

compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(i) 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.

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NM-02-AD]

RIN 2120-AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB-120 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain EMBRAER Model EMB-120 series airplanes. This proposal would require either revising the Airplane Flight Manual (AFM) to require a maximum operating altitude of 25,000 feet; or modifying the flight attendant's seat, or reworking the oxygen bottle kit, as applicable, and revising the AFM to require a maximum operating altitude of 30,000 feet. This action is necessary 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. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by April 4, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2003-NM-02-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-nprmccomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2003-NM-02-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 for Windows or ASCII text.

The service information referenced in the proposed rule 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 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. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT:

Robert D. Breneman, Aerospace Engineer, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-1263; fax (425) 227-1149.

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 2003-NM-02-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. 2003-NM-02-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Departamento de Aviacao Civil (DAC), which is the airworthiness authority for Brazil, notified the FAA that an unsafe condition may exist on certain EMBRAER Model EMB-120 series airplanes. The DAC advises that investigation has revealed that installation of the forward lavatory on these airplanes has resulted in the relocation of the oxygen dispensing units and masks to a location that cannot be reached by a flight attendant while seated in the attendant seat, when the oxygen masks are automatically deployed due to emergency cabin decompression. (The units and masks had previously been installed at the ceiling or at the wardrobe wall in front of the first double seat of the forward passenger cabin and had been dedicated to the right-hand front row passenger and flight attendant.) The unavailability of supplemental oxygen to the flight attendant in the event of cabin decompression, if not corrected, could result in loss of consciousness of the flight attendant.

Explanation of Relevant Service Information

EMBRAER has issued Service Bulletin 120-25-0264, Change 01, dated July 22, 2002, which describes the following procedures:

- For certain airplanes: Modifying the flight attendant's seat (figure 1) by replacing the shock absorber and installing an oxygen bottle under the seat, including installing placards (figure 2).
- For certain other airplanes: Reworking the oxygen bottle kit (figure

3), including installing placards and attaching the oxygen mask hose to the oxygen bottle.

The DAC classified Change 01 of EMBRAER Service Bulletin 120–25–0264 as mandatory and issued Brazilian airworthiness directive 2001–11–03 R1, dated September 13, 2002, in order to assure the continued airworthiness of these airplanes in Brazil.

FAA's Conclusions

This airplane model is manufactured in Brazil and is 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. Pursuant to this bilateral airworthiness agreement, the DAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DAC, 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 Proposed 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, the proposed AD would require either revising the Limitations Section of the Airplane Flight Manual (AFM) to require a maximum operating altitude of 25,000 feet; or modifying the flight attendant's seat, or reworking the oxygen bottle kit, as applicable, and revising the Limitations Section of the AFM to require a maximum operating altitude of 30,000 feet. Modification of the flight attendant's seat, or rework of the oxygen bottle kit, as applicable, are required to be accomplished per EMBRAER Service Bulletin 120–25–0264, Change 01, except as described below.

Clarification of Applicability

The applicability of Brazilian airworthiness directive 2001–11–03 R1 specifies all Model EMB–120 series airplanes equipped with a lavatory installed in the forward part of the passenger cabin. However, paragraph 1.1.1, part I, of Change 01 of the service bulletin limits its effectivity to certain serial numbers of the affected airplane models equipped with a forward toilet and galley and on which the original issue of the service bulletin has not been accomplished. In addition, paragraph 1.1.2, part II, of Change 01 of the service bulletin limits its effectivity to certain serial numbers of the affected airplane

models equipped with a forward toilet and galley and on which the original issue of the service bulletin has been accomplished.

The FAA considers that the effectivity of Change 01 of the service bulletin provides a more accurate listing of the specific airplanes that are applicable to the actions required by this proposed AD. For this reason, the applicability of this proposed AD specifies those airplanes as listed in the service bulletin.

Differences Between This Proposed AD and the Brazilian Airworthiness Directive

Operators should note the following differences:

- Part I of the Compliance section of the Brazilian airworthiness directive limits flight operations to 25,000 feet unless the right-hand aisle passenger seat in the front row is reserved for the flight attendant's use during operation above 25,000 feet.
- Part II of the Compliance section of the Brazilian airworthiness directive specifies that, for those airplanes that have accomplished Change 01 of EMBRAER Service Bulletin 120–25–0264, flight operations are limited to 30,000 feet unless the right-hand front row aisle passenger seat is reserved for flight attendant use during flight operations above 30,000 feet.

We have determined that reserving a passenger seat for use by the flight attendant does not adequately address the identified unsafe condition. During an emergency event such as the rapid loss of cabin pressure, it is necessary for the flight attendant to communicate with both the flightcrew and passengers via the airplane communication system. The existing system is located at the flight attendant's seat and is not within reach of the flight attendant if seated in the front row passenger seat. Therefore, in an emergency, the flight attendant would not be able to provide the flightcrew with emergency information about the passengers and airplane condition or to provide the necessary emergency instructions to the passengers. For these reasons, the AFM revisions required by this proposed AD limit flight operations to 25,000 feet, or to 30,000 feet if the actions required by this proposed AD (modification or rework, as applicable) have been accomplished.

We have consulted with the DAC about this difference between the maximum operating altitudes specified in the Brazilian airworthiness directive and the operating altitudes required by this proposed AD. After considering this information, the DAC has agreed with

the flight operation limitations required by this proposed AD.

Cost Impact

The FAA estimates that 150 Model EMB–120 series airplanes of U.S. registry would be affected by this proposed AD.

Should an operator be required to revise the AFM (maximum operating altitude of 25,000 feet), it would take approximately 1 work hour per airplane to accomplish the proposed AFM revision, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this proposed AFM revision on U.S. operators is estimated to be \$60 per airplane.

Should an operator be required to accomplish either the modification or rework action, it would take approximately 8 work hours per airplane to accomplish the proposed modification or rework action, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$3,960 per airplane. Based on these figures, the cost impact of the proposed modification on U.S. operators is estimated to be \$4,440 per airplane.

Should an operator be required to revise the AFM (maximum operating altitude of 30,000 feet), it would take approximately 1 work hour per airplane to accomplish the proposed AFM revision, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this proposed AFM revision on U.S. operators is estimated to be \$60 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the 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.

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 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.