

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 adding the following new airworthiness directive:

Empresa Brasileira De Aeronautica S.A.

(EMBRAER); Docket 2003–NM–02–AD.

Applicability: Model EMB–120 series airplanes as listed in EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002; 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 (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.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 2001–11–03 R1, dated September 13, 2002.

Issued in Renton, Washington, on February 27, 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 111

[Docket No. 95N–0304]

RIN 0910–AC51

Dietary Supplements Containing Ephedrine Alkaloids; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 30 days the comment period for a proposed rule entitled “Dietary Supplements Containing Ephedrine Alkaloids” that published in the **Federal Register** of June 4, 1997 (62 FR 30678) (the June 1997 proposal). In that document, FDA proposed a number of requirements relating to dietary supplements containing ephedrine alkaloids, including a requirement for a warning statement on the product label. Since publication of the June 1997 proposal, new scientific evidence has come to light concerning health risks associated with the use of dietary supplements containing ephedrine alkaloids. FDA is reopening the comment period to receive comment on this new evidence, as well as on the warning statement it is now considering for dietary supplements containing ephedrine alkaloids. FDA also intends to consider, to the extent possible, whether in light of current information FDA should determine that dietary supplements containing ephedrine alkaloids present a “significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”

DATES: Submit written or electronic comments April 4, 2003.