federal agencies. When we issued the proposed rule, we notified the States, and State and local health departments, among others, submitted comments to the proposal (65 FR 17474, April 3, 2000) (stating that State and local health departments and government agencies had commented on the proposed rule)). Furthermore, a subsequent notice, published on March 5, 2003, expressly asked whether we should determine that dietary supplements containing ephedrine alkaloids present a "significant or unreasonable risk of illness or injury" under section 402(f)(1)(A) of the act (68 FR at 10417, 10419, and 10420). Although the March 2003 notice did not contain a separate Federalism analysis, we believe that States were aware of the March 2003 notice because at least five State or local governments or legislators submitted comments in response to the March 2003 notice, and most of these comments urged us to ban the sale of such products.

XII. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Ephedra Monograph, Review of Natural Products, Der Marderosian, A., ed., DrugFacts.com (*http://www.factsandcomparisons.com*), 2003.

2. Chen, K. K. and C. F. Schmidt, "Ephedrine and Related Substances," *Medicine* vol. 9, pp. 1–117, 1930.

3. Mahuang (Appendix: Mahuanggen)., Chapter in Chang, H-M. and P. P-H. But, eds., *Pharmacology and Applications of Chinese Materia Medica*, pp. 1119–1124, Singapore: World Scientific Publishing Co. Pte. Ltd., pp. 1119–1124, 1987.

4. Karch, S. B., "Other Naturally Occurring Stimulants," Chapter in Karch, S. B., *The Pathology of Drug Abuse*, pp. 177–198, Boca Raton: CRC Press, 1996.

5. "Phenethylamines," Chapter in Bruneton, J., ed., *Pharmacognosy, Phytochemistry, Medicinal Plants*, pp. 711–715, New York: Laviosier Publishing, 1995.

6. Betz, J. M., Tab F, "Review of Plant Chemistry: Alkaloids of Ma Huang (ephedra

spp.)," Food and Drug Administration, Briefing Materials for Food Advisory Committee Special Working Group on Foods Containing Ephedrine Alkaloids, Center for Food Safety and Applied Nutrition, pp. 1–14, 1995.

7. World Health Organization (WHO) Monographs on Selected Medicinal Plants, *Herba Ephedrae*, pp. 145–153, 1999.

8. Oshio, H., M. Tsukui, and T. Matsuoka, "Isolation of *l*-Ephedrine From 'Pinelliae Tuber'," *Chemical and Pharmaceutical Bulletin* (Tokyo), vol. 26, pp. 2096–2097, 1978.

9. Ghosal, S., R. B. Chauhan, and R. Mehta, "Alkaloids of *Sida Cordifolia*," *Phytochemical Reports*, vol. 14, pp. 830–832, 1975.

10. Cui, J., T. Zhou, J. Zhang, and Z. Lou, "Analysis of Alkaloids in Chinese *Ephedra* Species by Gas Chromatographic Methods," *Phytochemical Analysis*, vol. 2, pp. 116–119, 1991.

11. Food and Drug Administration, Tab E: Additional Market Review Information. Briefing Materials for Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids, Center for Food Safety and Applied Nutrition, pp. 1–35, 1996.

12. Brevoort, P., "The U.S. Botanical Market—An Overview," *HerbalGram*, vol. 36, pp. 49–57, 1996.

13. Food and Drug Administration, Hardy, C., "FDA Market Review Update Ephedrine Alkaloid-Containing Dietary Supplements," 2000.

14. Food and Drug Administration, Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids, Meeting Transcript, Docket No. 1995N–0304, TR2, vol. 72–73, August 1996.

15. Food and Drug Administration, Food Advisory Committee, Special Working Group on Foods Containing Ephedrine Alkaloids, Meeting Transcript, Docket No. 1995N–0304, TR1, vol. 40–41, October 1995.

16. Commission on Dietary Supplement Labels: Report of the Commission on Dietary Supplement Labels, 1997.

17. U.S. General Accounting Office (GAO), "Dietary Supplements, Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids," GAO/Health, Education, and Human Services Division (HEHS)/General Government Division (GGD), pp. 99–90, 1999.

18. Food and Drug Administration, "Assessment of Public Health Risks Associated with the Use of Ephedrine Alkaloid-containing Dietary Supplements," 2000, Docket No. 2000N–1200, vol. 29–30, pp. 39–41, 2000.

19. Kernan, W. N., C. M. Viscoli, L. M. Brass, *et al.*, "Phenylpropanolamine and the Risk of Hemorrhagic Stroke," *New England Journal of Medicine*, vol. 343, pp. 1826–1832, 2000.

20. Department of Health and Human Services, Office of Inspector General, "Adverse Event Reporting for Dietary Supplements, An Inadequate Safety Valve," OEI–01–00–00180, 2001.

21. Shekelle P., S. Morton, M. Maglione, *et al.*, "Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. Evidence Report/Technology Assessment," No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290–97–0001, Task Order No. 9), AHRQ Publication No. 03–E022, Rockville, MD, Agency for Healthcare Research and Quality, Docket No. 1995N–0304, BKG3, vol. 300 (*http://www.fda.gov/OHRMS/DOCKETS/98fr/95n–0304–bkg0003–ref–07–01–index.htm*), 2003.

22. Shekelle, P. G., M. L. Hardy, S. C. Morton, *et al.*, "Efficacy and Safety of Ephedra and Ephedrine for Weight Loss and Athletic Performance: A Meta-Analysis," *Journal of the American Medical Association*, vol. 289, pp. 1537–1545, 2003.

23. U.S. General Accounting Office (GAO), "Dietary Supplements Containing Ephedra, Health Risks and FDA's Oversight," Testimony: Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, GAO–03–1042T, 2003.

24. U.S. General Accounting Office (GAO): "Dietary Supplements: Review of Health-Related Call Records for Users of Metabolife 356," GAO–03–494, 2003.

25. Caveney, S. and A. Starratt, "Glutamatergic Signals in Ephedra (Scientific Correspondence)," *Lancet*, vol. 372, p. 509, 1994.

26. Caveney, S., D. A. Charlet, H. Freitag, *et al.*, "New Observations on the Secondary Chemistry of World *Ephedra* (Ephedraceae)," *American Journal of Botany*, vol. 88, pp. 1199–1208, 2001.

27. Food and Drug Administration, L. A. Love, Tab E, "Evaluation of the Safety of Food Products Containing Sources of Ephedrine Alkaloids," Briefing Materials for Food Advisory Committee Special Working Group on Foods Containing Ephedrine Alkaloids, Center for Food Safety and Applied Nutrition, pp. 1–51, 1995.

28. Food and Nutrition Board, Institute of Medicine, *Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients*, Washington, DC, National Academy Press, pp. 1–71, 1999.

29. Vasan. R. S., M. G. Larson, E. P. Leip, *et al.*, "Impact of High-Normal Blood Pressure on the Risk of Cardiovascular Disease," *New England Journal of Medicine*, vol. 345, pp. 1291–1297, 2001.

29a. Vasan, R. S., J. M. Massaro, P. W. Wilson, *et al.*, "Antecedent Blood Pressure and Risk of Cardiovascular Disease: The Framingham Heart Study," *Circulation*, vol. 105, pp. 48–53, 2002.

30. Neaton, J. D., L. Kuller, J. Stamler, and D. N. Wentworth, Impact of Systolic and Diastolic Blood Pressure on Cardiovascular Mortality, Chapter in Laragh, J. H. and B. M. and Brenner, eds., *Hypertension: Pathophysiology, Diagnosis, and Management*, New York: Raven Press Ltd., pp. 127–144, 1995.

31. National Institutes of Health (NIH), Report of Ephedra Working Group to the National Advisory Council for Complementary and Alternative Medicine (*http://nccam.nih.gov/health/alerts/ephedra/working-group.htm*), 2003.

32. Goldman, S. A., D. L. Kennedy, D. J. Graham, *et al.*, "The Clinical Impact of Adverse Event Reporting," *MedWatch Continuing Education Article*, pp. 1–11. 1996.

33. Middleton, W. S. and K. K. Chen, "Ephedrine," *Archives of Internal Medicine*, vol. 39, pp. 385–403, 1927.

34. Haller, C. A. and N. L. Benowitz, "Adverse Cardiovascular and Central Nervous System Events Associated With Dietary Supplements Containing Ephedra Alkaloids," *New England Journal of Medicine*, vol. 343, pp. 1833–1838, 2000.

35. Hoffman, B. B. and R. J. Lefkowitz, "Catecholamines, Sympathomimetic Drugs, and Adrenergic Receptor Antagonists," Chapter in Hardman, J. G., A. G. Gilman, and L. E. Limbird, eds., *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, New York, St. Louis, McGraw-Hill Chapter, pp. 199–248, 1996.

36. Astrup, A., S. Toubro, S. Cannon, *et al.*, "Thermogenic Synergism Between Ephedrine and Caffeine in Healthy Volunteers: A Double-Blind, Placebo-Controlled Study," *Metabolism*, vol. 40, pp. 323–329, 1991.

37. Taguchi, N.,T. Nishikawa, S. Inomata, *et al.*, "Hemodynamic Effects of Intravenous Ephedrine in Infants and Children Anesthetized With Halothane and Nitrous Oxide," *Anesthesia and Analgesia*, vol. 82, pp. 568–573, 1996.

38. The Xamoterol in Severe Heart Failure Study Group, "Xamoterol in Severe Heart Failure," *Lancet*, vol. 336, pp. 1–6, 1990.

39. Packer, M., J. R. Carver, R. J. Rodeheffer, *et al.*, "Effect of Oral Milrinone on Mortality in Severe Chronic Heart Failure, The PROMISE Study Research Group," *New England Journal of Medicine*, vol. 325, pp. 1468–1475. 1991.

40. Cowley, A. J. and A. M. Skene, "Treatment of Severe Heart Failure: Quantity or Quality of Life? A Trial of Enoximone," Enoximone Investigators, *British Heart Journal*, vol. 72, pp. 226–230, 1994.

41. Brown, O. M., Adrenergic Drugs. Chapter in Smith, C. M. and A. M. Reynard, eds., *Essentials of Pharmacology*, Philadelphia, W. B. Saunders Co., pp. 75–85, 1995.

42. Haller, C. A., P. Jacob, III and N. L. Benowitz, "Pharmacology of Ephedra Alkaloids and Caffeine After Single-Dose Dietary Supplement Use," *Clinical Pharmacology and Therapeutics*, vol. 71, pp. 421–432, 2002.

43. White, L. M., S. F. Gardner, B. J. Gurley, *et al.*, "Pharmacokinetics and Cardiovascular Effects of Ma-huang (Ephedra Sinica) in Normotensive Adults," *Journal Clinical Pharmacology*, vol. 37, pp. 116–122, 1997.

44. Gurley, B. J., S. F. Gardner, L. M. White, *et al.*, "Ephedrine Pharmacokinetics After the Ingestion of Nutritional Supplements Containing Ephedra Sinica (Ma Huang)," *Therapeutic Drug Monitoring*, vol. 20, pp. 439–445, 1998.

45. Eggertsen, R., A. Andreasson, T. Hedner, *et al.*, "Effect of Coffee on Ambulatory Blood Pressure in Patients With Treated Hypertension," *Journal of Internal Medicine*, vol. 233, pp. 351–355, 1993.

46. Myers, M. G. and R. A. Reeves, "The Effect of Caffeine on Daytime Ambulatory Blood Pressure," *American Journal of Hypertension*, vol. 4, pp. 427–431, 1991.

47. Jacobs, I., H. Pasternak, and D. G. Bell, "Effects of Ephedrine, Caffeine, and Their Combination on Muscular Endurance," *Medicine and Science in Sports and Exercise*, vol. 35, pp. 987–994, 2003.

48. Berlin, I., D. Warot, G. Aymard, *et al.*, "Pharmacodynamics and Pharmacokinetics of Single Nasal (5 mg and 10 mg) and Oral (50 mg) Doses of Ephedrine in Healthy Subjects," *European Journal of Clinical Pharmacology*, vol. 57, pp. 447–455, 2001.

49. Boozer, C. N., P. A. Daly, P. Homel, *et al.*, "Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial," *International Journal of Obesity and Related Metabolic Disorders*, vol. 26, pp. 593–604, 2002.

50. Kaplan, N., Expert Opinion: A Review of Boozer, CN, *et al., Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial*, Review Prepared for the Food and Drug Administration, 2003.

51. Atkinson, R., Expert Opinion: A Review of Boozer, CN, *et al., Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial*, Review Prepared for the Food and Drug Administration, 2003.

52. Espeland, M., Expert Opinion: A Review of Boozer, CN, *et al., Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Randomized Safety and Efficacy Trial*, Review Prepared for the Food and Drug Administration, 2003.

53. Hajjar, I. and T. A. Kotchen, "Trends in Prevalence, Awareness, Treatment, and Control of Hypertension in the United States, 1988–2000," *Journal of the American Medical Association*, vol. 290, pp. 199–206, 2003.

54. Lewington, S., R. Clarke, N. Qizilbash, *et al.*, "Age-Specific Relevance of Usual Blood Pressure to Vascular Mortality: A Meta-Analysis of Individual Data for One Million Adults in 61 Prospective Studies," *Lancet*, vol. 360, pp. 1903–1913, 2002.

55. Collins, R., R. Peto, S. MacMahon, *et al.*, "Blood Pressure, Stroke, and Coronary Heart Disease, Part 2, Short-term Reductions in Blood Pressure: Overview of Randomised Drug Trials in Their Epidemiological Context," *Lancet*, vol. 335, pp. 827–838, 1990.

56. Staessen, J. A., J. G. Wang, and L. Thijs, "Cardiovascular Prevention and Blood Pressure Reduction: A Quantitative Overview Updated Until 1 March 2003," *Journal of Hypertension*, vol. 21, pp. 1055–1076, 2003.

57. Neal, B., S. MacMahon, and N. Chapman, "Effects of ACE Inhibitors, Calcium Antagonists, and Other Blood-Pressure-Lowering Drugs: Results of Prospectively Designed Overviews of Randomised Trials," Blood Pressure Lowering Treatment Trialists' Collaboration, *Lancet*, vol. 356, pp. 1955–1964, 2000.

58. MacMahon, S., R. Peto, J. Cutler, *et al.*, "Blood Pressure, Stroke, and Coronary Heart Disease. Part 1, Prolonged Differences in Blood Pressure: Prospective Observational Studies Corrected for the Regression Dilution Bias," *Lancet*, vol. 335, pp. 765–774, 1990.

59. Cohn, J. N., S. O. Goldstein, B. H. Greenberg, *et al.*, "A Dose-Dependent Increase in Mortality With Vesnarinone Among Patients With Severe Heart Failure," Vesnarinone Trial Investigators, *New England Journal of Medicine*, vol. 339, pp. 1810–1816, 1998.

60. Hampton, J. R., D. J. van Veldhuisen, F. X. Kleber, *et al.*, "Randomised Study of Effect of Ibopamine on Survival in Patients With Advanced Severe Heart Failure," Second Prospective Randomised Study of Ibopamine on Mortality and Efficacy (PRIME II) Investigators, *Lancet*, vol. 349. pp. 971–977, 1997.

61. Cuffe, M. S., R. M. Califf, K. F. Adams, Jr., *et al.*, "Short-Term Intravenous Milrinone for Acute Exacerbation of Chronic Heart Failure: A Randomized Controlled Trial," *Journal of the American Medical Association*, vol. 287, pp. 1541–1547, 2002.

62. Sears, M. R., "Adverse Effects of Aeta-Agonists," *Journal of Allergy and Clinical Immunology*, vol. 110, pp. S322–S328, 2002.

63. Wit, A. L., B. F. Hoffman, and M. R. Rosen, "Electrophysiology and Pharmacology of Cardiac Arrhythmias, IX. Cardiac Electrophysiologic Effects of Beta Adrenergic Receptor Stimulation and Blockade. Part C," *American Heart Journal*, vol. 90, pp. 795–803, 1975.

64. Mahaffey, K. W., J. A. Puma, N. A. Barbagelata, *et al.*, "Adenosine as an Adjunct to Thrombolytic Therapy for Acute Myocardial Infarction: Results of a Multicenter, Randomized, Placebo-Controlled Trial: The Acute Myocardial Infarction Study of Adenosine (AMISTAD) Trial," *Journal of the American College of Cardiology*, vol. 34, pp. 1711–1720, 1999.

65. Kenchaiah, S., J. C. Evans, D. Levy, *et al.*, "Obesity and the Risk of Heart Failure," *New England Journal of Medicine*, vol. 347, pp. 305–313, 2002.

66. National Institutes of Health, National Heart, Lung, and Blood Institute, "Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report," NIH Publication No. 98–4083, pp. 1–262 (*http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm*), 1998.

67. Astrup, A., L.Breum, S. Toubro, *et al.*, "The Effect and Safety of an Ephedrine/Caffeine Compound Compared to Ephedrine, Caffeine and Placebo in Obese Subjects on an Energy Restricted Diet, A Double Blind Trial," *International Journal of Obesity and Related Metabolic Disorders*, vol. 16, pp. 269–277, 1992.

68. Toubro, S., A. V. Astrup, L. Breu, F. Quaade, "Safety and Efficacy of Long-Term Treatment With Ephedrine, Caffeine and an Ephedrine/Caffeine Mixture," *International Journal of Obesity and Related Metabolic Disorders*, vol. 17, suppl. 1, pp. S69–S72, 1993.

69. Quaade, F., A. Astrup, L. Breum, *et al.*, "The effect of an Ephedrine/Caffeine Combination As a Supplement to a Weight-Reducing Diet. A Randomized, Placebo-Controlled, Double-Blind Trial," *Ugesk Laeger*, vol. 154, pp. 1258–1263, 1992.

70. Toubro, S., A. Astrup, L. Breum, *et al.*, "The Acute and Chronic Effects of Ephedrine/Caffeine Mixtures on Energy Expenditure and Glucose Metabolism in Humans," *International Journal of Obesity and Related Metabolic Disorders*, vol. 17, suppl. 3, pp. S73–S77, 1993.

71. Astrup, A., C. Lundsgaard, J. Madsen, *et al.*, "Enhanced Thermogenic Responsiveness During Chronic Ephedrine Treatment in Man," *American Journal Clinical Nutrition*, vol. 42, pp. 83–94, 1985.

72. Astrup, A. and S. Toubro, "Thermogenic, Metabolic, and Cardiovascular Responses to Ephedrine and Caffeine in Man," *International Journal of Obesity and Related Metabolic Disorders*, vol. 17, suppl. 1, pp. S41–S43, 1993.

73. Astrup, A., S. Toubro, S. Cannon, P. Hein, *et al.*, "Caffeine: A Double-Blind, Placebo-Controlled Study of its Thermogenic, Metabolic, and Cardiovascular Effects in Healthy Volunteers," *American Journal Clinical Nutrition*, vol. 51, pp. 759–767, 1990.

74. Breum, L., J. K. Pedersen, F. Ahlstrom, *et al.*, "Comparison of an Ephedrine/Caffeine Combination and Dexfenfluramine in the Treatment of Obesity. A Double-Blind Multi-Centre Trial in Ggeneral Practice," *International Journal of Obesity and Related Metabolic Disorders*, vol. 18, pp. 99–103, 1994.

75. Pasquali, R., G. Baraldi, M. P. Cesari, *et al.*, "A Controlled Trial Using Ephedrine in the Treatment of Obesity," *International Journal of Obesity and Related Metabolic Disorders*, vol. 9, pp. 93–98, 1985.

76. Pasquali, R., M. P. Cesari, N. Melchionda, *et al.*, "Does Ephedrine Promote Weight Loss in Low-Energy-Adapted Obese Women?," *International Journal of Obesity and Related Metabolic Disorders*, vol. 11, pp. 163–168, 1987.

77. Pasquali, R., F. Casimirri, N. Melchionda, *et al.*, "Effects of Chronic Administration of Ephedrine During Very-Low-Calorie Diets on Energy Expenditure, Protein Metabolism and Hormone Levels in Obese Subjects," *Clinical Science* (London), vol. 82, pp. 85–92, 1992.

78. Krieger, D. R., Daly, P. A., Dulloo, A. G., *et al.*, "Ephedrine, Caffeine and Aspirin Promote Weight Loss in Obese Subjects," *Transactions of the Association of American Physicians*, vol. 103, pp. 307–312, 1990.

79. Daly, P. A., D. R. Krieger, A. G. Dulloo, *et al.*, "Ephedrine, Caffeine and Aspirin: Safety and Efficacy for Treatment of Human Obesity," *International Journal of Obesity and Related Metabolic Disorders*, vol. 17, suppl. 1, pp. S73–S78, 1993.

80. Horton, T. J. and C. A. Geissler, "Aspirin Potentiates the Eeffect of Ephedrine on the Thermogenic Response to a Meal in Obese But Not Lean Women," *International Journal of Obesity and Related Metabolic Disorders*, vol. 15, pp. 359–366, 1991.

80a. Food and Drug Administration, Memorandum, Beaston, P., M.D., Ph.D., "Review of Boozer-Daly Article for Ephedrine and Caffeine," January 10, 2003, amended February 2, 2004.

81. Food and Drug Administration, Memorandum: Evaluation of Scientific References Considered by RAND, February 2, 2004.

81a. Friedman, L. M., C. D. Furberg, and D. L. DeMets, *Fundamentals of Clinical Trials*, 3rd ed., Springer, New York, 1998.

81b. Ingelfinger, J.A., F. Mosteller, L. A. Thibodeau, *et al.*, 3rd ed., *Biostatistics in Clinical Medicine*, McGraw-Hill, Inc., New York, 1994.

81c. Dawson, B. and R.G. Trapp, *Basic and Clinical Biostatistics*, 3rd ed., Lange Medical Books/McGraw-Hill, New York, 2001.

82. Niemann R.A. and M.L. Gay, "Determination of Ephedrine Alkaloids and Synephrine in Dietary Supplements by Column-Switching Cation Exchange High-Performance Liquid Chromatography with Scanning-Wavelength Ultraviolet and Fluorescence Detection," *Journal of Agricultural and Food Chemistry*, vol. 51, pp. 5630–5638, 2003.

83. Chua, S. S. and S. I. Benrimoj, "Non-Prescription Sympathomimetic Agents and Hypertension," *Medical Toxicology and Adverse Drug Experience*, vol. 3, pp. 387–417, 1988.

84. Inchiosa, M. A., "Dose-Related Cardiovascular Effects of Ephedrine in Humans," Report prepared for the Food and Drug Administration, July 6, 1999.

85. Inchiosa, M. A., "Bioavailability of Ephedrine Alkaloids," Report prepared for the Food and Drug Administration, June 14, 1999.

86. Food and Drug Administration, Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids, Meeting Transcript, II, pp. 136. 137, 203, 205, 221, 225, 227, 229–230, 236–237, 239–240, August 27–28, 1996.

87. Food and Drug Administration, Food Advisory Committee on Dietary Supplements Containing Ephedrine Alkaloids, Meeting Transcript, II, pp. 137, 233, 237, 240, 272, and 277, August 27–28, 1996.

88. Kerin, K. J., Dietary Supplements Containing Ephedrine Alkaloids, Comments from Circadian Technologies, Inc., FDA Docket No. 1995N–0304, c3923:1–3, 2003.

89. Lee, M. K., B. W. Cheng, C. T. Che, *et al.*, "Cytotoxicity Assessment of Ma-huang (Ephedra) Under Different Conditions of Preparation," *Toxicological Sciences*, vol. 56, pp. 424–430, 2000.

90. Hikino, H., K. Ogata, C. Konno, *et al.*, "Hypotensive Actions of Ephedradines, Macrocyclic Spermine Alkaloids of Ephedra Roots," *Planta Medica*, vol. 48, pp. 290–293, 1983.

91. Minematsu, S., Y. Kobayashi, N. Kobayashi, *et al.*, "Acute Ephedrae Herba and ephedrine poisoning in mice," *Japanese Journal of Toxicology*, vol. 4, pp. 143–149, 1991.

92. Lee, M. K., Y. H. Wong, C. T. Che. *et al.*, "Adrenergic Agonistic Effects and Cyto-Toxicity of Chinese Ephedra (Ma-Huang) Used for Weight Reduction," *Toxicological Sciences, The Toxicologist*, vol. 48, p. 58, abstract no. 272, 1999.

93. CANTOX Health Sciences International, "Safety Assessment and Determination of a Tolerable Upper Limit for Ephedra," pp. 1–273, Docket No. 2000N–1200, Sup2 (*http://www.crnusa.org/cantoxreportindex.html*), 2000.

94. Ad Hoc Committee Reports, On the Safety of Ma Huang (1995, 1996), On the Safety of Dietary Supplements (1997), FDA Docket Nos. 1995N–0304, RPT 1, vols. 36–38; 1995N–0304, C57, vol. 76; 1995N–0304, C3391, vol. 280.

95. Ephedra Education Council Expert Panel Report, Docket No. 2000N–1200, C30, vol. 70, 2000.

96. Boozer, C. N., P. A. Daly, D. Blanchard, *et al.*, "Herbal Ephedra/Caffeine for Weight Loss: A 6-Month Safety and Efficacy Trial," *North American Association for the Study of Obesity*, 2000.

97. Dulfano, M. J. and P. Glass, "Evaluation of a New B_2 Adrenergic Receptor Stimulant, Terbutaline, in Bronchial Asthma. II. Oral Comparison With Ephedrine," *Current Therapeutic Research*, vol. 15, pp. 150–157, 1973.

98. Tashkin, D. P., R. Meth, D. H. Simmons, *et al.*, "Double-Blind Comparison of Acute Bronchial and Cardiovascular Effects of Oral Terbutaline and Ephedrine," *Chest*, vol. 68, pp. 155–161, 1975.

99. Brown, S. D., Jr., and F. J. Landry, "Recognizing, Reporting, and Reducing Adverse Drug Reactions," *Southern Medical Journal*, vol. 94, pp. 370–373, 2001.

100. Lazarou, J., B. H. Pomeranz, and P. N. Corey, "Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies," *Journal of the American Medical Association*, vol. 279, pp. 1200–1205, 1998.

101. American Herbal Products Association, *Code of Ethics and Business Conduct*, pp. 1–9, July 2002.

102. Lake, C. R. and R. S. Quirk, "CNS Stimulants and the Look-Alike Drugs," *Psychiatric Clinics of North America*, vol. 7, pp. 689–701, 1984.

103. Furuya, I. and S. Watanabe, "Discriminative Stimulus Properties of Ephedra Herb (Ephedra Sinica) in Rats," *Yakubutsu Seishin Kodo* (Japanese Journal of Psychopharmacology), vol. 13, pp. 33–38, 1993.

104. Tinsley, J. A. and D. D. Watkins, "Over-the-Counter Stimulants: Abuse and Addiction," *Mayo Clinic Proceedings*, vol. 73, pp. 977–982, 1998.

105. Ephedra Sinica, In Gruenwald, J., T. Brendler, and C. Jaenicke, eds., *PDR for Herbal Medicines*, 1st ed., Montvale: Medical Economics Co., Inc., pp. 826–827, 1998.

106. The Complete German Commission E Monographs, Therapeutic Guide to Herbal Medicines (English Translation), Blumenthal, M., W. R. Busse, A. Goldberg, *et al.*, pp. 125–126, 1998.

107. Huang, K. C., Antiasthmatic Herbs, Chapter in *The Pharmacology of Chinese Herbs*, pp. 229–232, Boca Raton, CRC Press, 1993.

108. Hsu, H. Y., Y. P. Chen, S. J. Shen, et. al. Ephedrae Herba (Ephedra, Ma-Huang), *Oriental Materica Medica: A Concise Guide*, pp. 52–53, Long Beach, CA, Oriental Healing Arts Institute, 1986.

109. Food and Drug Administration, Clinical Research and Review Staff: Evaluation of Adverse Events Reported With the Use of Ephedrine Alkaloid-containing Dietary Supplements (June 1, 1997, through March 31, 1999), 2000.

110. Food and Drug Administration, Chen, M. and C. B.Karwoski, Office of Post Market Drug Risk Assessment Postmarketing Safety Review, "Evaluation of Adverse Event Reports Associated With Ephedrine Alkaloid-Containing Dietary Supplements," 2000.

111. Woosley, R. L., "Summary of Analysis of Adverse Event Reports for Dietary Supplements Containing Ephedrine Alkaloids," Report Prepared for the Food and Drug Administration, 1999.

112. Benowitz, N. L., "Review of Adverse Reaction Reports Involving Ephedrine-Containing Herbal Products," Report Prepared for the Food and Drug Administration, 2000.

113. Ricaurte, G. A., "Review of FDA Neuropsychiatric/central nervous system adverse events related to ephedrine-containing dietary supplements," Report Prepared for the Food and Drug Administration, 2000.

114. Stoll, A. L., "FDA Ephedrine Adverse Event Case Review: Summary," 1999.

115. Woosley, R. L., "FDA Addendum: Summary of Analysis of Adverse Event Reports for Dietary Supplements Containing Ephedrine Alkaloids," Report Prepared for the Food and Drug Administration, 2000.

116. Food and Drug Administration, Love, L. A., "FDA Review of the Published Literature on the Physiological, Pharmacological and Toxic Effects of Ephedrine Alkaloids," 2000.

117. U.S. House of Representatives, Committee on Government Reform. Minority Staff Report, "Adverse Event Reports from Metabolife," 2002.

118. Shekelle, P. G., E-Mail Response to Questions on the RAND Report on Ephedra, April 7, 2003.

119. Shekelle, P. G., M. Maglione, and S. C. Morton, "Preponderance of Evidence. Judging What to Do About Ephedra," RAND Review, vol. 27, pp. 16–21, (*http://www.rand.org/publications/randreview/issues/spring2003/evidence.html*), 2003, accessed in January 2004.

120. "Danish Medicines Agency: Letigen® has been suspended," Danish Medicines Agency 2002 (*http://www.laegemiddelstyrelsen.dk/en/news/letigen_6_en.asp*), accessed as of March 3, 2003. (To obtain a paper copy *see* the **FOR FURTHER INFORMATION CONTACT** section of this document.)

121. "Adverse Reactions Letigen," Danish Medicines Agency, 2002 Company Report, 18, 2002.

122. Walker, A. M., "The Relation Between Voluntary Notification and Material Risk in Dietary Supplement Safety," Report prepared for the Food and Drug Administration, 2000.

123. Food and Drug Administration, Letter from Melinda Plaisier to Congressman Henry Waxman (CA) dated July 11, 2001 and Tab C (preliminary evaluation of data from American Association of Poison Control Centers) enclosed with the letter, 2001.

124. U.S. General Accounting Office (GAO), GAO Report, "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids," GAO, 1999, submitted to Docket No. 2000N–1200, BKG 1, vol. 32.

125. Boozer, C. N., J. A. Nasser, S. B Heymsfield, *et al.*, "An Herbal Supplement Containing Ma Huang-Guarana For Weight Loss: A Randomized, Double-Blind Ttrial," *International Journal of Obesity and Related Metabolic Disorders*, vol. 25, pp. 316–324, 2001.

126. National Institutes of Health, National Heart, Lung, and Blood Institute, Third Report of the Expert Panel on Detection,

Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report, NIH Publication No. 02–5215 (*http://www.nhlbi.nih.gov/guidelines/cholesterol*), 2002.

127. Bray, G. A. and F. L. Greenway, "Current and Potential Drugs for Treatment of Obesity," *Endocrine Reviews*, vol. 20, pp. 805–875, 1999.

128. Yanovski, S. Z. and J. A. Yanovski, "Obesity," *New England Journal of Medicine*, vol. 346, pp. 591–602, 2002.

129. Food and Drug Administration, Division of Metabolic and Endocrine Drug Products, FDA Draft Guidance for the Clinical Evaluation of Weight-Control Drugs, 1996.

130. International Committee on Harmonization (ICH): Guidance for Industry, S7A Safety Pharmacology Studies for Human Pharmaceuticals, ICH, pp. 1–11 (*http://www.fda.gov/cder/guidance/4461fnl.pdf*), 2001.

131. Filozof, C., C. Gonzalez, and E. Hofman, "The Effect Ephedrine Plus Caffeine After a 4-week Portion-Controlled Diet," *Ninth International Congress on Obesity*, Abstract 591, *Ninth International Congress on Obesity*, vol. 26, suppl. 1, p. S156, 2002, August 2002.

132. Food and Drug Administration, "Evidence On The Safety And Effectiveness Of Ephedra: Implications For Regulation," (*http://www.fda.gov/bbs/topics/NEWS/ephedra/whitepaper.html*), 2003.

133. Boerth, J. M., C. F. Caley, "Possible Case of Mania Associated With Ma-huang," *Pharmacotherapy*, vol. 23, pp. 380–383, 2003.

134. Samenuk, D., M. S. Link, M. K. Homoud, *et al.*, "Adverse Cardiovascular Events Temporally Associated With Ma-huang, an Herbal Source of Ephedrine," *Mayo Clinic Proceedings*, vol. 77, pp. 12–16, 2002.

135. Bent, S., T. N. Tiedt, M. C. Odden, *et al.*, "The Relative Safety of Ephedra Compared With Other Herbal Products," *Annals of Internal Medicine*, vol. 138, pp. 468–471, 2003.

136. Morgenstern, L. B., C. M. Viscoli, W. N. Kernan, *et al.*, "Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke," *Neurology*, vol. 60, pp. 132–135, 2003.

137. Food and Drug Administration, Policy and Guidance Handbook For FDA Advisory Committees, pp. 113–114, 1994.

138. Food and Drug Administration, Nightingale, S. L., FDA "Dear Colleague" Letter Regarding the Research on Eosinophilia-Myalgia Syndrome and Current Regulatory Status of L-*Tryptophan*, 1992 (*http://www.cfsan.fda.gov/~dms/ds-ltr3.html*).

139. Chyka, P. A., McCommon, S. W., "Reporting of adverse drug reactions by poison control centres in the U.S.," *Drug Safety*, vol. 23, pp. 87–93, 2000.

140. Office of Management and Budget: Regulatory Analysis, Circular A–4 (*http://www.whitehouse.gov/omb/circulars/a004/a-4.html*), 2003.

141. Shekelle P, S. Morton, M. Maglione, *et al.*, "Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. Evidence Report/Technology Assessment," No. 76 (Prepared by Southern California Evidence-Based Practice Center, RAND, under Contract No. 290–97–0001, Task Order No. 9), AHRQ Publication No. 03–E022, Rockville, MD, Agency for Healthcare Research and Quality, Table 23, 2003.

142. Centers for Disease Control and Prevention, "Life Expectancy" (Data are for U.S. in 2001). National Center for Health Statistics, Centers for Disease Control and Prevention, U. S. Department of Health and Human Services (*http://www.cdc.gov/nchs/fastats/lifexpec.htm*), accessed on December 9, 2003.

143. Derdeyn, C. P., Powers, and W. J., "Cost-Effectiveness of Screening for Asymptomatic Carotid Atherosclerotic Disease," *Stroke*, vol. 27, pp. 1944–1950, 1996.

144. Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project, 2001 National Statistics, The "National Bill" for Conditions Treated in Hospitals (Top 100 Clinical Classifications Software (CCS) Diagnoses), (*http://www.hcup.ahrq.gov/HCUPnet.asp*), 2001 .

145. GNC Plans to Drop Ephedra Private-Label Supplements, *FDC Reports—Tan Sheet*, pp. 11–12, 1996.

146. Redfearn, S., "Ephedra Products Thin Out: Braced for the Worst, Makers Sell New Herbs," *The Washington Post*, HE01, 2003 (*http://www.washingtonpost.com/wp-dyn/articles/A52270–2003Jan13.html*).

147. Letter Correction: The Relative Safety of Ephedra Compared with Other Herbal Products, *Annals of Internal Medicine*, vol. 138, pp. 1012, 2003 (*http://www.annals.org/cgi/content/full/138/12/1012*), accessed on December 11, 2003.

148. Dickinson, A., Letter, "The Relative Safety of Ephedra Compared With Other Herbal Products," *Annals of Internal Medicine*, vol. 139, pp. 385–386 (*http://www.annals.org/cgi/content/full/139/5__Part__1/385–b*) 2003, accessed on September 2, 2003.

149. Nutrition Business Journal, 2002 Facts and Stats about Dietary Supplements (obtained from *http://www.nnfa.org/facts*), 2002.

150. Kaufman, D. W., Kelly, J. P., Mitchell, A. A., "Use of Ephedra-Containing Products in the U.S. Population," *Data from the Slone Survey*, FDA Docket No. 1995N–0304, emc126, vol. 297, 2003.

151. Research Triangle Institute, "Cost of Reformulating Foods and Cosmetics," Final Report, Report Prepared for the Food and Drug Administration, RTI Project Number 08184.003, 2002.

152. Gugliotta, G., "Ephedra Lawsuits Show Big Increase," *The Washington Post*, July 23, 2000, (*http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A25415-2000Jul21&notFound=true*), accessed on February 3, 2004.

153. Gugliotta, G., "Woman Wins $13.3 Million Against Dietary Company," *The Washington Post*, February 2, 2001 (*http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A40923-2001Feb7&notFound=true*), accessed on February 3, 2004.

154. Prevention Magazine, "Consumer Use of Dietary Supplements," 1999.

155. National Consumers League, National Consumers League's Survey of Consumers Using Over-the-Counter (OTC) Medications, 2003.

156. Geiger, C. J., "Health Claims: History, Current Regulatory Status, and Consumer Research," *Journal of the American Dietetic Association*, vol. 98, pp. 1312–1322, 1998.

157. MacKinnon, D. P., L. Nohre, J. Cheong, *et al.*, "Longitudinal Relationship Between the Alcohol Warning Label and Alcohol Consumption," *Journal of Studies on Alcohol*, vol. 62, pp. 221–227, 2001.

158. Food and Drug Administration, Memorandum: Label Analysis for Dietary Supplements Containing Ephedrine Alkaloids, January 28, 2004.

159. Research Triangle Institute, Dietary Supplement Sales Information, Supplement to the Final Report, Report Prepared for the Food and Drug Administration, Contract No. 223–96–2290 Task Order 4:1999 (*http://www.foodriskclearinghouse.umd.edu/dspd.htm*), accessed on October 1999.

160. Research Triangle Institute, Survey of Manufacturing Practices in the Dietary Supplement Industry. Final Report, Report prepared for the Food and Drug Administration, RTI Project Number 6673–6:2000 (*http://www.foodriskclearinghouse.umd.edu/smpds.htm*), accessed on May 17, 2000.

161. Office of Management and Budget, *Guidance for Implementing E.O. 13132, "Federalism,"* October 28, 1999.

List of Subjects in 21 CFR Part 119

Dietary ingredients, Dietary supplements, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 119 is added as follows:

■ 1. Part 119 consisting of § 119.1 is added to read as follows:

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

Authority: 21 U.S.C. 321, 342, 343, 371.

Dated: January 28, 2004.
Mark B. McClellan,
Commissioner of Food and Drugs.

Dated: February 4, 2004.
Tommy G. Thompson,
Secretary of Health and Human Services.
[FR Doc. 04–2912 Filed 2–6–04; 2:00 pm]
BILLING CODE 4160–01–S

Federal Register

Wednesday,
February 11, 2004

Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Part 36

Noise Stringency Increase for Single-Engine Propeller-Driven Small Airplanes; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 36

[Docket No. FAA–2004–17041]

RIN 2120–AH44

Noise Stringency Increase for Single-Engine Propeller-Driven Small Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA is proposing a change to the noise limits for propeller-driven small airplanes. The proposal is based on the noise limit change adopted by the International Civil Aviation Organization (ICAO) Annex 16 on February 26, 1999. The Federal Aviation Administration (FAA), the European Joint Aviation Authorities (JAA), and representatives from the United States and European propeller-driven small airplane industries developed the ICAO Annex 16 noise limit change in a joint effort. The proposed change would provide nearly uniform noise certification standards for airplanes certificated in the United States and in the JAA countries. The harmonization of the noise limits would simplify airworthiness approvals for import and export purposes.

DATES: Send your comments on or before June 10, 2004.

ADDRESSES: You may send comments (identified by Docket Number FAA–2004–17041) using any of the following methods:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Fax: 1–202–493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For more information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read background documents or comments received, go to *http://dms.dot.gov* at any time or 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.

FOR FURTHER INFORMATION CONTACT: Mehmet Marsan, Office of Environment and Energy (AEE), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7703.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, 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 this proposed rulemaking. 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 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also review the docket using the Internet at the Web address in the **ADDRESSES** section.

Privacy Act: Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

Before acting on this proposal, 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 this proposal 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 to you.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

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

(2) Visiting the Office of Rulemaking's Web page at *http://www.faa.gov/avr/arm/index.cfm;* or

(3) Accessing the Government Printing Office's Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

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

Background

Current Regulations

Under 49 U.S.C. 44715, the Administrator of the Federal Aviation Administration is directed to prescribe "standards to measure aircraft noise and sonic boom; * * * and regulations to control and abate aircraft noise and sonic boom." Part 36 of title 14 of the Code of Federal Regulations contains the FAA's noise standards and regulations that apply to the issuance of type certificates for all types of aircraft. The standards and requirements that apply to propeller-driven small airplanes and propeller-driven commuter category airplanes are found in § 36.501 and Appendix G to part 36. Appendix G was added to part 36 in 1988 to require actual takeoff noise tests instead of the level flyover test that was formerly required under Appendix F, for airplanes for which certification tests were completed before December 22, 1988.

Appendix G specifies the test conditions, procedures, and noise levels necessary to demonstrate compliance with certification requirements for propeller driven small airplanes and propeller-driven, commuter category airplanes.

Synopsis of the Proposal

In June 1995, the ICAO Committee on Aviation and Environmental Protection (CAEP) met in Montreal, Canada. Representatives that attended the meeting were from the Joint Aviation Authorities (JAA) Council, which consists of JAA members from European countries, the U.S. and European aviation industries, and the FAA. At the meeting, the need to study the environmental impact of propeller-driven small airplane noise was identified and added to the work plan of CAEP's aircraft noise working group.

The aircraft noise working group formed a task group to study the environmental impact of propeller-driven small airplane noise. The task group was also asked to recommend remedies to reduce environmental impact depending on the study results, such as a stringency increase, operational limitations, and economic incentives. During the initial meetings, the task group agreed that it was important to base any remedy on the current technology, and that any changes recommended would be aimed at preventing noise levels from increasing beyond the best current technology in production.

In subsequent meetings, the task group concluded that the noise problem from propeller-driven small airplanes is regional in nature and characterized primarily by training flights using single-engine airplanes. This conclusion by the task group led to the decision to limit its review of available technology to noise abatement of single-engine small propeller-driven airplanes. The task group agreed that the multi-engine small propeller airplanes were not the noise problem because single-engine airplanes are the ones most frequently used for training.

The task group compiled a database of noise certification level and performance data for each model of single-engine small propeller-driven airplanes in production. The purpose of the database was to identify the effectiveness of available noise abatement technologies applicable to single-engine propeller-driven airplanes that would not affect airworthiness of the airplanes.

The task group studied several stringency options for the airplanes in the database, and decided to propose new noise stringency levels that are at the noise levels of current production airplanes. The proposed noise stringency level reflects the current noise abatement technology that is applied to the single-engine propeller-driven small airplanes in production. Raising the stringency to the level of current production guarantees that future designs do not generate greater noise levels than current production airplanes.

The proposed rule includes a 6 dBA noise limit reduction for single-engine propeller-driven small airplanes having maximum take-off weight less than 1,257 lb. (570 kg), and a 3 dBA noise limit reduction for airplanes with weights above 3,307 lb. (1,500 kg). The new limits will apply to new type certificates (TC's) and Supplemental Type Certificates (STC's) for which application is made after November 4, 2004.

Section-by-Section Analysis

Section G36.301 Aircraft Noise Limits

Current § G36.301(b) covers both single and multi-engine small propeller driven airplanes. These current noise limits are not changing for multi-engine airplanes and the proposal changes the application of paragraph (b) to multi-engine airplanes only. We are proposing a new paragraph (c) for the single-engine airplanes.

Proposed new paragraph (c) would require a 6 dBA noise limit reduction for single-engine propeller-driven small airplanes having maximum take-off weight less than 1,257 lb. (570 kg) and a 3 dBA noise limit reduction for airplanes with weights above 3,307 lb. (1,500 kg). The noise limit would increase at a rate of 10.75 dB per doubling of weight between 1,257 lb. and 3,307 lb. The proposed change would ensure that the noise level of single-engine propeller-driven small airplanes is held to that appropriate for current noise abatement technology.

Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act requires agencies to analyze the economic effect of regulatory changes on small businesses and other small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. In conducting these analyses, the FAA has determined that this proposed rule: (1) Would generate benefits that justify its costs and is not a "significant regulatory action" as defined in the Executive Order; (2) is not significant as defined in the Department of Transportation's Regulatory Policies and Procedures; (3) would not have a significant impact on a substantial number of small entities; (4) would not constitute a barrier to international trade; and (5) would not contain any Federal intergovernmental or private sector mandate. These analyses are summarized here in the preamble.

This proposed rule would make the FAA's single-engine propeller-driven small airplanes noise regulation more consistent with international standards.

The FAA has determined that this proposed rule would provide more uniform noise certification standards for airplanes certificated in the United States and in the Joint Aviation Authorities (JAA) countries and would ensure that future type certificate applicants incorporate at least the current noise reduction technology. The FAA believes that this proposed rule would impose minimal, if any, costs on supplemental type certificate applicants and would impose no cost on type certificate applicants, because airplanes in current production already meet the proposed noise standards.

Initial Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA) of 1980 establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation." To achieve that principal, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

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

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and an RFA is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The FAA believes that very few, if any, small entities that apply for supplemental type certificate would be rejected as a result of the proposed rule, so small entities would incur minimal, if any, costs. The FAA also believes that no new type certificate applicant would fail the more stringent noise standard required by this proposed rule because airplanes in current production already meet the proposed standards. Thus, the FAA has determined that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities, therefore, a regulatory flexibility analysis is not required under the terms of the RFA. The FAA solicits comments with respect to this finding and determination and requests that all comments be accompanied by clear documentation.

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards.

This proposed rule would provide more uniform noise certification standards for airplanes certificated in the United States and in the JAA countries. The harmonization of the noise limits would simplify airworthiness approvals for import and export purposes.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104–4 on March 22, 1995, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure of $100 million or more (when adjusted annually for inflation) in any one year by State, local, and tribal governments in the aggregate, or by the private sector. Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed "significant intergovernmental mandate." A "significant intergovernmental mandate" under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments in the aggregate of $100 million (adjusted annually for inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that, before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan, which, among other things, must provide for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity for these small governments to provide input in the development of regulatory proposals.

This proposed rule does not contain any Federal intergovernmental or private sector mandates. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these proposed regulations.

Executive Order 13132, Federalism

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

Paperwork Reduction Act

There are no requirements for information collection associated with this proposed rule that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), regulations, standards, and exemptions (including those, which if implemented may cause a significant impact on the human environment) qualify for a categorical exclusion. The FAA proposes that this NPRM qualifies for a categorical exclusion because no significant impacts to the environment are expected to result from its implementation.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

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

List of Subjects in 14 CFR Part 36

Aircraft, Noise control.

Proposed Amendments

In consideration of the foregoing, the Federal Aviation Administration proposes to amend part 36 of title 14 Code of Federal Regulations as follows:

PART 36—NOISE STANDARDS: AIRCRAFT TYPE AND AIRWORTHINESS CERTIFICATION

1. The authority citation for part 36 continues to read as follows:

Authority: 49 U.S.C. 4321 *et seq.* 49 U.S.C. 106(g), 40113, 44701–44702, 44704, 44715, sec. 305, Pub. L. 96–193, 94 Stat. 50, 57; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp., p. 902.

2. Section G36.301 of Appendix G is amended by revising the first sentence in paragraph (b); revising Figure G2; and, adding new paragraph (c) to read as follows:

Appendix G to Part 36—Takeoff Noise Requirements for Propeller-Driven Small Airplane and Propeller-Driven Commuter Category Airplane Certification Tests on or After December 22, 1988

* * * * *

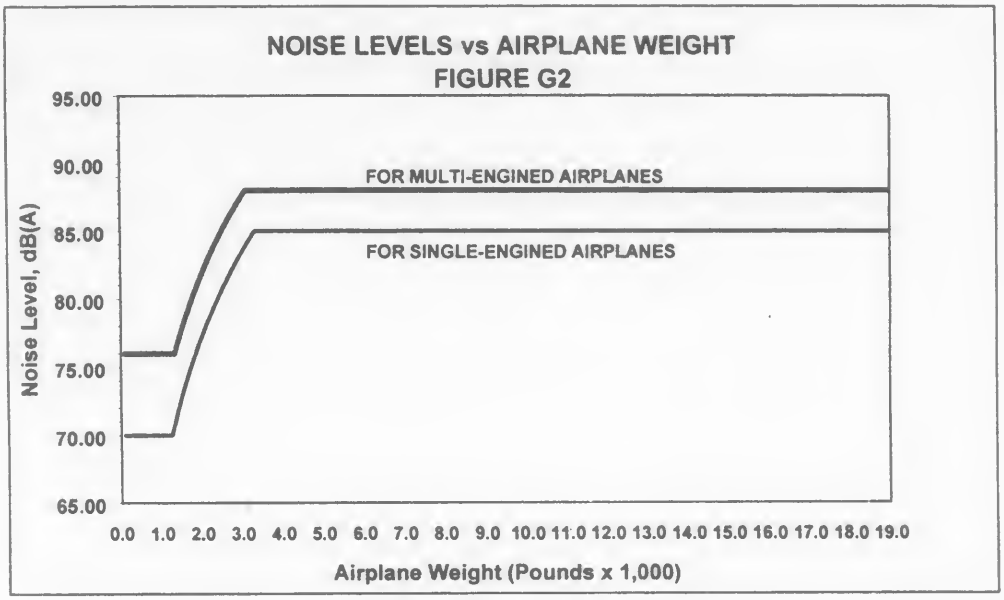
Sec. G36.301 Aircraft noise limits.

(a) * * *

(b) For multi-engine airplanes, the noise level must not exceed 76 dB(A) up to and including aircraft weights of 1,320 pounds (600 kg). * * *

(c) For single-engine airplanes, the noise level must not exceed 70 dB (A) for aircraft having a maximum certificated take-off weight of 1,257 pounds (570 kg) or less. For

aircraft weights greater than 1,257 pounds, the noise limit increases from that point with the logarithm of airplane weight at the rate of 10.75 dB (A) per doubling of weight, until the limit of 85 dB (A) is reached, after which the limit is constant up to and including 19,000 pounds (8,618 kg). Figure G2 depicts noise level limits for airplane weights for single-engine airplanes.



Issued in Washington, DC, on February 4, 2004.

Paul R. Dykeman,

Deputy Director of Environment and Energy.

[FR Doc. 04–2891 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–13–P

Federal Register

Wednesday,
February 11, 2004

Part V

Department of Labor

Employee Benefits Security Administration

Publication of Year 2003 Form M–1 With Electronic Filing Option; Notice

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Publication of Year 2003 Form M–1 With Electronic Filing Option

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice on the availability of the Year 2003 Form M–1 with electronic filing option.

SUMMARY: This document announces the availability of the Year 2003 Form M–1, Annual Report for Multiple Employer Welfare Arrangements and Certain Entities Claiming Exception. A copy of this new form is attached. It is substantively identical to the 2002 Form M–1, except that 2003 filings may be made electronically over the Internet.

FOR FURTHER INFORMATION CONTACT: For inquiries regarding the Form M–1 filing requirement, contact Amy J. Turner or Katina W. Lee, Office of Health Plan Standards and Compliance Assistance, at (202) 693–8335. For inquiries regarding electronic filing capability, contact the EBSA computer help desk at (202) 693–8600. Questions on completing the form are being directed to the EBSA Form M–1 help desk at (202) 693–8360.

SUPPLEMENTARY INFORMATION:

I. Background

The Form M–1 is required to be filed under section 101(g) and section 734 of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and 29 CFR 2520.101–2.

II. The Year 2003 Form M–1

This document announces the availability of the Year 2003 Form M–1, Annual Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs). A copy of the new form is attached.

This year's Form M–1 is substantively identical to the Year 2002 Form M–1. However, the filing deadlines for the Year 2003 Form M–1 have been delayed due to the addition of the electronic filing option and to encourage filers to file the 2003 Form M–1 electronically. Specifically, the Year 2003 Form M–1 is now due May 1, 2004, with an extension until July 1, 2004 available.

The Employee Benefits Security Administration (EBSA) is committed to working together with administrators to help them comply with this filing requirement. Additional copies of the Form M–1 are available on the Internet at *http://www.dol.gov/ebsa*. In addition, after printing, copies will be available by calling the EBSA toll-free publication hotline at 1–866–444–EBSA (3272). Questions on completing the form are being directed to the EBSA help desk at (202) 693–8360.

Statutory Authority: 29 U.S.C. 1021–1025, 1027, 1029–31, 1059, 1132, 1134, 1135, 1181–1183, 1181 note, 1185, 1185a–b, 1191, 1191a–c; Secretary of Labor's Order No. 1–2003, 68 FR 5374 (February 2, 2003).

Signed at Washington, DC, this 5th day of February, 2004.

Ann L. Combs,

Assistant Secretary, Employee Benefits Security Administration.

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Form M-1 Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs)

ALERT: Due to increased usage of computer generated forms, the DOL will not mail this package to filers of record next year. The form and instructions will continue to be available upon request.

This package contains the following form and related instructions:

Form M-1
Instructions
Self-Compliance Tool

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Enjoy these additional benefits not available for paper filings:

Greater Accuracy
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If you have additional questions about the Form M-1 filing requirement or the ERISA health coverage requirements, there's help for you.

Form M-1 Filing Requirement

(1) For questions on completing the Form M-1, contact the Employee Benefits Security Administration's (EBSA) Form M-1 help desk at 202-693-8360.

(2) For inquiries regarding electronic filing capability, contact the EBSA computer help desk at 202-693-8600.

(3) For inquiries regarding the Form M-1 filing requirement, contact the Office of Health Plan Standards and Compliance Assistance at 202-693-8335.

ERISA Health Coverage Requirements

(1) For questions about ERISA's health coverage requirements, contact EBSA by calling toll-free 1-866-444-EBSA (3272) or electronically at www.askebsa.dol.gov.

(2) EBSA's Health Benefits Education Campaign offers compliance assistance seminars across the country addressing a wide variety of health care issues, including HIPAA, COBRA and the benefit claims procedure regulation. For information on upcoming compliance assistance seminars, go to www.dol.gov/ebsa/hbec.html.

The Department of Labor's EBSA has many helpful compliance assistance publications on ERISA's health benefits requirements, including:

- MEWAs (Multiple Employer Welfare Arrangements): A Guide to Federal and State Regulation
- Compliance Assistance Guide: Recent Changes in Health Care Law
- Compliance Assistance for Group Health Plans: HIPAA and Other Recent Health Care Laws
- New Health Laws Notice Guide
- Self-Compliance Tool for Part 7 of ERISA: HIPAA and Other Health Care-Related Laws (included as an attachment to this document)
- Your Rights After a Mastectomy . . . Women's Health and Cancer Rights Act of 1998
- Health Benefits Under the Consolidated Omnibus Budget Reconciliation Act (COBRA)
- Compliance Assistance for Group Health and Disability Plans - The Benefit Claims Procedure Regulation

EBSA also has many publications to assist participants and beneficiaries. EBSA's publications are available on the Internet at www.dol.gov/ebsa or by calling toll-free 1-866-444-EBSA (3272).

2003 Form M-1

MEWA/ECE Form

This Form is Open to Public Inspection

Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs)

This report is required to be filed under section 101(g) of the Employee Retirement Income Security Act of 1974 and 29 CFR 2520.101-2.
→ See separate instructions before completing this form.

OMB No. 1210-0116

Department of Labor
Employee Benefits Security Administration

PART I REPORT IDENTIFICATION INFORMATION

Complete either Item **A** or Item **B** (as applicable) and Item **C**.

A If this is an annual report, specify whether it is for:
(*1*) ❑ The 2003 calendar year; or
(*2*) ❑ The fiscal year beginning _____ and ending _____.
mm/dd/yyyy mm/dd/yyyy

B If this is a special filing, specify whether it is:
(*1*) ❑ A 90-day origination report;
(*2*) ❑ An amended report; or
(*3*) ❑ A request for an extension.

C If this is a final report, check here . . . . . → ❑

PART II MEWA OR ECE IDENTIFICATION INFORMATION

1a Name and address of the MEWA or ECE	**1b** Telephone number of the MEWA or ECE
	1c Employer Identification Number (EIN)
	1d Plan Number (PN)
2a Name and address of the administrator of the MEWA or ECE	**2b** Telephone number of the administrator
	2c EIN
	2d E-mail address of the Administrator
3a Name and address of the entity sponsoring the MEWA or ECE	**3b** Telephone number of the sponsor
	3c EIN

PART III REGISTRATION INFORMATION

4 Specify the most recent date the MEWA or ECE was originated . . . . . → _____

5 Complete the following chart. (See Instructions for **Item 5**)

5a	5b	5c	5d	5e	5f	5g
Enter all States where the entity provides coverage.	Is the entity a licensed health insurance issuer in this State?	If you answer "yes" to **5b**, list any NAIC number.	If you answer "no" to **5b**, is the entity fully insured?	If you answer "yes" to **5d**, enter the name of the insurer and its NAIC number.	Does the entity purchase stop-loss coverage?	If you answer "yes" to **5f**, enter the name of the stop-loss insurer and its NAIC number.
	❑ Yes ❑ No		❑ Yes ❑ No		❑ Yes ❑ No	
	❑ Yes ❑ No		❑ Yes ❑ No		❑ Yes ❑ No	
	❑ Yes ❑ No		❑ Yes ❑ No		❑ Yes ❑ No	
	❑ Yes ❑ No		❑ Yes ❑ No		❑ Yes ❑ No	
	❑ Yes ❑ No		❑ Yes ❑ No		❑ Yes ❑ No	

6 Of the States identified in **Item 5a**, list those States in which the MEWA or ECE conducted 20 percent or more of its business (based on the number of participants receiving coverage for medical care under the MEWA or ECE).

7 Total number of participants covered under the MEWA or ECE . . . . . → _____

PART IV INFORMATION FOR COMPLIANCE WITH PART 7 OF ERISA

8a Has the MEWA or ECE been involved in any litigation or enforcement proceeding in which noncompliance with any provision of Part 7 of Subtitle B of Title I (Part 7) of ERISA was alleged? Answer for the year to which this filing applies and any time since then up to the date of completing this form. Answer "Yes" for any State or Federal litigation or enforcement proceeding (including any administrative proceeding), whether the allegation concerns a provision under Part 7 of ERISA, a corresponding provision under the Internal Revenue Code or Public Health Service Act, a breach of any duty under Title I of ERISA if the underlying violation relates to a requirement under Part 7 of ERISA, or a breach of a contractual obligation if the contract provision relates to a requirement under Part 7 of ERISA. (The instructions to this form contain additional information that may be helpful in answering this question.) . . . . . → ❑ Yes ❑ No

8b If you answered "Yes" to **Item 8a**, identify each litigation or enforcement proceeding. With respect to each, include (if applicable): (1) the case number, (2) the date, (3) the nature of the proceedings, (4) the court, (5) all parties (for example, plaintiffs and defendants or petitioners and respondents), and (6) the disposition. You may answer this question by attaching a copy of the complaint with the name of the MEWA or ECE, the disposition of the case, and the phrase "Item 8b Attachment," noted in the upper right corner.

9 Complete the following. (Note: The instructions to this form contain a Self-Compliance Tool which may be helpful in completing this item. Please read the instructions carefully before answering the following questions.)

9a Is the coverage provided by the MEWA or ECE in compliance with the portability provisions of the Health Insurance Portability and Accountability Act of 1996 and the Department of Labor's (Department's) regulations issued thereunder? (See Part I of the Self-Compliance Tool) . . . . . →	❑ Yes	❑ No	❑ N/A
9b Is the coverage provided by the MEWA or ECE in compliance with the Mental Health Parity Act of 1996 and the Department's regulations issued thereunder? (See Part II of the Self-Compliance Tool) . . . . . →	❑ Yes	❑ No	❑ N/A
9c Is the coverage provided by the MEWA or ECE in compliance with the Newborns' and Mothers' Health Protection Act of 1996 and the Department's regulations issued thereunder? (See Part III of the Self-Compliance Tool) . . . . . →	❑ Yes	❑ No	❑ N/A
9d Is the coverage provided by the MEWA or ECE in compliance with the Women's Health and Cancer Rights Act of 1998? (See Part IV of the Self-Compliance Tool) . . . . . →	❑ Yes	❑ No	❑ N/A

IF MORE SPACE IS REQUIRED FOR ANY ITEM, YOU MAY ATTACH ADDITIONAL PAGES. (SEE INSTRUCTIONS SECTION 2.4)

Caution: *Penalties may apply in the case of a late or incomplete filing of this report.*

Under penalty of perjury and other penalties set forth in the instructions, I declare that I have examined this report, including any accompanying attachments, and to the best of my knowledge and belief, it is true and correct. Under penalty of perjury and other penalties set forth in the instructions, I also declare that, unless this is an extension request, this report is complete.

Signature of administrator → _____ Date → _____

Type or print name of administrator → _____

Department of Labor
Employee Benefits Security Administration

Year 2003 Instructions for Form M-1

Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exception (ECEs)

ERISA refers to the Employee Retirement Income Security Act of 1974, as amended

Changes to Note for 2003

- Part II of the Form - A new line 2(d) has been added requesting the email address of the MEWA or ECE administrator. At the administrator's discretion, the 2003 Form M-1 can be filed electronically with the Department of Labor (Department). Inclusion of an email address allows the Department to contact the administrator in the event problems arise, particularly with an electronic filing.
- The voluntary worksheets have been replaced with the Employee Benefits Security Administration's (EBSA's) new Self-Compliance Tool.
- Section 1.2 of the Instructions has been amended to coincide with the Department's recently published final regulations governing reporting by MEWAs and certain other entities that offer or provide coverage for medical care to employees of two or more employers (29 CFR 2520.101-2).
- Section 1.2 has also been amended to eliminate good faith determinations regarding whether an entity is an entity claiming exception (ECE). For guidance regarding ECE determinations see the Department's final regulations at 29 CFR 2510.3-40.
- The deadline for this year's Form M-1 has been extended due to the new electronic feature. The Year 2003 Form M-1 is now due May 1, 2004, with an extension until July 1, 2004, available to give plan administrators time to prepare their 2003 Form M-1 information and to encourage the use of the new electronic filing option.

Introduction

This form is required to be filed under sections 101(g) and 734 of ERISA and 29 CFR 2520.101-2.

The Department of Labor, EBSA, is committed to working together with administrators to help them comply with this filing requirement. Additional copies of the Form M-1 are available by calling the **EBSA toll-free hotline at 1-866-444-3272** and on the Internet at: **www.dol.gov/ebsa**. If you have any questions (such as whether you are required to file this report) or if you need any assistance in completing this report, please call the **EBSA Form M-1 help desk at (202) 693-8360.**

All Form M-1 reports are subject to a computerized review. It is in the filer's best interest that the responses accurately reflect the circumstances they were designed to report.

Contents

The instructions are divided into three main sections.

SECTION 1

1.1 Definitions

"Administrator"
For purposes of this report, the "administrator" is the person specifically designated by the terms of the MEWA or ECE. However, if the MEWA or ECE is a group health plan and the administrator is not so designated, the "plan sponsor" is the administrator. ("Plan sponsor" is defined in ERISA section 3(16)(B) as (i) the employer in the case of an employee benefit plan established or maintained by a single employer; (ii) the employee organization in the case of a plan established or maintained by an employee organization; or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan.) Moreover, in the case of a MEWA or ECE for which an administrator is not designated and a plan sponsor cannot be identified, the administrator is the person or persons actually responsible (whether or not so designated under the terms of the MEWA or ECE) for the control, disposition, or management of the cash or property received by or contributed to the MEWA or ECE, irrespective of whether such control, disposition, or management is exercised directly by such person or persons or indirectly through an agent or trustee designated by such person or persons.

"Employer Identification Number" or "EIN"
An EIN is a nine-digit employer identification number (for example, 00-1234567) that has been assigned by the IRS. Entities that do not have an EIN should apply for one on Form SS-4, Application for Employer Identification Number as soon as possible. You can obtain Form SS-4 by calling 1-800-TAX-FORM (1-800-829-3676) or at the IRS website at www.irs.gov. EBSA does NOT issue EINs.

"Entity Claiming Exception" or "ECE"
For purposes of this report, the term "entity claiming exception" or "ECE" means any plan or other arrangement that is established or maintained for the purpose of offering or providing medical benefits to the employees of two or more employers (including one or more self-employed individuals), or to their beneficiaries, and that claims it is not a MEWA because the plan or other arrangement claims the exception relating to plans established or maintained pursuant to one or more collective bargaining agreements (see section 3(40)(A)(i) of ERISA and 29 CFR 2510.3-40 of the Department's regulations.)

The administrator of an ECE must file this report each year for the first 3 years after the ECE is "originated." (Warning: An ECE may be "originated" more than once. Each time an ECE is "originated" more filings are triggered.)

"Employee Welfare Benefit Plan"
In general, an employee welfare benefit plan means any plan, fund, or program established or maintained by an employer or by an employee organization, or by both, to the extent such plan, fund, or program provides its participants or beneficiaries the benefits listed in section 3(1) of ERISA (including benefits for medical care).

"Excepted Benefits"
Part 7 of Subtitle B of Title I (Part 7) of ERISA does not apply to any group health plan or group health insurance issuer in relation to its provision of excepted benefits.

Certain benefits that are generally not health coverage are excepted in all circumstances. These benefits are: coverage only for accident (including accidental death and dismemberment), disability income insurance, liability insurance (including general liability insurance and automobile liability insurance), coverage issued as a supplement to liability insurance, workers' compensation or similar insurance, automobile medical payment insurance, credit-only insurance (for example, mortgage insurance), and coverage for on-site medical clinics.

Other benefits that generally are health coverage are excepted if certain conditions are met. Specifically, limited scope dental benefits, limited scope vision benefits, and long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of the group health plan. For more information on these limited excepted benefits, see the Department of Labor's regulations at 29 CFR 2590.732(b)(3).

In addition, noncoordinated benefits may be excepted benefits. The term "noncoordinated benefits" refers to coverage for a specified disease or illness (such as cancer-only coverage) or hospital indemnity or other fixed dollar indemnity insurance (such as insurance that pays $100/day for a hospital stay as its only insurance benefit), if three conditions are met. First, the benefits must be provided under a separate policy, certificate, or contract of insurance. Second, there can be no coordination between the provision of these benefits and another exclusion of benefits under a group health plan maintained by the same plan sponsor. Third, benefits must be paid without regard to whether benefits are provided with respect to the same event under a group health plan maintained by the same plan sponsor. For more information on these noncoordinated excepted benefits, see the Department of Labor's regulations at 29 CFR 2590.732(b)(4).

Finally, supplemental benefits may be excepted if certain conditions are met. Specifically, the benefits are excepted only if they are provided under a separate policy, certificate or contract of insurance, and the benefits are medicare supplemental (commonly known as "Medigap" or "MedSupp") policies, TRICARE supplements, or supplements to certain employer group health plans. Such supplemental coverage cannot duplicate primary coverage and must be specifically designed to fill gaps in primary coverage, coinsurance, or deductibles.

Note that retiree coverage under a group health plan that coordinates with Medicare may serve a supplemental function similar to that of a Medigap policy. However, such employer-provided retiree "wrap around" benefits are not excepted benefits (because they are expressly excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Social Security Act). For more information on supplemental excepted benefits, see the Department of Labor's regulations at 29 CFR 2590.732(b)(5).

"Group Health Plan"
In general, a group health plan means an employee welfare benefit plan to the extent that the plan provides benefits for medical care to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. See ERISA section 733(a).

"Health Insurance Issuer" or "Issuer"
The term "health insurance issuer" or "issuer" is defined, in pertinent part, in §2590.701-2 of the Department's regulations as "an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law which regulates insurance . . . . Such term does not include a group health plan."

"Multiple Employer Welfare Arrangement" or "MEWA"
In general, a multiple employer welfare arrangement (MEWA) is an employee welfare benefit plan or other arrangement that is established or maintained for the purpose of offering or providing medical benefits to the employees of two or more employers (including one or more self-employed individuals), or to their beneficiaries, except that the term does not include any such plan or other arrangement that is established or maintained under or pursuant to one or more agreements that the Secretary finds to be collective bargaining agreements, by a rural electric cooperative, or by a rural telephone cooperative association. See ERISA section 3(40) and 29 CFR 2510.3-40 of the Department's regulations. (Note: Many States regulate entities as MEWAs using their own, State definition of the term. Whether or not an entity meets a State's definition of a MEWA for purposes of regulation under State law is a matter of State law.)

For more information on MEWAs, visit EBSA's Web site at **www.dol.gov/ebsa** or call the **EBSA toll-free hotline** at **1-866-444-3272** and ask for the booklet entitled, "MEWAs: Multiple Employer Welfare Arrangements Under the Employee Retirement Income Security Act: A Guide to Federal and State Regulation."

For information on State MEWA regulation, contact your State Insurance Department.

"Originated"
For purposes of this report, a MEWA or ECE is "originated" each time any of the following events occur:

(1) The MEWA or ECE first begins offering or providing coverage for medical care to the employees of two or more employers (including one or more self-employed individuals);

(2) The MEWA or ECE begins offering or providing such coverage after any merger of MEWAs or ECEs (unless all MEWAs or ECEs involved in the merger were last originated at least 3 years prior to the merger); or

(3) The number of employees to which the MEWA or ECE provides coverage for medical care is at least 50 percent greater than the number of such employees on the last day of the previous calendar year (unless such increase is due to a merger with another MEWA or ECE under which all MEWAs and ECEs that participate in the merger were last originated at least 3 years prior to the merger).

Therefore, a MEWA or ECE may be originated more than once.

"Plan Number" or "PN"
A PN is a three-digit number assigned to a plan or other entity by an employer or plan administrator. For plans or other entities providing welfare benefits, the first plan number should be number 501 and additional plans should be numbered consecutively. For MEWAs and ECEs that file a Form 5500 Annual Return/Report of Employee Benefit Plan (Form 5500), the same PN should be used for the Form M-1. (For more information on the Form 5500 you can access **www.efast.dol.gov** or call toll-free at **1-866-463-3278**.)

"Sponsor"
For purposes of this report, the "sponsor" means:

(1) If the MEWA or ECE is a group health plan, the sponsor is the "plan sponsor," which is defined in ERISA section 3(16)(B) as (i) the employer in the case of an employee benefit plan established or maintained by a single employer; (ii) the employee organization in the case of a plan established or maintained by an employee organization; or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan; or

(2) If the MEWA or ECE is not a group health plan, the sponsor is the entity that establishes or maintains the MEWA or ECE.

1.2 Who Must File

General Rules
The administrator of a MEWA generally must file this report for every calendar year, or portion thereof, that the MEWA offers or provides benefits for medical care to the employees of two or more employers (including one or more self-employed individuals). The administrator of an ECE must file the report if the ECE was last originated at any time within 3 years before the annual filing due date. (See the definition of "originated" in Section 1.1 and the discussion of When to File in Section 1.3.) **(Caution:** An ECE may be "originated" more than once. Each time an ECE is "originated," more filings are triggered.)

Exceptions

(1) Irrespective of the general rules (described above), in no event is reporting required by the administrator of a MEWA or ECE if the MEWA or ECE meets any of the following conditions:

(i) It is licensed or authorized to operate as a health insurance issuer in every State in which it offers or provides coverage for medical care to employees (or to their beneficiaries).

(ii) It provides coverage that consists solely of excepted benefits (defined above), which are not subject to Part 7 of ERISA. (However, if the MEWA or ECE provides coverage that consists both of excepted benefits and other benefits for medical care that are not excepted benefits, the administrator of the MEWA or ECE is required to file the Form M-1.)

(iii) It is a group health plan that is not subject to ERISA, including a governmental plan, church plan, or plan maintained only for the purpose of complying with workers' compensation laws within the meaning of sections 4(b)(1), 4(b)(2), or 4(b)(3) of ERISA, respectively.

(iv) It provides coverage only through group health plans that are not covered by ERISA, including governmental plans, church plans, and plans maintained only for the purpose of complying with workers' compensation laws within the meaning of sections 4(b)(1), 4(b)(2), or 4(b)(3) of ERISA, respectively.

(2) In addition, in no event is reporting required by the administrator of an entity that would not constitute a MEWA or ECE but for the following circumstances:

(i) It provides coverage to the employees of two or more trades or businesses that share a common control interest of at least 25 percent at any time during the plan year, applying principles similar to the principles applied under section 414(b) or (c) of the Internal Revenue Code.

(ii) It provides coverage to the employees of two or more employers due to a change in control of businesses (such as a merger or acquisition) that occurs for a purpose other than avoiding Form M-1 filing and is temporary in nature (*i.e.*, it does not extend beyond the end of the plan year in which the change in control occurs).

(iii) It provides coverage to persons (excluding spouses and dependents) who are not employees or former employees of the plan sponsor, such as nonemployee members of the board of directors or independent contractors, and the number of such persons who are not employees or former employees does not exceed one percent of the total number of employees or former employees covered under the arrangement, determined as of the last day of the year to be reported or, in the case of a 90-day origination report, determined as of the 60th day following the origination date.

1.3 When to File

General Rule

The Form M-1 must be filed no later than March 1 following any calendar year for which a filing is required (unless March 1 is a Saturday, Sunday, or federal holiday, in which case the form must be filed no later than the next business day).

Exception for 2003 Filings

The deadline for this year's Form M-1 has been extended from March 1, 2004 to May 1, 2004 and the automatic 60-day extension has been extended from May 1, 2004 to July 1, 2004.

90-Day Origination Report

In general, an expedited filing is also required after a MEWA or ECE is originated. To satisfy this requirement, the administrator must complete and file the Form M-1 within 90 days of the date the MEWA or ECE is originated (unless the last day of the 90-day period is a Saturday, Sunday, or federal holiday, in which case the form must be filed no later than the next business day).

Exception to the 90-Day Origination Report Requirement

No 90-Day Origination Report is required if the entity was originated in October, November, or December.

Extensions of Time

A one-time extension of time to file will automatically be granted if the administrator of the MEWA or ECE requests an extension. To request an extension, the administrator must: (1) complete Parts I and II of the Form M-1 (and check Box B(3) in Part I); (2) sign, date, and type or print the administrator's name at the end of the form; and (3) file this request for extension no later than the normal due date for the Form M-1. In such a case, the administrator will have an additional 60 days to file a completed Form M-1. A copy of this request for extension must be attached to the completed Form M-1 when filed.

1.4 How to File

The 2003 Form M-1 can be filed electronically with the Department of Labor by going to www.askebsa.dol.gov/mewa.

In addition, completed paper copies of the Form M-1 can be sent to:

Public Documents Room, EBSA
Room N-1513, U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

1.5 Penalties

ERISA provides for a civil penalty for failure to file a Form M-1, failure to file a completed Form M-1, and late filings. In the event of no filing, an incomplete filing, or a late filing, a penalty may apply of up to $1,100 a day for each day that the administrator of the MEWA or ECE fails or refuses to file a complete report (or a higher amount if adjusted pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996). In addition, certain other penalties may apply.

SECTION 2

2.1 Year to be Reported

General Rule
The administrator of a MEWA or ECE that is required to file must complete the Form M-1 using the previous calendar year's information. (For example, for a filing due by March 1, 2004, calendar year 2003 information should be used.) See Exception for 2003 Filings in Section 1.3 on when to file.

Fiscal Year Exception
The administrator of a MEWA or ECE that is required to file may report using fiscal year information if the administrator of the MEWA or ECE has at least 6 continuous months of fiscal year information to report. (Thus, for example, for a filing that is due by March 1, 2004, fiscal year 2003 information may be used if the administrator has at least 6 continuous months of fiscal year 2003 information to report.) In this case, the administrator should check Box A(2) in Part I and specify the fiscal year. See Exception for 2003 Filings in Section 1.3 on when to file.

2.2 90-Day Origination Report

When a MEWA or ECE is originated, a 90-Day Origination Report is generally required. (See Section 1.3 on When to File). When filing a 90-Day Origination Report, the administrator is required to complete the Form M-1 using information based on at least 60 continuous days of operation by the MEWA or ECE.

Remember, there is an exception to the 90-Day Origination Report requirement. No 90-Day Origination Report is required if the entity was originated in October, November, or December.

2.3 Signature and Date

For paper filings, the administrator must sign and date the report. The signature must be original. The name of the individual who signed as the administrator must be typed or printed clearly on the line under the signature line.

If filing online, the administrator must safeguard the EBSA-assigned Personal Identification Number (PIN) and acknowledge the online certification that the online filer is the administrator authorized to submit the filing on behalf of the MEWA or ECE. This electronic acknowledgement will bind the administrator to the information submitted on the electronic filing in lieu of an original signature.

2.4 Attaching Additional Pages

For paper filings, if more space is needed to complete any item on the Form M-1, additional pages may be attached. Additional pages must be the same size as this form (8 1/2" x 11") and should include the name of the MEWA or ECE, the Item number, and the word "Attachment" in the upper right corner. In addition, the attachment for any item should be in a format similar to that item on the form.

If filing online, these additional pages may be uploaded online at the web filing site.

2.5 Amended Report

For paper filings, to correct errors and/or omissions on a previously filed Form M-1, submit a completed Form M-1 with Part I, Box B(2) checked and an original signature. When filing an amended report on paper, answer all questions and circle the amended line numbers.

Online filers may file an amended report by selecting *New Filing* at the web filing site and selecting Item B(2) "An amended report."

SECTION 3

Important: "Yes/No" questions must be marked "Yes" or "No," but not both. "N/A" is not an acceptable response unless expressly permitted in the instructions to that line.

3.1 Line-By-Line Instructions

Part I - Report Identification Information
Complete either Item A or Item B, as applicable.

Annual Reports: If this is an annual report, check either box A(1) or box A(2).

Box A(1): Check this box if calendar year information is being used to complete this report. (See Section 2.1 on Year to be Reported.)

Box A(2): Check this box if fiscal year information is being used to complete this report. Also specify the fiscal year. (For example, if fiscal year 2003 information is being used instead of calendar year 2003 information, specify the dates the fiscal year begins and ends.) (See Section 2.1 on Year to be Reported.)

Special Filings: If this is a special filing, check either box B(1), box B(2), or box B(3).

Box B(1): Check this box if the filing is a 90-Day Origination Report. (See Section 1.2 on Who Must File, Section 1.3 on When to File, and Section 2.2 on 90-Day Origination Report.)

Box B(2): Check this box if the filing is an Amended Report. (See Section 2.5 on Amended Reports.)

Box B(3): Check this box if the administrator of the MEWA or ECE is requesting an extension. (See Section 1.3 on When to File.)

Final Reports: Check the box in Item C if the administrator does not intend to file a Form M-1 next year. For example, if this is the third filing following an origination for an ECE, or if a MEWA has ceased operations, the administrator must check this box.

Part II - MEWA or ECE Identification Information

Items 1a through 1d: Enter the name, address, and telephone number of the MEWA or ECE, and any EIN and PN used by the MEWA or ECE in reporting to the Department of Labor or the Internal Revenue Service. If the MEWA or ECE does not have any EINs associated with it, leave Item 1c blank. If the MEWA or ECE does not have any PNs associated with it, leave Item 1d blank. In answering these questions, list only EINs and PNs used by the MEWA or ECE itself and not those used by group health plans or employers that purchase coverage through the MEWA or ECE. For more information on EINs or PNs see Section 1.1 on Definitions.

Items 2a through 2d: Enter the name, address, telephone number and email address of the administrator of the MEWA or ECE, and the EIN used by the administrator in reporting to the Department of Labor or the Internal Revenue Service. For this purpose, use only an EIN associated with the administrator as a separate entity. Do not use any EIN associated with the MEWA or ECE itself. Inclusion of an email address allows the Department of Labor to contact the administrator in the event problems arise, particularly with an electronic filing. For more information on the definition of "administrator," and on EINs, see Section 1.1 on Definitions.

Items 3a through 3c: Enter the name, address, and telephone number of the entity sponsoring the MEWA or ECE, and any EIN used by the sponsor in reporting to the Department of Labor or the Internal Revenue Service. For this purpose, use only an EIN associated with the sponsor. Do not use any EIN associated with the MEWA or ECE itself. For more information on the definition of "sponsor," and on EINs, see Section 1.1 on Definitions. If there is no such entity, leave Item 3 blank and skip to Item 4.

Part III - Registration Information

Item 4: Enter the date the MEWA or ECE was most recently "originated." For this purpose, see the definition of "originated" in Section 1.1.

Item 5: Complete the chart. If the report is a 90-Day Origination Report, complete this item with information that is current as of the 60th day following the origination date. Otherwise, complete this item with information that is current as of the last day of the year to be reported. (See Section 2.1 on Year to be Reported.) When completing the chart, complete Item 5a first. Then for each row, complete Item 5b through Item 5g as it applies to the State listed in Item 5a.

Item 5a. Enter all States in which the MEWA or ECE provides benefits for medical coverage. For this purpose, list the State(s) where the employers (of the employees receiving coverage) are domiciled. In answering this question, a "State" includes any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, and the Northern Mariana Islands. Enter one State per row.

Item 5b. For each State listed in Item 5a, specify whether the MEWA or ECE is licensed or otherwise authorized to operate as a health insurance issuer in the State listed in that row. (For a definition of the term "health insurance issuer," see Section 1.1.) For more information on whether an entity that is a licensed or registered MEWA in a State meets the definition of a health insurance issuer in that State, contact the State Insurance Department.

Item 5c. For each "yes" answer in Item 5b, enter the National Association of Insurance Commissioners (NAIC) number.

Item 5d. For each "no" answer in Item 5b, specify whether the MEWA or ECE is fully insured through one or more health insurance issuers in each State.

Item 5e. For each "yes" answer in Item 5d, enter the name of the insurer and its NAIC number (if available). If there is more than one insurer, enter all insurers and their NAIC numbers (if available).

Item 5f. In each State listed in Item 5a, specify whether the MEWA or ECE has purchased any stop-loss coverage. For this purpose, stop-loss coverage includes any coverage defined by the State as stop-loss coverage. For this purpose, stop-loss coverage also includes any financial reimbursement instrument that is related to liability for the payment of health claims by the MEWA or ECE, including reinsurance and excess loss insurance.

Item 5g. For each "yes" answer in Item 5f, enter the name of the stop-loss insurer and its NAIC number (if available). If there is more than one stop-loss insurer, enter all stop-loss insurers and their NAIC numbers (if available).

Item 6: Of the States identified in Item 5a, identify all States in which the MEWA or ECE conducted 20 percent or more of its business (based on the number of participants receiving coverage for medical care under the MEWA or ECE).

For example, consider a MEWA that offers or provides coverage to the employees of six employers. Two employers are located in State X and 70 participants in the MEWA receive coverage through these two employers. Three employers are located in State Y and 30 participants in the MEWA receive coverage through these three employers. Finally, one employer is located in State Z and 200 participants in the MEWA receive coverage through this employer. In this example, the administrator of the MEWA should specify State X and State Z under Item 6 because the MEWA conducts 23 1/3 percent of its business in State X (70/300 = 23 1/3 percent) and 66 2/3 percent of its business in State Z (200/300 = 66 2/3 percent). However, the administrator should not specify State Y because the MEWA conducts only 10 percent of its business in State Y (30/300 = 10 percent).

If the report is a 90-Day Origination Report, complete this item with information that is current as of the 60th day following the origination date. Otherwise, complete this item with information that is current as of the last day of the year to be reported. (See Section 2.1 on Year to be Reported.)

Item 7: Identify the total number of participants covered under the MEWA or ECE. For more information on determining the number of participants, see the Department of Labor's regulations at 29 CFR 2510.3-3(d).

If the report is a 90-Day Origination Report, complete this item with information that is current as of the 60th day following the origination date. Otherwise, complete this item with information that is current as of the last day of the year to be reported. (See Section 2.1 on Year to be Reported.)

Part IV - Information for Compliance with Part 7 of ERISA

Background Information on Part 7 of ERISA: On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted. On September 26, 1996, both the Mental Health Parity Act of 1996 (MHPA) and the Newborns' and Mothers' Health Protection Act of 1996 (Newborns' Act) were enacted. On October 21, 1998, the Women's Health and Cancer Rights Act of 1998 (WHCRA) was enacted. All of the foregoing laws amended Part 7 of Subtitle B of Title I (Part 7) of ERISA with new requirements for group health plans. With respect to most of these requirements, corresponding provisions are contained in Chapter 100 of Subtitle K of the Internal Revenue Code (Code) and Title XXVII of the Public Health Service Act (PHS Act). These provisions generally are substantively identical.

The Departments of Labor, the Treasury, and Health and Human Services first issued interim final regulations implementing HIPAA's portability, access, and renewability provisions on April 1, 1997 (published in the Federal Register on April 8, 1997, 62 FR 16893). Two clarifications of the HIPAA regulations were published in the Federal Register on December 29, 1997, at 62 FR 67687. Additional interim final regulations and proposed regulations on HIPAA's nondiscrimination provisions were published in the Federal Register on January 8, 2001, at 66 FR 1378. Regulations implementing the MHPA provisions were published in the Federal Register on December 22, 1997, at 62 FR 66931. The sunset date of these regulations has been extended through 2003. See 68 FR 18048 (April 14, 2003). Also, regulations implementing the substantive provisions of the Newborns' Act were published in the Federal Register on October 27, 1998, at 63 FR 57545. Moreover, the notice requirements with respect to group health plans that provide coverage for maternity or newborn infant coverage are described in the Department of Labor's summary plan description content regulations at 2520.102-3(u). Finally, the Department of Labor has published two sets of informal, question-and-answer guidance on WHCRA. These sets of question-and-answer guidance are available on the Department's website at **www.dol.gov/ebsa** and from **EBSA's toll-free hotline at 1-866-444-3272.**

General Information Regarding the Applicability of Part 7: In general, the foregoing provisions apply to group health plans and health insurance issuers in connection with a group health plan.

Many MEWAs and ECEs are group health plans or health insurance issuers. However, even if a MEWA or ECE is neither a group health plan nor a health insurance issuer, if the MEWA or ECE offers or provides benefits for medical care through one or more group health plans, the coverage is required to comply with Part 7 of ERISA and the MEWA or ECE is required to complete Items 8a through 9d.

Relation to Other Laws: States may, under certain circumstances, impose stricter laws with respect to health insurance issuers. Generally, questions concerning State laws should be directed to that State's Insurance Department.

For More Information: EBSA has published four compliance assistance publications on these recent health care laws. The first, "Compliance Assistance Guide: Recent Changes in Health Care Law," includes comprehensive information on HIPAA, MHPA, the Newborns' Act, and WHCRA. The second, "Compliance Assistance for Group Health Plans: HIPAA and Other Recent Health Care Laws" provides key compliance considerations for group health plans. The third, the "New Health Laws Notice Guide" summarizes the new health law notice requirements and includes sample language. The fourth, "Self-Compliance Tool for Part 7 of ERISA: HIPAA and other Health Care-Related Provisions" (Self-Compliance Tool) assists health plans and issuers in assessing their compliance line by line with the health laws and is also attached to the Form M-1. You may obtain all of these publications, or speak to a benefits advisor about these laws, by calling the **EBSA toll-free hotline at 1-866-444-3272.** These booklets are also available on the Internet at: **www.dol.gov/ebsa.**

Items 8a and 8b: With respect to Item 8a, check "yes" or "no" as applicable. For this purpose, do not include any audit that does not result in required corrective action. If you answer "yes" under Item 8a, identify, in Item 8b, any such litigation or enforcement proceeding.

Item 9a: The HIPAA portability requirements added sections 701, 702, and 703 of ERISA.

General Applicability. In general, you must answer "yes" or "no" to this question if you are the administrator of a MEWA or ECE that is a group health plan or if you are providing benefits for medical care to employees through one or more group health plans.

Exceptions. You may answer "N/A" if either of the following paragraphs apply:

(1) The MEWA or ECE is a small health plan (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

(2) The MEWA or ECE offers coverage only to small group health plans (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

Self-Compliance Tool. For purposes of determining if a MEWA or ECE is in compliance with these provisions, Part I of the Self-Compliance Tool may be helpful.

Item 9b: MHPA added section 712 of ERISA.

General Applicability. In general, you must answer "yes" or "no" to this question if you are the administrator of a MEWA or ECE that is a group health plan or if you are providing benefits for medical care to employees through one or more group health plans.

Exceptions. You may answer "N/A" if any of the following paragraphs apply:

(1) The MEWA or ECE is a small group health plan (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

(2) The MEWA or ECE offers coverage only to small group health plans (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

(3) The MEWA or ECE does not provide both medical/surgical benefits and mental health benefits.

(4) The MEWA or ECE offers or provides coverage only to small employers (as described in the small employer exemption contained in section 712(c)(1) of ERISA and §2590.712(e) of the Department's regulations).

(5) The coverage has satisfied the requirements for the increased cost exemption (described in section 712(c)(2) of ERISA and §2590.712(f) of the Department's regulations).

Self-Compliance Tool. For purposes of determining if a MEWA or ECE is in compliance with these provisions, Part II of the Self-Compliance Tool may be helpful.

Item 9c: The Newborns' Act added section 711 of ERISA.

General Applicability. In general, you must answer "yes" or "no" to this question if you are the administrator of a MEWA or ECE that is a group health plan or if you are providing benefits for medical care to employees through one or more group health plans.

Exceptions. You may answer "N/A" if either of the following paragraphs apply:

(1) The MEWA or ECE does not provide benefits for hospital lengths of stay in connection with childbirth.

(2) The MEWA or ECE is subject to State law regulating such coverage, instead of the federal Newborns' Act requirements, in all States identified in Item 5a, in accordance with section 711(f) of ERISA and §2590.711(e) of the Department's regulations.

Self-Compliance Tool. For purposes of determining if a MEWA or ECE is in compliance with these provisions, Part III of the Self-Compliance Tool may be helpful.

Item 9d: WHCRA added section 713 of ERISA.

General Applicability. In general, you must answer "yes" or "no" to this question if you are the administrator of a MEWA or ECE that is a group health plan or if you are providing benefits for medical care to employees through one or more group health plans.

Exceptions. You may answer "N/A" if any of the following paragraphs apply:

(1) The MEWA or ECE is a small health plan (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

(2) The MEWA or ECE offers coverage only to small group health plans (as described in section 732(a) of ERISA and §2590.732(a) of the Department's regulations).

(3) The MEWA or ECE does not provide medical/surgical benefits with respect to a mastectomy.

Self-Compliance Tool. For purposes of determining if a MEWA or ECE is in compliance with these provisions, Part IV of the Self-Compliance Tool may be helpful.

3.2 Self-Compliance Tool

A Self-Compliance Tool, which may be used to help assess an entity's compliance with Part 7 of ERISA, is included on the following pages of these instructions. This tool may also be helpful in answering Items 9a through 9d of the Form M-1.

Paperwork Reduction Act Notice

We ask for the information on this form to carry out the law as specified in ERISA. You are required to give us the information. We need it to determine whether the MEWA or ECE is operating according to law. You are not required to respond to this collection of information unless it displays a current, valid OMB control number.

The average time needed to complete and file the form is estimated below. These times will vary depending on individual circumstances.

Learning about the law or the form: 2 hrs.

Preparing the form: 50 min. - 1 hr. and 35 min.

Self-Compliance Tool for Part 7 of ERISA: HIPAA and Other Health Care-Related Provisions

SPRING 2003

INTRODUCTION

This checklist is a useful self-compliance tool for group health plans, plan sponsors, plan administrators, health insuranee issuers, and other parties to determine whether a group health plan is in eomplianee with the provisions of Part 7 of Subtitle B of Title I (Part 7) of thc Employee Rctiremcnt Ineomc Sccurity Aet of 1974 (ERISA). The Part 7 provisions were added to ERISA by four separate laws: the Health Insuranee Portability and Aeeountability Act of 1996 (HIPAA); the Mental Health Parity Act of 1996 (MHPA); the Newborns' and Mothers' Health Protection Aet of 1996 (Newborns' Act); and the Women's Health and Caneer Rights Aet of 1998 (WHCRA). ERISA is administcred by thc Employee Bcnefits Security Administration (EBSA).

All of the foregoing laws amended Part 7 of ERISA by adding new requirements for group health plans. With respect to most of these requirements, eorresponding provisions are eontained in Chapter 100 of Subtitle K of the Internal Revenue Code (Code) and Part A of Title XXVII of the Publie Health Service Aet (PHS Aet).

Arrangements Subject to Part 7 of ERISA: In general, Part 7 of ERISA applies to group health plans and health insurance issuers in the group market.

- A group health plan means an employee welfare benefit plan to the extent that the plan provides medieal eare (ineluding items and serviees paid for as medieal eare) to employees (including partners in a partnership) or their dependents (defined under the terms of the plan) direetly or through insurance, reimbursement, or otherwise.
- A health insuranee issuer or issuer means an insuranee company, insuranee scrvice, or insurance organization (ineluding a health maintenanee organization (HMO)) that is required to be lieensed to engage in the business of insuranee in a State and that is subjeet to State law that regulates insuranee.
- Group market generally means the markct for health insurance coverage offered in eonneetion with a group health plan.
  - Even though issuers in the group market arc subjcct to Part 7, the Department of Labor eannot cnforee against thcm. Howcvcr, participants may bring a eause of aetion against an issucr for violations of Part 7.
  - States can enforce against issuers for violations of these new health eare laws. Therefore, questions eoneerning issuers or suspected violations by issuers should be referred to the applieable State insuranec departmcnt.

Arrangements Not Subject to Part 7 of ERISA: Certain arrangemcnts that are group health plans are not subject to Part 7. These arrangements are listed below.

- Very Small Group Health Plans are generally not subjeet to Part 7 (except very small group health plans are subjeet to seetion 711 of ERISA, the Newborns' Aet provisions). A very small group health plan is a group health plan that has fewer than two partieipants who are eurrent employees on the first day of the plan year.

- Group health plans are not subject to Part 7 of ERISA in their provision of "excepted benefits." There are several types of "excepted benefits."
  - Certain benefits are always treated as "excepted benefits" because they are **not considered health coverage**, such as accident-only or disability income insurance and workers' compensation insurance.
  - Other benefits are treated as "excepted benefits" if they are **offered separately or are not an integral part of the plan**, including limited-scope dental or vision benefits or long-term care benefits.
  - Moreover, other benefits are treated as "excepted benefits" if they are **offered separately and not coordinated** with benefits under another group health plan, including coverage for a specific disease, and hospital indemnity or other fixed indemnity insurance.
  - Finally, other benefits are treated as "excepted benefits" if they are **offered separately and supplemental** to Medicare, Armed Forces health care coverage, or group health plan coverage.
- Church Plans are not subject to Part 7 because they are not subject to Title I of ERISA. (However, they are generally subject to parallel provisions in the Code. Questions concerning these plans should be referred to the Internal Revenue Service (IRS).)
- Governmental Plans are not subject to Part 7 because they are not subject to Title I of ERISA. (However, nonfederal governmental plans may be subject to parallel provisions in the PHS Act. Questions concerning these plans should be referred to the Department of Health and Human Services (HHS).)

Preemption: Part 7 of ERISA contains new preemption and applicability rules for group health plans and health insurance issuers.

(1) Group Health Plans. In general, section 514 of ERISA continues to apply with respect to group health plans.

(2) Group Health Insurance Issuers.

- With respect to the requirements of section 701 of ERISA, State laws regarding issuers cannot "differ" from the requirements of ERISA section 701, except as listed below:
  - State law may shorten the 6-month "look-back" period prior to the enrollment date to determine what is a preexisting condition;
  - State law may shorten the 12-month (18-month for late enrollees) maximum preexisting condition exclusion period;
  - State law may lengthen the 63-day significant-break-in-coverage period;
  - State law may lengthen the 30-day special enrollment period for newborns, adopted children, and children placed for adoption to enroll in the plan without a preexisting condition exclusion period;
  - State law may expand the prohibitions on conditions and individuals to whom a preexisting condition exclusion period may not be applied beyond the exceptions for newborns, adopted children, and children placed for adoption enrolled within 30 days of birth, adoption and placement for adoption, and pregnancy;
  - State law may require additional special enrollment periods; and
  - State law may reduce the maximum HMO affiliation period to less than 2 months (3 months for late enrollees).
- With respect to all other HIPAA provisions and the MHPA provisions, State laws relating to health insurance issuers continue to apply, except to the extent that the State law "prevents the application of a requirement of" these HIPAA and MHPA provisions.
- With respect to the WHCRA provisions, State law protections may apply to certain health insurance coverage if the State law was in effect on October 21, 1998 (the date of enactment of WHCRA) and the State law requires at least the coverage of reconstructive breast surgery that is required by WHCRA.

(3) Special Applicability Rule. The Newborns' Act contains a special applicability rule. This applicability rule is explained on page 19 of this checklist.

Cumulative List of Checklist Questions for HIPAA and Other Health Care-Related Statutes Added to Part 7 of ERISA			
I. Determining Compliance with the HIPAA Provisions in Part 7 of ERISA			
If you answer "No" to any of the questions below, the group health plan is in violation of the HIPAA provisions in Part 7 of ERISA.			
	YES	**NO**	**N/A**
SECTION A — Limits on Preexisting Condition Exclusions If the plan imposes a preexisting condition exclusion period, the plan must comply with this section. Check for *hidden* preexisting condition exclusion provisions. A hidden preexisting condition exclusion is not designated as a preexisting condition exclusion, but restricts benefits based on when a condition arose in relation to the effective date of coverage. ◆ If the plan imposes a hidden preexisting condition exclusion, the plan may violate many or all of the provisions discussed in this section. For example, if the plan excludes coverage for cosmetic surgery unless it is required by reason of an accidental injury occurring after the effective date of coverage, there could be multiple violations of this SECTION A. If the plan does not impose a preexisting condition exclusion period, including a *hidden* preexisting condition exclusion period, check "N/A" and skip to **SECTION B**			☐
Question 1 — Six-month look-back period **Does the plan comply with the 6-month look-back period requirement?** ..... ◆ A preexisting condition exclusion may apply only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received during the 6-month period ending on an individual's "enrollment date." *See ERISA section 701(a)(1); 29 CFR 2590.701-3(a)(1)(i).* **Note: An individual's enrollment date is the earlier of – (1) the first day of coverage; or (2) the first day of any waiting period for coverage. (Waiting period means the period that must pass before an employee or dependent is eligible to enroll under the terms of the plan. If an employee or dependent enrolls as a late enrollee or special enrollee, any period before such enrollment date is not a waiting period.) Therefore, if the plan has a waiting period, the 6-month look-back period ends on the first day of the waiting period, not the first day of coverage.	☐	☐	

	YES	NO	N/A
Question 2 — 12/18-month look-forward period **Does the plan comply with HIPAA's 12-month (or 18-month) look-forward period requirement?** ..... ◆ The maximum preexisting condition exclusion period is 12 months (18 months for late enrollees), measured from an individual's enrollment date. *See ERISA section 701(a)(2); 29 CFR 2590.701-3(a)(1)(ii).* **Note: If the plan has a waiting period, the 12-month (or 18-month) look-forward period must begin on the first day of the waiting period, not the first day of coverage.	☐	☐	
Question 3 — Offsetting the length of preexisting condition exclusions by creditable coverage **Does the plan offset the length of its preexisting condition exclusion by an individual's creditable coverage?** ..... ◆ The length of the plan's preexisting condition exclusion must be offset by an individual's creditable coverage. However, days of coverage prior to a "significant break in coverage" are not required to be taken into account. Under Federal law, a significant break in coverage is a period of 63 days or more without any health coverage. *See ERISA section 701(a)(3); 29 CFR 2590.701-3(a)(1)(iii) [using ERISA section 701(c) rules for crediting previous coverage].*	☐	☐	
Question 4 — Preexisting condition exclusion on genetic information **Does the plan comply with HIPAA by not imposing a preexisting condition exclusion with respect to genetic information?** ..... ◆ Genetic information alone cannot be treated as a preexisting condition in the absence of a diagnosis of a condition related to such information. *See ERISA section 701(a)(1); 29 CFR 2590.701-3(a)(1)(i) [using ERISA section 701(b)(1) definition of a preexisting condition exclusion].*	☐	☐	
Question 5 — Preexisting condition exclusion on newborns **Does the plan comply with HIPAA by not imposing an impermissible preexisting condition exclusion on newborns?** ..... ◆ The plan generally may not impose a preexisting condition exclusion on a child who enrolls in creditable coverage within 30 days of birth. *See ERISA section 701(d)(1); 29 CFR 2590.701-3(b)(1).*	☐	☐	

	YES	NO	N/A
Question 6 — Preexisting condition exclusion on children adopted or placed for adoption **Does the plan comply with HIPAA by not imposing an impermissible preexisting condition exclusion on adopted children or children placed for adoption?** ..... ◆ The plan generally may not impose a preexisting condition exclusion on a child who enrolls in creditable coverage within 30 days of adoption or placement for adoption. *See ERISA section 701(d)(2); 29 CFR 2590.701-3(b)(2).*	☐	☐	
Question 7 — Preexisting condition exclusion on pregnancy **Does the plan comply with HIPAA by not imposing a preexisting condition exclusion on pregnancy?** ..... ◆ The plan may not impose a preexisting condition exclusion relating to pregnancy. *See ERISA section 701(d)(3); 29 CFR 2590.701-3(b)(4).*	☐	☐	
Question 8 — Adequate general notices of preexisting condition exclusions **Does the plan provide adequate general notices of preexisting condition exclusions?** ..... ◆ A group health plan (or issuer) may not impose a preexisting condition exclusion with respect to a participant or dependent before notifying the participant, in writing, of— ✧ The existence and terms of any preexisting condition exclusion under the plan; and ✧ The rights of individuals to demonstrate creditable coverage (and any applicable waiting periods), including (1) a description of the right of the individual to request a certificate from a prior plan or issuer, if necessary, and (2) a statement that the current plan (or issuer) will assist in obtaining a certificate from any prior plan or issuer, if necessary. *See 29 CFR 2590.701-3(c).* Guidelines for the general notice of preexisting condition exclusion are available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.	☐	☐	
Question 9 — Adequate individual notices of preexisting condition exclusions **Does the plan provide adequate individual notices of preexisting condition exclusions?** ..... ◆ A group health plan (or issuer) seeking to impose a preexisting condition exclusion with respect to an individual must, within a reasonable time following receipt of creditable coverage information, make a determination about the individual's period of creditable coverage.	☐	☐	

	YES	NO	N/A
◆ If the individual does not have enough creditable coverage to completely offset the preexisting condition exclusion period, the plan must then provide, in writing, to the individual— ✧ Its determination of the length of any preexisting condition exclusion that applies to the individual, including the source and substance of any information on which the plan or issuer relied; and ✧ A written explanation of any appeal procedures established by the plan or issuer. The plan must also allow the individual a reasonable opportunity to submit additional evidence of creditable coverage. *See 29 CFR 2590.701-5(d)(2).* ◆ Guidelines for the individual notice of preexisting condition exclusion are available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.			
SECTION B — Compliance with the Certificate of Creditable Coverage Provisions A group health plan (or a group health insurance issuer, on the plan's behalf) must issue complete certificates of creditable coverage (free of charge) automatically to individuals whose coverage under the plan ends, and (free of charge) to individuals upon request. A model certificate that may be used to satisfy this notice requirement is available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa. Check to see that the plan issues complete certificates of creditable coverage within the required time frames. ** Special Accountability Rule for Insured Plans: ◆ Under a special accountability rule in ERISA section 701(e)(1)(C) and 29 CFR 2590.701-5(a)(1)(iii), a health insurance issuer, rather than the plan, may be responsible for providing certificates of creditable coverage by virtue of an agreement between the two that makes the issuer responsible. In this case, the plan cannot be held accountable for a violation of Part 7. (**Note: An agreement with a third-party administrator (TPA) that is not insuring benefits will not transfer responsibility from the plan.) ◆ Despite this special accountability rule under Part 7, other responsibilities, such as a plan administrator's duty to monitor compliance with a contract, remain unaffected. Accordingly, this section of the checklist is organized differently to take into account this special accountability rule.			

	YES	NO	N/A
Question 10 — Automatic certificates of creditable coverage upon loss of coverage **Does the plan provide complete certificates of creditable coverage to individuals automatically upon loss of coverage?** ..... ◆ Plans are required to provide each participant and dependent covered under the plan a certificate, free of charge, when coverage ceases. ◆ If the plan is insured and there is an agreement with the issuer that the issuer is responsible for providing the certificates, check "N/A" and go to **Question 11.** ◆ To be complete, under 29 CFR 2590.701-5(a)(3)(ii), each certificate must include: 1. Date issued; 2. Name of plan; 3. The individual's name and identification information (**Note: Dependent information can be included on the same certificate with the participant information or on a separate certificate. The plan is required to have used reasonable efforts to get dependent information. *See 29 CFR 2590.701-5(a)(5)(i));* 4. Plan administrator (or issuer) name, address, and telephone number; 5. Telephone number for further information (if different); and 6. Individual's creditable coverage information: ✧ Either — (1) that the individual has at least 18 months of creditable coverage; or (2) the date any waiting period (or affiliation period) began and the date creditable coverage began. ✧ Also, either — (1) the date creditable coverage ended; or (2) that creditable coverage is continuing. ✧ Automatic certificates of creditable coverage should reflect the last period of continuous coverage.	☐	☐	☐
Question 11 — Automatic certificate upon loss of coverage — *Issuer Responsibility* **If there is an agreement between the plan and the issuer stating that the issuer is responsible for providing certificates of creditable coverage, does the issuer provide complete certificates?** ..... ◆ Even if the plan is not responsible for issuing certificates of creditable coverage, the plan should monitor issuer compliance with the certification provisions. ◆ If the plan is self-insured, or if there is no such agreement between the plan and the issuer, check "N/A" and skip to **Question 12.**	☐	☐	☐

	YES	NO	N/A
Question 12 — Certificates of creditable coverage upon request **Does the plan provide complete certificates of creditable coverage upon request?** ..... ◆ If the plan is insured and the issuer is responsible for issuing certificates pursuant to an agreement, check "N/A" and go to **Question 13.** ◆ Certificates of creditable coverage must also be provided free of charge upon request to individuals while covered under the plan and for up to 24 months after coverage ends. *See ERISA section 701(e)(1)(A); 29 CFR 2590.701-5(a)(2)(iii).* ◆ Requested certificates of creditable coverage should reflect periods of continuous coverage that an individual had in the 24 months prior to the date of the request (up to 18 months of creditable coverage). *See 29 CFR 2590.701-5(a)(3)(iii).* ◆ The plan should also have a procedure for individuals to request and receive certificates of creditable coverage. *See 29 CFR 2590.701-5(a)(4)(ii).*	☐	☐	☐
Question 13 — Certificates upon request—*Issuer Responsibility* **If the plan is insured and there is an agreement between the plan and the issuer stating that the issuer is responsible for providing certificates of creditable coverage, does the issuer provide complete certificates?** ..... ◆ Even if the plan is not responsible for issuing certificates of creditable coverage, the plan should monitor issuer compliance with the certification provisions. ◆ If the plan is self-insured, or if there is no such agreement between the plan and the issuer, check "N/A" and skip to **Question 14.**	☐	☐	☐
Question 14 — Certificates within required time frames **If the plan issues certificates of creditable coverage, are they issued within the required time frames?** ..... ◆ If the plan is insured and the issuer is responsible for issuing certificates pursuant to an agreement, check "N/A" and go to **Question 15.** ◆ Under 29 CFR 2590.701-5(a)(2)(ii), plans and issuers must furnish an automatic certificate of creditable coverage: ❖ To an individual who is entitled to elect COBRA, at a time no later than when a notice is required to be provided for a qualifying event under COBRA (usually not more than 44 days); ❖ To an individual who loses coverage under the plan and who is not entitled to elect COBRA, within a reasonable time after coverage ceases; and ❖ To an individual who ceases COBRA, within a reasonable time after the plan learns that COBRA has ceased.	☐	☐	☐

	YES	NO	N/A
◆ Plans and issuers must also generally provide a certificate of creditable coverage upon request, at the earliest time that a plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate of creditable coverage. *See 29 CFR 2590.701-5(a)(2)(iii).*			
Question 15 — Certificates within required time frames — *Issuer Responsibility* **If the plan is insured and there is an agreement with the issuer stating that the issuer is responsible for providing certificates of creditable coverage, are those certificates being provided timely?** ..... ◆ Even if the plan is not responsible for issuing certificates of creditable coverage, the plan should monitor issuer compliance with the certification provisions. ◆ If the plan is self-insured, or if there is no such agreement between the plan and the issuer, check "N/A" and skip to **SECTION C.**	☐	☐	☐
SECTION C — Compliance with the Special Enrollment Provisions Group health plans must allow individuals (who are otherwise eligible) to enroll upon certain specified events, if enrollment is requested within 30 days of the event. The plan must provide for special enrollment, as follows:			
Question 16 — Special enrollment upon loss of other coverage **Does the plan provide special enrollment upon loss of other coverage? (The plan must comply with *all* of the following.)** ..... ◆ Plans must permit loss-of-coverage special enrollment upon: (1) loss of eligibility for group health plan coverage or health insurance coverage; **and** (2) termination of employer contributions toward coverage. *See ERISA section 701(f)(1); 29 CFR 2590.701-6(a).* ◆ Plans must permit eligible employees and dependents to special enroll because of a loss of eligibility (other than loss due to failure to pay premiums or termination of coverage for cause -- such as for fraud). ✧ Examples of reasons for loss of eligibility include: legal separation, divorce, death, termination of employment - voluntary or involuntary (with or without electing COBRA), exhaustion of COBRA, reduction in hours, "aging out" under other parent's coverage, or moving out of an HMO's service area. ◆ Plans must permit eligible employees and dependents to special enroll due to termination of employer contributions towards the other coverage whether or not they also lost the other coverage as a result. ◆ Coverage must become effective no later than the first day of the first month following a completed request for enrollment. *See 29 CFR 2590.701-6(a)(7).*	☐	☐	

	YES	NO	N/A
Question 17 — Dependent special enrollment **Does the plan provide special enrollment rights to individuals upon marriage, birth, adoption, and placement for adoption? (The plan must comply with *all* of the following.)** ..... ◆ Plans must permit employees, spouses, **and** new dependents to enroll upon marriage, birth, adoption, and placement for adoption. *See ERISA section 701(f)(2); 29 CFR 2590.701-6(b).* ◆ In the case of marriage, coverage must become effective not later than the first day of the month following a completed request for enrollment. *See 29 CFR 2590.701-6(b)(8)(i).* ◆ In the case of birth, adoption, or placement for adoption, coverage must become effective as of the date of the birth, adoption, or placement for adoption. *See 29 CFR 2590.701-6(b)(8)(ii) and (iii).*	☐	☐	
Question 18 — Notice of special enrollment rights **Does the plan provide notices of special enrollment rights?** ..... ◆ On or before the time an employee is offered the opportunity to enroll in the plan, the plan must provide the employee with a description of the plan's special enrollment rules. ◆ A model description of special enrollment rights is available at 29 CFR 2590.701-6(c) and in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.	☐	☐	
SECTION D — Compliance with the HIPAA Nondiscrimination Provisions Overview. HIPAA prohibits group health plans and health insurance issuers from discriminating against individuals in eligibility and continued eligibility for benefits and in individual premium or contribution rates based on health factors. These health factors include: health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence and participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities), and disability. *See ERISA section 702; 29 CFR 2590.702.* Similarly Situated Individuals. It is important to recognize that the nondiscrimination rules prohibit discrimination within a group of similarly situated individuals. Under 29 CFR 2590.702(d), plans may treat distinct groups of similarly situated individuals differently, if the distinctions between or among the groups are not based on a health factor. If distinguishing among groups of participants, plans and issuers must base distinctions on bona fide employment-based classifications			

	YES	NO	N/A
consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is based on relevant facts and circumstances, such as whether the employer uses the classification for purposes independent of qualification for health coverage. Bona fide employment-based classifications might include: full-time versus part-time employee status; different geographic location; membership in a collective bargaining unit; date of hire or length of service; or differing occupations. In addition, plans may treat participants and beneficiaries as two separate groups of similarly situated individuals. Plans may also distinguish among beneficiaries. Distinctions among groups of beneficiaries may be based on bona fide employment-based classifications of the participant through whom the beneficiary is receiving coverage, relationship to the participant (such as spouse or dependent), marital status, age or student status of dependent children, or any other factor that is not a health factor. Benign Discrimination. The nondiscrimination rules do not prohibit a plan from establishing more favorable rules for eligibility or premium rates for individuals with an adverse health factor, such as a disability. *See 29 CFR 2590.702(g).* Check to see that the plan complies with HIPAA's nondiscrimination provisions as follows:			
Question 19 — Nondiscrimination in rules for eligibility **Does the plan allow individuals eligibility and continued eligibility under the plan regardless of any adverse health factor?** ..... ◆ Examples of plan provisions that violate ERISA section 702(a) because they discriminate in eligibility based on a health factor include - ✧ Plan provisions that require "evidence of insurability," such as passing a physical exam, providing a certification of good health, or demonstrating good health through answers to a health care questionnaire in order to enroll. (This is a violation, even if the plan provision is imposed only at late enrollment.) ◆ Also, note that it may be permissible for plans to require individuals to complete physical exams or health care questionnaires for purposes other than for determining eligibility to enroll in the plan, such as for determining an appropriate blended, aggregate group rate for providing coverage to the plan as a whole.	☐	☐	
Question 20 — Benefit restrictions **Does the plan uniformly provide benefits to participants and beneficiaries?**..... ◆ A plan is not required to provide any benefits, but benefits provided must be uniformly available and any benefit restrictions must be applied uniformly to all similarly situated individuals and cannot be directed at any individual participants or beneficiaries based on a health factor. If benefit exclusions or limitations are applied only to certain individuals based on a health factor, this would violate ERISA section 702(a) and 29 CFR 2590.702(b)(2).	☐	☐	

	YES	NO	N/A
◆ Examples of plan provisions that would be permissible under ERISA section 702(a) include - ❖ A lifetime or annual limit on all benefits, ❖ A lifetime or annual limit on the treatment of a particular condition, ❖ Limits or exclusions for certain types of treatments or drugs, ❖ Limitations based on medical necessity or experimental treatment, and ❖ Cost-sharing, if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on a health factor. ◆ A plan amendment applicable to all similarly situated individuals and made effective no earlier than the first day of the next plan year is not considered directed at individual participants and beneficiaries. *See 29 CFR 2590.702(b)(2)(i)(C).*			
Question 21 — Source-of-injury restrictions **If the plan imposes a source-of-injury restriction, does it comply with the HIPAA nondiscrimination provisions?** ..... ◆ Plans may exclude benefits for the treatment of certain injuries based on the source of that injury, except that plans may not exclude benefits otherwise provided for treatment of an injury if the injury results from an act of domestic violence or a medical condition. *See 29 CFR 2590.702(b)(2)(iii).* An example of a permissible source-of-injury exclusion would include - ❖ A plan provision that provides benefits for head injuries generally, but excludes benefits for head injuries sustained while participating in bungee jumping, as long as the injuries do not result from a medical condition or domestic violence. ◆ An impermissible source-of-injury exclusion would include - ❖ A plan provision that generally provides benefits for medical/surgical benefits, including hospital stays that are medically necessary, but excludes benefits for self-inflicted injuries or attempted suicide. This is impermissible because the plan provision excludes benefits for treatment of injuries that may result from a medical condition (such as depression). ◆ If the plan does not impose a source-of-injury restriction, check "N/A" and skip to **Question 22.**	☐	☐	☐
Question 22 — Nondiscrimination in premiums or contributions **Does the plan comply with HIPAA's nondiscrimination rules regarding individual premium or contribution rates?** ..... ◆ Under ERISA section 702(b) and 29 CFR 2590.702(c), plans may not require an individual to pay a premium or contribution that is greater than a premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health factor. For example, it would be impermissible for a plan to require	☐	☐	

	YES	NO	N/A
certain full-time employees to pay a higher premium than other full-time employees based on their prior claims experience. ◆ Nonetheless, the nondiscrimination rules do not prohibit a plan from providing a reward based on adherence to a bona fide wellness program. *See ERISA section 702(b)(2)(B); 29 CFR 2590.702(c)(3).* Proposed rules describing bona fide wellness programs were published on January 8, 2001 at 66 FR 1421. Essentially, these proposed rules permit rewards that are not contingent on an individual meeting a standard related to a health factor. In addition, these proposed rules permit rewards that are contingent on an individual meeting a standard related to a health factor if: ✧ The reward does not exceed a specified percentage of the total employee-only premium. (Comments were invited as to whether a 10%, 15%, or 20% limitation might be appropriate.) ✧ The program is reasonably designed to promote good health or prevent disease. (For this purpose, a program must allow individuals an opportunity to qualify for the reward at least once each year.) ✧ The reward is available to all similarly situated individuals. In particular, the program must allow a reasonable alternative standard for individuals for whom it is unreasonably difficult due to a medical condition to satisfy the original program standard or for whom it is medically inadvisable to attempt to satisfy the original program standard during that time period. ✧ The plan must also disclose the availability of a reasonable alternative standard in all plan materials describing the terms of the program.			
Question 23 — List billing **Is there compliance with the list billing provisions?** ..... ◆ Under 29 CFR 2590.702(c)(2)(ii), plans and issuers may not charge or quote an employer a different premium for an individual in a group of similarly situated individuals based on a health factor. This practice is commonly referred to as list billing. If an issuer is list billing an employer and the plan is passing the separate and different rates on to the individual participants and beneficiaries, both the plan and the issuer are violating the prohibition against discrimination in premium rates. This does not prevent plans and issuers from taking the health factors of each individual into account in establishing a blended/aggregate rate for providing coverage to the plan.	☐	☐	
Question 24 — Nonconfinement clauses **Is the plan free of any nonconfinement clauses?** ..... ◆ Typically, a nonconfinement clause will deny or delay eligibility for some or all benefits if an individual is confined to a hospital or other health care institution. Sometimes nonconfinement clauses also deny or delay eligibility if an individual cannot perform ordinary life activities. Often a nonconfinement clause is imposed only with respect to dependents, but they may also be imposed with respect to employees. 29 CFR 2590.702(e)(1) explains that these nonconfinement clauses	☐	☐	

	YES	NO	N/A
violate ERISA sections 702(a) (if the clause delays or denies eligibility) and 702(b) (if the clause raises individual premiums).			
Question 25 — Actively-at-work clauses **Is the plan free of any impermissible actively-at-work clauses?** ..... ◆ Typically, actively-at-work provisions delay eligibility for benefits based on an individual being absent from work. 29 CFR 2590.702(e)(2) explains that actively-at-work provisions generally violate ERISA sections 702(a) (if the clause delays or denies eligibility) and 702(b) (if the clause raises individual premiums or contributions), unless absence from work due to a health factor is treated, for purposes of the plan, as if the individual is at work. Nonetheless, an exception provides that a plan may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan before eligibility commences. Further, plans may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in 29 CFR 2590.702(d). For example, a plan that treats full-time and part-time employees differently for other employment-based purposes, such as eligibility for other employee benefits, may distinguish in rules for eligibility under the plan between full-time and part-time employees.	☐	☐	
SECTION E — Compliance with the HMO Affiliation Period Provisions If the plan provides benefits through an HMO and imposes an HMO affiliation period in lieu of a preexisting condition exclusion period, answer **Question 26.** If the plan does not provide benefits through an HMO, or if there is no HMO affiliation period, check "N/A" and go to **Section F.**			☐
Question 26 — HMO affiliation period provisions **Does the plan comply with the limits on HMO affiliation periods?** ..... ◆ An affiliation period is a period of time that must expire before health insurance coverage provided by an HMO becomes effective and during which the HMO is not required to provide benefits. ◆ A group health plan offering coverage through an HMO may impose an affiliation period only if— ❖ No preexisting condition exclusion is imposed; ❖ No premium is charged to a participant or beneficiary for the affiliation period; ❖ The affiliation period is applied uniformly without regard to any health factor; ❖ The affiliation period does not exceed 2 months (or 3 months for late enrollees); ❖ The affiliation period begins on an individual's "enrollment date;" and ❖ The affiliation period runs concurrently with any waiting period. *See ERISA section 701(g); 29 CFR 2590.701-7.*	☐	☐	

	YES	NO	N/A
SECTION F — Compliance with the MEWA or Multiemployer Plan Guaranteed Renewability Provisions If the plan is a multiple employer welfare arrangement (MEWA) or a multiemployer plan, it is required to provide guaranteed renewability of coverage in accordance with ERISA section 703. If the plan is a MEWA or multiemployer plan, it must comply with Question 27. If the plan is not a MEWA or multiemployer plan, check "N/A" and go to **Part II** of this checklist.			☐
Question 27 — Multiemployer plan and MEWA guaranteed renewability **If the plan is a multiemployer plan, or a MEWA, does the plan provide guaranteed renewability?** ◆ Group health plans that are multiemployer plans or MEWAs may not deny an employer continued access to the same or different coverage, other than— ✧ For nonpayment of contributions; ✧ For fraud or other intentional misrepresentation by the employer; ✧ For noncompliance with material plan provisions; ✧ Because the plan is ceasing to offer coverage in a geographic area; ✧ In the case of a plan that offers benefits through a network plan, there is no longer any individual enrolled through the employer who lives, resides or works in the service area of the network plan and the plan applies this paragraph uniformly without regard to the claims experience of employers or any health-related factor in relation to such individuals or dependents; or ✧ For failure to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other agreement requiring or authorizing contributions to the plan, or to employ employees covered by such agreement. *See ERISA section 703.* **Note: The PHS Act contains different guaranteed renewability requirements for issuers. For more information, see PHS Act section 2712.	☐	☐	

II. Determining Compliance with the MHPA Provisions in Part 7 of ERISA			
If you answer "No" to any of the questions below, the group health plan is in violation of the MHPA provisions in Part 7 of ERISA.			
	YES	**NO**	**N/A**
If the plan provides both mental health and medical/surgical benefits, the plan may be subject to MHPA. If this is the case, answer **Questions 28-32.** If the plan does not provide mental health benefits, check "N/A" here and skip to **Part III** of this checklist. Also, the plan may be exempt from MHPA under the small employer (50 employees or fewer) exception or the increased cost exception. (To be eligible for the increased cost exception, the plan must have filed with EBSA and notified participants and beneficiaries.) If the plan is exempt, check "N/A" here and skip to **Part III** of this checklist			☐
Question 28 — Lifetime dollar limit **Does the plan comply with MHPA's rules for lifetime dollar limits on mental health benefits (excluding constructive dollar limits)?** ..... ◆ A plan may not impose a lifetime dollar limit on mental health benefits that is lower than the lifetime dollar limit imposed on medical/surgical benefits. *See ERISA section 712; 29 CFR 2590.712.* (Only limits on what the plan is willing to pay are taken into account. A plan may impose annual dollar out-of-pocket limits on participants and beneficiaries without implicating MHPA.) ** Note: Limits on out-of-network mental health benefits may be lower than limits on medical/surgical benefits if limits on in-network mental health benefits are unlimited, or in parity with medical/surgical limits. *See 29 CFR 2590.712(b)(4), Example 3.* But, limits on inpatient and outpatient mental health benefits must separately be in parity with limits on medical/surgical benefits. *See 29 CFR 2590.712(b)(4), Example 2.*	☐	☐	
Question 29 — Constructive lifetime dollar limit **If the plan imposes a "constructive lifetime dollar limit" on mental health benefits (see explanation and examples below), is the limit *greater than or equal to* that imposed on medical/surgical benefits?** ..... ◆ A lifetime visit limit that is coupled with a maximum dollar amount payable by the plan per visit is, in effect, a lifetime dollar limit. This is referred to as a constructive lifetime dollar limit. ◆ For example, a 100-visit lifetime limit on mental health benefits that is payable to a maximum of $40 per visit is a constructive lifetime dollar limit of $4,000 on mental health benefits. If this limit is less than the limit for medical/surgical benefits (or if there is no limit for medical/surgical benefits), the plan is not in compliance with MHPA.	☐	☐	

	YES	NO	N/A
◆ Again, remember only limits on what the plan is willing to pay are taken into account.			
Question 30 — Annual dollar limit **Does the plan comply with MHPA's rules for annual dollar limits on mental health benefits (excluding constructive dollar limits)?** ..... ◆ A plan may not impose an annual dollar limit on mental health benefits that is lower than the annual dollar limit imposed on medical/surgical benefits. *See ERISA section 712; 29 CFR 2590.712.* ** Note: Limits on out-of-network mental health benefits may be lower than limits on medical/surgical benefits if limits on in-network mental health benefits are unlimited, or in parity with medical/surgical limits. *See 29 CFR 2590.712(b)(4), Example 3.* But, limits on inpatient and outpatient mental health benefits must separately be in parity with limits on medical/surgical benefits. *See 29 CFR 2590.712(b)(4), Example 2.* ◆ Remember only limits on what the plan is willing to pay are taken into account. A plan may impose annual dollar out-of-pocket limit on participants and beneficiaries without implicating MHPA.	☐	☐	
Question 31 — Constructive annual dollar limit **If the plan imposes a "constructive annual dollar limit" on mental health benefits, is the limit *greater than or equal to* that imposed on medical/surgical benefits?** ..... ◆ An annual visit limit that is coupled with a maximum dollar amount payable by the plan per visit is, in effect, an annual dollar limit. This is referred to as a constructive annual dollar limit. ◆ Again, remember only limits on what the plan is willing to pay are taken into account.	☐	☐	
Question 32 — Substance abuse dollars counting against mental health dollar limit **Does the plan *exclude* substance abuse or chemical dependency benefits from its definition of "mental health benefits?"** ..... ◆ If the plan does not impose any explicit or constructive annual or lifetime dollar limits on mental health benefits, check "N/A" and skip to **Part III** of this checklist.	☐	☐	☐

	YES	NO	N/A
◆ If the plan imposes any explicit or constructive annual or lifetime dollar limit on mental health benefits, the plan must not count benefits for substance abuse or chemical dependency against the mental health dollar limit. Instead, benefits for substance abuse and chemical dependency can be counted against a medical/surgical cap, or a separate substance abuse or chemical dependency cap. *See 29 CFR 2590.712(b)(4), Example 4 [using ERISA section 712(e)(4) definition of mental health benefits].*			

III. Determining Compliance with the Newborns' Act Provisions in Part 7 of ERISA			
If you answer "No" to any of the questions below, the group health plan is in violation of the Newborns' Act provisions in Part 7 of ERISA.			
	YES	**NO**	**N/A**
SECTION A — Newborns' Act Substantive Provisions The substantive provisions of the Newborns' Act apply only to certain plans, as follows: If the plan does not provide benefits for hospital stays in connection with childbirth, check "N/A" and go to **Part IV** of this checklist. (Note: Under the Pregnancy Discrimination Act, most plans are required to cover maternity benefits.) ..... Special applicability rule for *insured coverage* that provides benefits for hospital stays in connection with childbirth: If the plan provides benefits for hospital stays in connection with childbirth and is insured, whether the plan is subject to the Newborns' Act depends on State law. Based on a preliminary review of State laws as of July 1, 2002, if the coverage is in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, or Wyoming, it appears that State law applies in lieu of the Federal Newborns' Act. If this is the case, check "N/A" and skip to **SECTION B** .... If the plan provides benefits for hospital stays in connection with childbirth, the plan is insured, and the coverage is in Wisconsin, Puerto Rico, the Virgin Islands, American Samoa, Wake Island, or the Northern Mariana Islands, it appears that the Federal Newborns' Act applies to the plan. If this is the case, answer **Questions 33-36.** *Self-insured* coverage that provides benefits for hospital stays in connection with childbirth: If the plan provides benefits for hospital stays in connection with childbirth and is *self-insured*, the Federal Newborns' Act applies. Answer **Questions 33-36.**		☐	☐
Question 33 — General 48/96-hour stay rule **Does the plan comply with the general 48/96-hour rule?** ..... ◆ Plans generally may not restrict benefits for a hospital length of stay in connection with childbirth to less than 48 hours in the case of a vaginal delivery *(see ERISA section 711(a)(1)(A)(i))*, or less than 96 hours in the case of a cesarean section (*see ERISA section 711(a)(1)(A)(ii)*).	☐	☐	

	YES	NO	N/A
◆ Therefore, the plan cannot deny a mother or her newborn benefits for a 48/96-hour stay based on medical necessity. (A plan may require a mother to notify the plan of a pregnancy to obtain more favorable cost-sharing for the hospital stay. This second type of plan provision is permissible under the Newborns' Act if the cost-sharing is consistent throughout the 48/96-hour stay.) ◆ An attending provider may, however, decide, in consultation with the mother, to discharge the mother or newborn earlier.			
Question 34 — Provider must not be required to obtain authorization from plan **Does the plan defer to the provider for a decision on hospital length of stay within the first 48/96-hour period?** ..... ◆ Plans may not require that a provider (such as a doctor) obtain authorization from the plan to prescribe a 48/96-hour stay. *See ERISA section 711(a)(1)(B); 29 CFR 2590.711(a)(4).*	☐	☐	
Question 35 — Incentives/penalties to mothers or providers **Does the plan comply with the Newborns' Act by avoiding impermissible incentives or penalties with respect to mothers or attending providers?** ..... ◆ Penalties to attending providers to discourage 48/96-hour stays violate ERISA section 711(b)(3) and 29 CFR 2590.711(b)(3)(i). ◆ Incentives to attending providers to encourage early discharges violate ERISA section 711(b)(4) and 29 CFR 2590.711(b)(3)(ii). ◆ Penalties imposed on mothers to discourage 48/96-hour stays violate ERISA section 711(b)(1) and 29 CFR 2590.711(b)(1)(i)(A). ◆ Incentives to mothers to encourage early discharges violate ERISA section 711(b)(2) and 29 CFR 2590.711(b)(1)(i)(B). ✣ An example of this would be if the plan waived the mother's co-payment or deductible if mother or newborn leaves within 24 hours. ◆ Benefits and cost-sharing may not be less favorable for the latter portion of any 48/96-hour hospital stay. In this case less favorable benefits would violate ERISA section 711(b)(5) and 29 CFR 2590.711(b)(2) and less favorable cost-sharing would violate ERISA section 711(c)(3) and 29 CFR 2590.711(c)(3).	☐	☐	

	YES	NO	N/A
SECTION B — Disclosure Provisions Group health plans that provide benefits for hospital stays in connection with childbirth are required to make certain disclosures, as follows:			
Question 36 — Disclosure with respect to hospital lengths of stay in connection with childbirth **Does the plan comply with the notice provisions relating to hospital stays in connection with childbirth?** ..... ◆ Group health plans that provide benefits for hospital stays in connection with childbirth are required to make certain disclosures. *See the Summary Plan Description (SPD) content regulations at 29 CFR 2520.102-3(u).* ◆ Model language for the Newborns' Act disclosure requirement is available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.	☐	☐	

IV. Determining Compliance with the WHCRA Provisions in Part 7 of ERISA			
If you answer "No" to any of the questions below, the group health plan is in violation of the WHCRA provisions in Part 7 of ERISA.			
	YES	**NO**	**N/A**
WHCRA applies only to plans that offer benefits with respect to a mastectomy. If the plan does not offer these benefits, check "N/A" and you are finished with this checklist..... If the plan does offer benefits with respect to a mastectomy, answer **Questions 37-40.**			☐
Question 37 — Four required coverages under WHCRA **Does the plan provide the four coverages required by WHCRA?** ..... ◆ In the case of a participant or beneficiary who is receiving benefits in connection with a mastectomy, the plan shall provide coverage for the following benefits for individuals who elect them — ✧ All stages of reconstruction of the breast on which the mastectomy has been performed; ✧ Surgery and reconstruction of the other breast to produce a symmetrical appearance; ✧ Prostheses; and ✧ Treatment of physical complications of mastectomy, including lymphedemas, in a manner determined in consultation with the attending provider and the patient. *See ERISA section 713(a).* ◆ These required coverages can be subject to annual deductibles and coinsurance provisions if consistent with those established for other benefits under the plan or coverage.	☐	☐	
Question 38 — Annual notice **Does the plan provide annual notices as required by WHCRA?** ..... ◆ Plans must provide notices describing the benefits required under WHCRA upon enrollment in the plan and annually thereafter. *See ERISA section 713(a).* ◆ The annual notice must include— ❖ Information on the availability of benefits under the plan for the treatment of mastectomy-related services, including benefits for reconstructive surgery, surgery to achieve symmetry between the breasts, prostheses, and physical complications resulting from mastectomy (including lymphedemas); and ❖ Information (telephone number, Web address, etc.) on how to obtain a detailed description of the mastectomy-related benefits available under the plan.	☐	☐	

	YES	NO	N/A
◆ Model language for WHCRA's annual notice requirement is available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.			
Question 39 — Enrollment notice **Does the plan provide enrollment notices as required by WHCRA?** ..... ◆ Plans must provide notices describing the benefits required under WHCRA upon enrollment in the plan and annually thereafter. *See ERISA section 713(a).* ◆ The enrollment notice must describe the benefits that WHCRA requires the group health plan to cover. Additionally, the enrollment notice must describe any deductibles and coinsurance limitations applicable to such coverage. (Under WHCRA, coverage of the required benefits may be subject only to deductibles and coinsurance limitations consistent with those established for other benefits under the plan or coverage.) ◆ Model language for WHCRA's enrollment notice requirement is available in EBSA's publication, ***Compliance Assistance Guide: Recent Changes in Health Care Law,*** which is located in the Compliance Assistance section of the agency's Web site at www.dol.gov/ebsa.	☐	☐	
Question 40 — Incentive provisions **Does the plan comply with WHCRA by not providing impermissible incentives or penalties with respect to patients or attending providers?** ..... ◆ A plan may not deny a patient eligibility to enroll or renew coverage solely to avoid WHCRA's requirements under ERISA section 713(c)(1). ◆ In addition, under ERISA section 713(c)(2), a plan may not penalize or offer incentives to an attending provider to induce the provider to furnish care in a manner inconsistent with WHCRA.	☐	☐	

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Wednesday,
February 11, 2004

Part VI

The President

Executive Order 13328—Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction

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Presidential Documents

Title 3—

The President

Executive Order 13328 of February 6, 2004

Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Establishment.* There is established, within the Executive Office of the President for administrative purposes, a Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction (Commission).

Sec. 2. *Mission.* (a) The Commission is established for the purpose of advising the President in the discharge of his constitutional authority under Article II of the Constitution to conduct foreign relations, protect national security, and command the Armed Forces of the United States, in order to ensure the most effective counterproliferation capabilities of the United States and response to the September 11, 2001, terrorist attacks and the ongoing threat of terrorist activity. The Commission shall assess whether the Intelligence Community is sufficiently authorized, organized, equipped, trained, and resourced to identify and warn in a timely manner of, and to support United States Government efforts to respond to, the development and transfer of knowledge, expertise, technologies, materials, and resources associated with the proliferation of Weapons of Mass Destruction, related means of delivery, and other related threats of the 21st Century and their employment by foreign powers (including terrorists, terrorist organizations, and private networks, or other entities or individuals). In doing so, the Commission shall examine the capabilities and challenges of the Intelligence Community to collect, process, analyze, produce, and disseminate information concerning the capabilities, intentions, and activities of such foreign powers relating to the design, development, manufacture, acquisition, possession, proliferation, transfer, testing, potential or threatened use, or use of Weapons of Mass Destruction, related means of delivery, and other related threats of the 21st Century.

(b) With respect to that portion of its examination under paragraph 2(a) of this order that relates to Iraq, the Commission shall specifically examine the Intelligence Community's intelligence prior to the initiation of Operation Iraqi Freedom and compare it with the findings of the Iraq Survey Group and other relevant agencies or organizations concerning the capabilities, intentions, and activities of Iraq relating to the design, development, manufacture, acquisition, possession, proliferation, transfer, testing, potential or threatened use, or use of Weapons of Mass Destruction and related means of delivery.

(c) With respect to its examination under paragraph 2(a) of this order, the Commission shall:

(i) specifically evaluate the challenges of obtaining information regarding the design, development, manufacture, acquisition, possession, proliferation, transfer, testing, potential or threatened use, or use of Weapons of Mass Destruction, related means of delivery, and other related threats of the 21st Century in closed societies; and

(ii) compare the Intelligence Community's intelligence concerning Weapons of Mass Destruction programs and other related threats of the 21st Century in Libya prior to Libya's recent decision to open its programs to inter national scrutiny and in Afghanistan prior to removal of the Taliban government with the current assessments of organizations examining those programs.

(d) The Commission shall submit to the President by March 31, 2005, a report of the findings of the Commission resulting from its examination and its specific recommendations for ensuring that the Intelligence Community of the United States is sufficiently authorized, organized, equipped, trained, and resourced to identify and warn in a timely manner of, and to support United States Government efforts to respond to, the development and transfer of knowledge, expertise, technologies, materials, and resources associated with the proliferation of Weapons of Mass Destruction, related means of delivery, and other related threats of the 21st Century and their employment by foreign powers (including terrorists, terrorist organizations, and private networks, or other entities or individuals). The Central Intelligence Agency and other components of the Intelligence Community shall utilize the Commission and its resulting report. Within 90 days of receiving the Commission's report, the President will consult with the Congress concerning the Commission's report and recommendations, and will propose any appropriate legislative recommendations arising out of the findings of the Commission.

Sec. 3. *Membership.* The Commission shall consist of up to nine members appointed by the President, two of whom the President shall designate as Co-Chairs. Members shall be citizens of the United States. It shall take two-thirds of the members of the Commission to constitute a quorum.

Sec. 4. *Meetings of the Commission and Direction of Its Work.* The Co-Chairs of the Commission shall convene and preside at the meetings of the Commission, determine after consultation with other members of the Commission its agenda, direct its work, and assign responsibilities within the Commission.

Sec. 5. *Access to Information.* (a) To carry out this order, the Commission shall have full and complete access to information relevant to its mission as described in section 2 of this order and in the possession, custody, or control of any executive department or agency to the maximum extent permitted by law and consistent with Executive Order 12958 of April 17, 1995, as amended. Heads of departments and agencies shall promptly furnish such information to the Commission upon request. The Attorney General and the Director of Central Intelligence shall ensure the expeditious processing of all appropriate security clearances necessary for the members of the Commission to fulfill their functions.

(b) Promptly upon commencing its work, the Commission shall adopt, after consultation with the Secretary of Defense, the Attorney General, and the Director of Central Intelligence, rules and procedures of the Commission for physical, communications, computer, document, personnel, and other security in relation to the work of the Commission. The Secretary of Defense, the Attorney General, and the Director of Central Intelligence shall promptly and jointly report to the President their judgment whether the security rules and procedures adopted by the Commission are clearly consistent with the national security and protect against unauthorized disclosure of information required by law or executive order to be protected against such disclosure. The President may at any time modify the security rules or procedures of the Commission to provide the necessary protection.

Sec. 6. *General Provisions.* (a) In implementing this order, the Commission shall solely advise and assist the President.

(b) In performing its functions under this order, the Commission shall, subject to the authority of the President, be independent from any executive department or agency, or of any officer, employee, or agent thereof.

(c) Nothing in this order shall be construed to impair or otherwise affect the authorities of any department, agency, entity, officer, or employee of the United States under applicable law.

(d) Nothing in this order shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(e) The Director of the Office of Administration shall provide or arrange for the provision of administrative support and, with the assistance of the Director of the Office of Management and Budget, ensure funding for the Commission consistent with applicable law. The Director of the Office of Administration shall ensure that such support and funding meets the Commission's reasonable needs and that the manner of provision of support and funding is consistent with the authority of the Commission within the executive branch in the performance of its functions.

(f) Members of the Commission shall serve without compensation for their work on the Commission. Members who are not officers or employees in the executive branch, while engaged in the work of the Commission, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701 through 5707), consistent with the availability of funds.

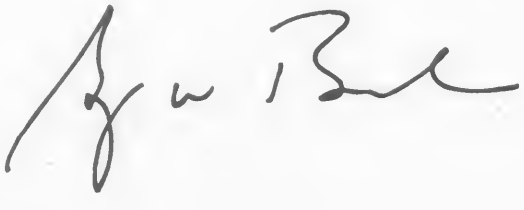
(g) The Commission shall have a staff headed by an Executive Director. The Co-Chairs shall hire and employ, or obtain by assignment or detail from departments and agencies, the staff of the Commission, including the Executive Director.

(h) The term "Intelligence Community" is given the same meaning as contained in section 3(4) of the National Security Act of 1947, as amended (50 U.S.C. 401a(4)).

(i) The term "Weapons of Mass Destruction" is given the same meaning as contained in section 1403(1) of the Defense Against Weapons of Mass Destruction Act of 1996 (50 U.S.C. 2302(1)).

Sec. 7. *Judicial Review.* This order is intended only to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.

Sec. 8. *Termination.* The Commission shall terminate within 60 days after submitting its report.



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[FR Doc. 04–3170
Filed 2–10–04; 8:50 am]
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Wednesday, February 11, 2004

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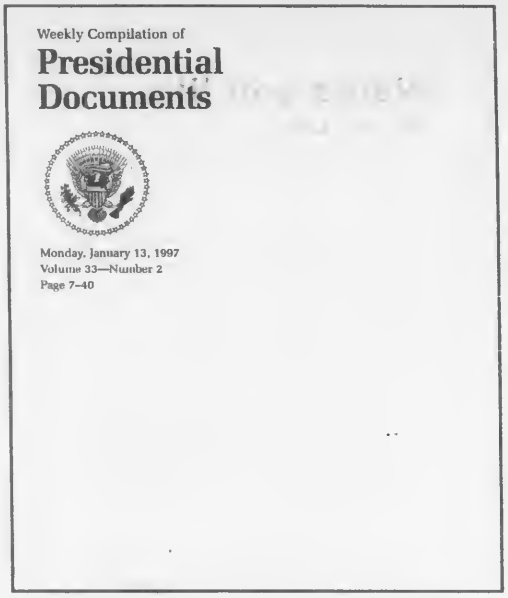

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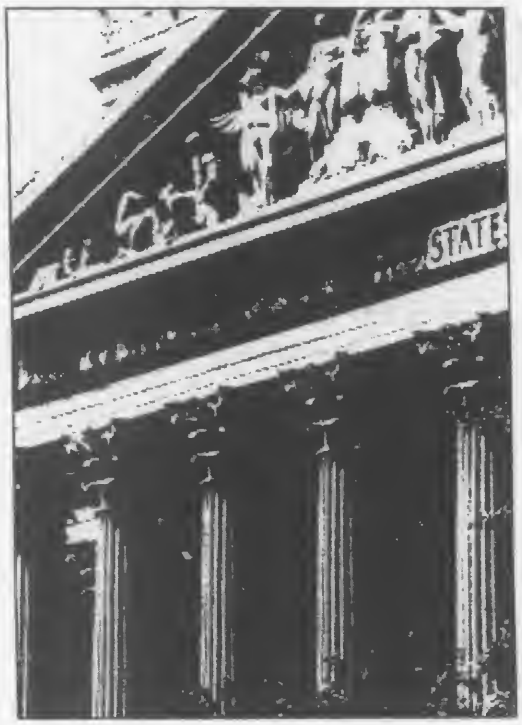

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