applicants and petitioners after they filed their applications or petitions to appear at an Application Support Center or other Service-designated location, including State or local law enforcement agencies, to be fingerprinted.

Before publication of the interim rule, the regulations required an applicant for a replacement Alien Registration Receipt Card (currently Permanent Resident Card) to be fingerprinted:

- Only if he or she was applying for a replacement Alien Registration Receipt Card because he or she had reached the age of 14 years, unless
- The existing Alien Registration Receipt Card would expire before his or her 16th birthday.

The interim rule inadvertently changed the regulations to require all applicants for a replacement of, or renewal of, an Alien Registration Receipt Card (currently Permanent Resident Card) to be fingerprinted.

What Does This Final Rule Do?

This final rule amends the Service's regulations to correct the inadvertent error made in the interim rule. The Service will fingerprint an applicant filing Form I–90 for replacement of, or renewal of, a Permanent Resident Card only if:

- He or she is applying for a replacement Permanent Resident Card because he or she has reached the age of 14 years.

Accordingly, § 264.5(e)(3)(i) will be amended to clarify that except for those applications filed pursuant to § 264.5(b)(8), applicants for a replacement Permanent Resident Card are not required to be fingerprinted on Form FD–258, unless otherwise instructed by the Attorney General.

Will the Service Finalize the March 17, 1998, Interim Rule?

Yes, the Service will finalize the interim rule later this fiscal year and address all comments at that time.

Good Cause Exception

The Service's implementation of this rule as a final rule is based on the ''good cause'' exceptions found at 5 U.S.C. 553(b)(B) and (d)(3). The reason and necessity for immediate implementation of this final rule without prior notice and comment are as follows:

Alien Registration Receipt Cards (currently Permanent Resident Cards), that were issued with 10-year expiration dates, are beginning to expire and must be renewed. Under the current regulations all permanent residents who have a Permanent Resident Card that is expiring must be fingerprinted after they file a Form I–90, Application to Replace Permanent Resident Card.

This final rule is needed to correct an inadvertent error in the regulations so that the Service only requires certain applicants for a replacement Permanent Resident Card to be fingerprinted.

Accordingly, delaying implementation of this final rule would:

- Require all applicants to be fingerprinted unnecessarily,
- Delay the filing and adjudication of these applications, and
- Would be contrary to the public interest.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects individual applicants for a replacement Permanent Resident Card. It does not affect small entities as that term is defined in 5 U.S.C. 601(b).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any 1 year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

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

Executive Order 12866

This rule is considered by the Department of Justice, Immigration and Naturalization Service, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, this regulation has been submitted to the Office of Management and Budget for review.

Executive Order 13132

This rule 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 section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988 Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988.

List of Subjects in 8 CFR Part 264

Aliens, Immigration, Reporting and recordkeeping requirements.

Accordingly, part 264 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 264—REGISTRATION AND FINGERPRINTING OF ALIENS IN THE UNITED STATES

1. The authority citation for part 264 continues to read:

Authority: 8 U.S.C. 1103, 1201, 1201a, 1301–1305.

§ 264.5 [Amended]

2. In § 264.5, paragraph (e)(3)(i) is amended by adding the phrase ''filing under paragraph (b)(8) of this section'' immediately after the word ''applicant'' and before the word ''shall''.

Dated: February 9, 2000.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 00–24600 Filed 9–25–00; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–122–AD; Amendment 39–11908; AD 2000–19–07]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–120, EMB–120ER, and EMB–120RT Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain EMBRAER Model EMB–120, EMB–120ER, and EMB–120RT series airplanes, that requires removal of a certain fastener, if applicable, and sealing of the corresponding fastener hole. This action is necessary to prevent contact between one of the bolts that attaches the direct current (DC) relay box on the left-hand side of the airplane and one of the power terminals of electrical emergency contactor 2, which could result in a short circuit in the DC relay box, and consequent partial loss of the electrical system, and degraded operation of airplane systems. This action is intended to address the identified unsafe condition.

DATES: Effective October 31, 2000. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 31, 2000.

ADDRESSES: The service information referenced in this AD may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. 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, 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: Carla Worthey, Program Manager, Program Management and Systems Branch, ACE–118A, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703–6062; fax (770) 703–6097.

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 EMBRAER Model EMB–120, EMB–120ER, and EMB–120RT series airplanes was published in the **Federal Register** on June 27, 2000 (65 FR 39576). That action proposed to require removal of a certain fastener, if applicable, and sealing of the corresponding fastener hole.

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 240 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 $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $14,400, or $60 per airplane.

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

2000–19–07 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–11908. Docket 2000–NM–122–AD.

Applicability: Model EMB–120, EMB–120ER, and EMB–120RT series airplanes; serial numbers 120004 and 120006 through 120321 inclusive; certificated in any category; on which EMBRAER Service Bulletin 120–24–0051, dated March 1, 1994; Revision 1, dated May 5, 1994; Revision 2, dated May 31, 1994; Revision 3, dated November 3, 1994; Revision 4, dated March 8, 1995; or the production equivalent, has been accomplished.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent contact between one of the bolts that attaches the direct current (DC) relay box on the left-hand (LH) side of the airplane (hereinafter referred to as the ''LH DC relay box'') and one of the power terminals of electrical emergency contactor 2 (K0519), which could result in a short circuit in the LH DC relay box, and consequent partial loss of the electrical system, and degraded operation of airplane systems, accomplish the following:

Bolt/Washer Removal and Hole Sealing

(a) Within 75 flight hours after the effective date of this AD, remove the bolt and washer on the LH DC relay box that is in the area of electrical emergency contactor 2 (K0519) and seal the corresponding fastener hole, in accordance with EMBRAER Alert Service Bulletin 120–24–A057, dated November 14,

1996. If no fastener is installed, seal the corresponding fastener hole only, in accordance with the alert service bulletin.

Alternative Methods of Compliance

(b) 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. 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 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permits

(c) 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

(d) The actions shall be done in accordance with EMBRAER Alert Service Bulletin 120–24–A057, dated November 14, 1996. 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 Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, 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.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 96–12–02, dated December 13, 1996.

Effective Date

(e) This amendment becomes effective on October 31, 2000.

Issued in Renton, Washington, on September 14, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–24113 Filed 9–25–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 94N–0380]

Gastroenterology and Urology Devices; Effective Date of Requirement for Premarket Approval of the Implanted Mechanical/Hydraulic Urinary Continence Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the implanted mechanical/hydraulic urinary continence device, a generic type of medical device intended for the treatment of urinary incontinence. 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.

EFFECTIVE DATE: This rule is effective October 26, 2000.

FOR FURTHER INFORMATION CONTACT: Nicole L. Wolanski, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Introduction

SMDA added new section 515(i) to the act (21 U.S.C. 360e(i)). 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 to determine whether each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval.

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA published a final rule classifying into class III (premarket approval) the implanted mechanical/hydraulic urinary continence device, a medical device. Section 876.5280 (21 CFR 876.5280) of FDA's regulations setting forth the classification of the implanted mechanical/hydraulic urinary continence device applies to: (1) Any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976, and (2) any device that FDA has found to be substantially equivalent to an implanted mechanical/hydraulic urinary continence device in commercial distribution before May 28, 1976.

In the **Federal Register** of February 15, 1995 (60 FR 8595), FDA published a proposed rule, under section 515(b) of the act (21 U.S.C. 360e(b)), to require the filing of PMA's or PDP's for the classified implanted mechanical/hydraulic urinary continence device and all substantially equivalent devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble, the agency's proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and (2) the benefits to the public from use of the device.

The preamble also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, it also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the implanted mechanical/hydraulic urinary continence device was required to be submitted by March 2, 1995. The comment period closed on June 15, 1995.

The agency received three comments in response to the February 15, 1995, proposed rule. These comments were from physicians and a manufacturer. These three comments raised numerous issues. A summary of the comments and FDA's responses are set out below.

This regulation is final upon publication and requires PMA's or notices of completion of a PDP for all implanted mechanical/hydraulic urinary continence devices classified under § 876.5280 and all devices that are substantially equivalent to them. PMA's or notices of completion of a PDP for these devices must be filed with FDA within 90 days of the effective date of this regulation. (See section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)).)