may be submitted at any time before 5:00 p.m. on May 14, 1999.

Please note: Comments and exhibits will be made part of the record of the rulemaking proceeding only if they identify the author's name, address and occupation, and if they include a sworn and notarized statement indicating that the comment and/or exhibit is presented based upon the author's personal knowledge and belief. Facsimile copies will be accepted up until the 5:00 p.m. deadline, but the original must then be sent by ordinary mail.

List of Subjects in 7 CFR Part 1361

Administrative practice and procedure, Rulemaking, Milk.

Codification in Code of Federal Regulations

For reasons set forth in the preamble, the Northeast Dairy Compact Commission amends 7 CFR Part 1361 as follows:

PART 1361— RULEMAKIMG PROCEDURES

1. The authority citation for part 1361 continues to read as follows:

Authority: 7 U.S.C. 7256.

2. Section 1361.11 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1361.11 Ex parte communications.

(a) Following notice of a rulemaking proceeding, pursuant to § 1361.3, and prior to the conclusion of a producer referendum, or the final decision of the Commission, whichever is later, no Compact Commission member or Commission staff person shall communicate, either directly or indirectly, in connection with the merits of the rulemaking proceeding with any person having an interest in the proceeding or with any representative of such person.

(b) Following notice of a rulemaking proceeding, pursuant to § 1361.3, and prior to the close of the comment period, pursuant to § 1361.7, Compact Commission members shall not discuss among themselves the merits of the rulemaking proceeding.

* * * * *

Dated: April 8, 1999.

Kenneth M. Becker,

Executive Director.

[FR Doc. 99–9273 Filed 4–13–99; 8:45 am]

BILLING CODE 1650–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 115

Surety Bond Guarantees

AGENCY: Small Business Administration.

ACTION: Final rule.

SUMMARY: This document amends 13 CFR 115.31(a)(2) to conform it to Section 411(c)(3)(B) of the Small Business Investment Act (the ''Act''), as amended by Section 604(d) of the Small Business Reauthorization Act of 1997 (the ''1997 Reauthorization Act''). The 1997 Reauthorization Act added bonds issued on behalf of qualified HUBZone small business concerns to those receiving a 90 percent guarantee under the Surety Bond Guarantee Program. Since this rule only implements the cited statute, it is published in final form without opportunity to comment.

EFFECTIVE DATE: This rule is effective May 14, 1999.

FOR FURTHER INFORMATION CONTACT: Robert J. Moffitt, Associate Administrator, Office of Surety Guarantees, (202) 205–6540.

SUPPLEMENTARY INFORMATION: This amendment only implements the cited statute to include bonds issued by a Prior Approval Surety on behalf of qualified HUBZone small business concerns among those to be covered by a 90 percent guarantee from SBA. The present regulation already provides a 90 percent guarantee for bonds issued on behalf of small disadvantaged concerns.

This change would affect only qualified HUBZone small business concerns that are already eligible to participate in the Surety Bond Guarantee Program. Publishing a proposed rule for notice and comment is unnecessary because the change to the regulation is minimal and SBA has no discretion.

Compliance With Executive Orders 12612, 12778, and 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612.) and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA certifies that this is not a significant regulatory action under E.O. 12866 and will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601–612.) This rule only affects those HUBZone small business concerns who may want to participate in SBA's Surety Bond Guarantee Program.

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA certifies that this rule contains no new reporting or record keeping requirements.

For purposes of E.O. 12612, SBA certifies that this rule would not have any federalism implications warranting the preparation of a Federalism Assessment.

For purposes of E.O. 12778, SBA certifies that this rule is drafted, to the extent practicable, under the standards set forth in Section 2 of that Order.

List of Subjects in 13 CFR Part 115

Surety bond guarantees.

For the reasons stated in the preamble, the Small Business Administration amends 13 CFR part 115 as follows:

PART 115—SURETY BOND GUARANTEES

1. The authority citation for part 115 is revised to read as follows:

Authority: 5 U.S.C. app 3; 15 U.S.C. 687b, 687c, 694a, 694b; Pub. L. 101–574, 104 Stat. 2823 (1990); Pub. L. 105–135.

§ 115.31 [Amended]

2. Amend § 115.31 to revise paragraph (a)(2) to read as follows:

(a) * * *

(2) The bond was issued on behalf of a small business owned and controlled by socially and economically disadvantaged individuals or on behalf of a qualified HUBZone small business concern.

* * * * *

Dated: March 31, 1999.

Aida Alvarez,

Administrator.

[FR Doc. 99–9268 Filed 4–13–99; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–315–AD; Amendment 39–11128; AD 99–08–20]

RIN 2120–AA64

Airworthiness Directives; Lockheed Model L–1011–385 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Lockheed Model L–1011–385 series airplanes, that currently requires a one-time inspection to detect cracking of the bulkhead at fuselage

station (FS) 1363 at butt line 42.5, and repair or additional inspections, if necessary. This amendment adds repetitive inspections to detect cracking of the bulkhead web and bulkhead cap (frame cap) at FS 1363, and repair, if necessary. This amendment is prompted by reports that additional, more extensive, fatigue cracking was found in the bulkhead web and cap. The actions specified by this AD are intended to detect and correct cracking of the bulkhead web and cap, which could result in reduced structural integrity of the fuselage.

DATES: Effective May 19, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 19, 1999.

The incorporation by reference of certain other publications, as listed in the regulations, was approved previously by the Director of the Federal Register as of July 3, 1995 (60 FR 31624, June 16, 1995).

ADDRESSES: The service information referenced in this AD may be obtained from Lockheed Martin Aircraft & Logistics Center, 120 Orion Street, Greenville, South Carolina 29605. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Thomas Peters, Aerospace Engineer, Systems and Flight Test Branch, ACE–116A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703–6063; fax (770) 703–6097.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 95–12–24, 39–9277 (60 FR 31624, June 16, 1995), applicable to all Lockheed Model L–1011–385 series airplanes, was published in the **Federal Register** on September 11, 1998 (63 FR 48655). The action proposed to continue to require a one-time visual inspection to detect cracking of the bulkhead at fuselage station (FS) 1363 at butt line 42.5, and repair or additional inspections, if necessary. The action also proposed to add repetitive visual and eddy current surface scan inspections to detect cracking of the bulkhead web at FS 1363; repetitive visual, eddy current bolt hole, eddy current surface scan, and X-ray inspections to detect cracking of the bulkhead cap at FS 1363; and repair, if necessary. The inspections would be required to be accomplished in accordance with the service bulletins described previously. The action also proposed to provide for modification of the bulkhead web or bulkhead cap, which, if accomplished, introduces a new threshold of 18,000 flight cycles for the repetitive inspections of the modified area.

In addition, the action also proposed that flight with a crack in the bulkhead web is allowed, provided that (1) the crack does not extend beyond a certain area, (2) the crack does not exceed a certain maximum length, (3) the horizontal stiffeners above and below the web crack have no detectable cracks, and (4) inspections of the bulkhead are repeated on a more frequent basis until repair is accomplished.

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

Support for the Proposal

Two commenters support the proposed rule.

Request To Add Approval for Previously Approved Alternative Methods of Compliance

One commenter requests that approval be granted to use previously issued alternative methods of compliance (AMOC) that were issued for AD 95–12–24.

The FAA concurs with the commenter's request. The FAA inadvertently omitted reference to the fact that AMOC's issued for AD 95–12–24 are approved for this AD. Accordingly, the final rule has been revised to add new paragraph (i)(2) to specify that AMOC's approved previously in accordance with AD 95–12–24 are approved as AMOC's for this AD.

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 change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 236 Model L–1011 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 118 airplanes of U.S. registry will be affected by this AD.

The actions that are currently required by AD 95–12–24 take approximately 16 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $113,280, or $960 per airplane.

The new inspections of the bulkhead web that are required by this new AD action will take approximately 16 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspections of the bulkhead web required by this AD on U.S. operators is estimated to be $113,280, or $960 per airplane, per inspection cycle.

The new inspections of the bulkhead cap that are required by this AD action will take approximately 40 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspections of the bulkhead cap required by this AD on U.S. operators is estimated to be $283,200, or $2,400 per airplane, per inspection cycle.

Should an operator be required to accomplish the repair of cracking in the bulkhead web, it will take between 8 to 32 work hours per airplane (8 work hours for each cracked area) to accomplish the repair, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of any necessary repair of the bulkhead web is estimated to be between $480 to $1,920 per airplane.

Should an operator be required to accomplish the repair of cracking in the bulkhead cap, it will take approximately 200 work hours per airplane to accomplish the repair, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of any necessary repair of the bulkhead cap is estimated to be $12,000 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.

Should an operator elect to accomplish the optional modification of the bulkhead web that will be provided by this AD action, it would take approximately 48 work hours to accomplish, at an average labor rate of

$60 per work hour. Based on these figures, the cost impact of the optional modification of the bulkhead web will be $2,880 per airplane.

Should an operator elect to accomplish the optional modification of the bulkhead cap that will be provided by this AD action, it would take approximately 200 work hours to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the optional modification of the bulkhead cap would be $12,000 per airplane.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9277 (60 FR 31624, June 16, 1995), and by adding a new airworthiness directive (AD), amendment 39–11128, to read as follows:

99–08–20 Lockheed: Amendment 39–11128. Docket 97-NM–315-AD. Supersedes AD 95–12–24, Amendment 39–9277.

Applicability: All Model L–1011–385 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 (i)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct cracking of the bulkhead web and cap, which could result in reduced structural integrity of the fuselage, accomplish the following:

Restatement of the Requirements of AD 95–12–24, Amendment 39–9277

(a) Prior to the accumulation of 18,000 total landings, or within 30 days after July 3, 1995 (the effective date of AD 95–12–24, amendment 39–9277), whichever occurs later, perform a visual inspection to detect cracking of the bulkhead at fuselage station (FS) 1363 in the area of the stiffeners at left and right butt line (BL) 42.5; in accordance with the procedures specified in paragraphs 2.A. and 2.B. of Part I of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; or in accordance with the procedures specified in paragraphs 2.A. and 2.B. of Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996.

Note 2: This AD does not require that the eddy current inspection referenced in paragraph 2.B. of Part I of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; and referenced in paragraph 2.B. of Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996; be accomplished as a requirement of paragraph (a) of this AD.

(b) Except as provided by paragraph (d) of this AD, if any cracking of the bulkhead is detected below waterline (WL) 117 during any inspection performed in accordance with paragraph (a) of this AD: Prior to further flight, perform the inspections required by paragraphs (b)(1), (b)(2), and (b)(3) of this AD, in accordance with Lockheed Document LCC–7622–373, dated May 9, 1995. Prior to further flight, repair any cracking of the bulkhead cap found during these inspections, in accordance with Lockheed Document LCC–7622–374, dated May 9, 1995.

(1) Perform a bolt hole eddy current inspection to detect cracking of the eight fastener holes at the intersection of the vertical stiffener at BL 42.5 and the bulkhead cap vertical flange; and

(2) Perform a bolt hole eddy current inspection to detect cracking at eight fastener locations in the bulkhead cap lower flange that connect the lower fuselage skin panel to the frame at the BL 42.5 vertical stiffener; and

(3) Perform a visual inspection to detect stress corrosion cracking of the accessible portions of the fillet radius of the bulkhead cap.

(c) Except as provided by paragraph (d) of this AD, if any cracking of the bulkhead is detected at or above WL 117 during any inspection performed in accordance with paragraph (a) of this AD: Prior to further flight, repair the bulkhead cracking in accordance with the procedures specified in Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; or in accordance with the procedures specified in Part III of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996.

(d) Continued flight with cracking of the bulkhead is permitted, provided that the conditions specified in paragraph 1.C. of the Planning Information of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; or Revision 1, dated July 2, 1996; are met. For flight with cracking, both the visual and eddy current inspections specified in paragraphs 2.B. and 2.C. of Part I of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; or specified in paragraphs 2.B. and 2.C. of Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996; must be accomplished prior to returning the aircraft to service. These visual and eddy current inspections must be repeated within 900 landings. Prior to the accumulation of 1,800 total landings, these inspections must be terminated by the installation of the repair specified in Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; or by installation of the repair specified in Part III of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996.

New Requirements of This AD

(e) Prior to the accumulation of 18,000 total landings, or within 6 months after the effective date of the AD, whichever occurs later, perform a visual and eddy current surface scan inspection for cracking of the bulkhead web at FS 1363, in accordance with Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996.

(1) If no cracking of the bulkhead web is detected, except as provided by paragraph (f) of this AD, repeat the visual and eddy current surface scan inspections thereafter at intervals not to exceed 2,000 landings.

(2) If cracking of the bulkhead web is detected, and that cracking is within the

limits specified in Part I of the Accomplishment Instructions of the service bulletin: Accomplish the requirements of either paragraph (e)(2)(i) or (e)(2)(ii) of this AD, in accordance with the service bulletin. Except as provided by paragraph (f) of this AD, repeat the inspections thereafter at intervals not to exceed 2,000 landings after repair of the cracking.

(i) Prior to further flight, repair the cracking. Or

(ii) Repeat the inspections specified in Part I of the Accomplishment Instructions of the service bulletin at intervals not to exceed 900 landings, and repair the cracking within 1,800 landings after the cracking was detected.

(3) If cracking of the bulkhead web is detected, and that cracking is outside the limits specified in Part I of the Accomplishment Instructions of the service bulletin: Prior to further flight, repair in accordance with Part III of the Accomplishment Instructions of the service bulletin. Except as provided by paragraph (f) of this AD, repeat the inspections thereafter at intervals not to exceed 2,000 landings.

(f) For airplanes on which modification of the bulkhead web is accomplished in accordance with Part IV of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996: Repeat the inspections specified in paragraph (e) of this AD within 18,000 landings after accomplishment of the modification, in accordance with the service bulletin.

(g) Prior to the accumulation of 18,000 total landings, or within 6 months after the effective date of this AD, whichever occurs later, perform visual, bolt hole eddy current, eddy current surface scan, and X-ray inspections for cracking of the bulkhead cap at FS 1363, in accordance with Lockheed L–1011 Service Bulletin 093–53–272, dated November 12, 1996.

(1) If no cracking of the bulkhead cap is detected, except as provided by paragraph (h) of this AD, repeat the inspections thereafter at intervals not to exceed 2,000 landings, in accordance with the service bulletin.

(2) If any cracking of the bulkhead cap is detected, accomplish the requirements of either paragraph (g)(2)(i) or (g)(2)(ii) of this AD, in accordance with the service bulletin.

(i) Prior to further flight, repair in accordance with Part I of the Accomplishment Instructions of the service bulletin. Thereafter, repeat the inspections at intervals not to exceed 2,000 landings. Or

(ii) Prior to further flight, replace the bulkhead cap, in accordance with Part II of the Accomplishment Instructions of the service bulletin. Following such replacement, repeat the inspection within 18,000 landings, in accordance with the service bulletin.

(h) For airplanes on which replacement of the bulkhead cap is accomplished in accordance with Part II of the Accomplishment Instructions of Lockheed L–1011 Service Bulletin 093–53–272, dated November 12, 1996: Repeat the inspections specified in paragraph (g) of this AD within 18,000 landings after accomplishment of the replacement, in accordance with the service bulletin.

(i)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

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

(i)(2) Alternative methods of compliance approved previously in accordance with AD 95–12–24, amendment 39–9277, are approved as alternative methods of compliance for this AD.

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

Incorporation by Reference

(k) The actions shall be done in accordance with Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996; Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; Lockheed Document LCC–7622–373, dated May 9, 1995; Lockheed Document LCC–7622–374, dated May 9, 1995; and Lockheed L–1011 Service Bulletin 093–53–272, dated November 12, 1996; as applicable.

(1) The incorporation by reference of Lockheed L–1011 Service Bulletin 093–53–268, Revision 1, dated July 2, 1996, and Lockheed L–1011 Service Bulletin 093–53–272, dated November 12, 1996, 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 Lockheed L–1011 Service Bulletin 093–53–268, dated April 15, 1993; Lockheed Document LCC–7622–373, dated May 9, 1995; and Lockheed Document LCC–7622–374, dated May 9, 1995, was approved previously by the Director of the Federal Register as of July 3, 1995 (60 FR 31624, June 16, 1995).

(3) Copies may be obtained from Lockheed Martin Aircraft & Logistics Center, 120 Orion Street, Greenville, South Carolina 29605. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(l) This amendment becomes effective on May 19, 1999.

Issued in Renton, Washington, on April 6, 1999.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–9130 Filed 4–13–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 874 and 882

[Docket No. 98N–0405]

Medical Devices; Retention in Class III and Effective Date of Requirement for Premarket Approval for Three Preamendment Class III Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to retain in class III, three preamendment medical devices and to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for the suction antichoke device, the tongs antichoke device, and the implanted neuromuscular stimulator. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: April 14, 1999.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

The SMDA (Pub. L. 101–629) added new section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMA's and