

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 (c) 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 the unavailability of supplemental oxygen to the flight attendant in the event of cabin decompression, which could result in loss of consciousness of the flight attendant, accomplish the following:

(a) Within 100 flight hours after the effective date of this AD, accomplish either paragraph (a)(1) or (a)(2) of this AD.

Airplane Flight Manual (AFM) Revision

(1) Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM-120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

“Maximum operating altitude is limited to 25,000 feet.”

(2) Accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD, as applicable.

Modification

(i) For airplanes listed in paragraph 1.1.1., Part I, of the effectivity of EMBRAER Service Bulletin 120-25-0264, Change 01, dated July 22, 2002: Replace the shock absorber of the flight attendant's seat with a new part, and install an oxygen bottle kit under the seat (including installing placards); per paragraph 2.1 of the Accomplishment Instructions of that service bulletin.

Rework

(ii) For airplanes listed in paragraph 1.1.2., Part II, of the effectivity of EMBRAER Service Bulletin 120-25-0264, Change 01, dated July 22, 2002: Rework the oxygen bottle kit (including installing placards and attaching the oxygen mask hose to the oxygen bottle), per paragraph 2.2 of the Accomplishment Instructions of that service bulletin.

AFM Revision

(b) Before further flight following the accomplishment of paragraph (a)(2) of this AD: Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM-120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

“Maximum operating altitude is limited to 30,000 feet.”

Alternative Methods of Compliance

(c) 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, International Branch, ANM-116, Transport

Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

Special Flight Permits

(d) 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

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with EMBRAER Service Bulletin 120-25-0264, Change 01, dated July 22, 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 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 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 2001-11-03 R1, dated September 13, 2002.

Effective Date

(f) This amendment becomes effective on July 28, 2003.

Issued in Renton, Washington, on June 11, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2003N-0235]

Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulations concerning FDA's procedures for determining which component within FDA will have

primary jurisdiction for the premarket review and regulation of a product composed of a combination of a drug, device, or biological product; or any drug, device, or biological product where the agency component with jurisdiction is unclear or in dispute. FDA is taking this action to implement the requirement of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) that FDA establish an office within FDA's Office of the Commissioner to ensure the prompt assignment of combination products to agency centers.

DATES: This rule is effective June 23, 2003.

FOR FURTHER INFORMATION CONTACT:

Mark D. Kramer, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-827-9229, e-mail: combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A combination product is a product containing a combination of a drug, a device, or a biological product. The Safe Medical Devices Act of 1990 (Public Law 101-629) added new section 503(g) (21 U.S.C. 353(g)) to the Federal Food, Drug, and Cosmetic Act (the act)), relating to combination products. This section requires that the agency assign a component of FDA to have primary jurisdiction for the premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product. It further requires FDA to make this assignment based upon a determination of the primary mode of action of the combination product. In the **Federal Register** of November 21, 1991 (56 FR 58754), FDA issued a final rule establishing the procedures for implementing section 503(g) in part 3 (21 CFR part 3).

MDUFMA amended section 503(g) of the act to require that FDA establish within its Office of the Commissioner an office to ensure: (1) The prompt assignment of combination products to agency centers, (2) the timely and effective premarket review of such products, and (3) consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. New section 503(g)(4) further states that, in carrying out its duties, this office shall:

- Promptly assign an agency center with primary jurisdiction for the premarket review of the product. The office, in determining whether a product