submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2003–NM–134–AD.'' The postcard will be date stamped and returned to the commenter.

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, 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:

2003–13–02 Airbus: Amendment 39–13202. Docket 2003–NM–134–AD.

Applicability: All Model A321–131 series airplanes; certificated in any category; equipped with International Aero Engines (IAE) V25()()–A5 series engines.

Compliance: Required as indicated, unless accomplished previously.

To require the flightcrew to follow the procedures necessary to prevent smoke caused by an oil filter clog from entering the cabin during flight, accomplish the following:

Airplane Flight Manual (AFM) Revision

(a) Within 7 days after the effective date of this AD, revise the Limitations section of the Airbus A321 AFM to include the following statements (this may be accomplished by inserting a copy of this AD into the AFM):

''Procedure for Oil Filter Clog ECAM Caution

The ECAM does not require any pilot action in case of ENG 1(2) OIL FILTER CLOG ECAM warning. However, to minimize the risk of air conditioning system contamination by oil fumes, systematically apply the following procedure in any event of oil filter clog:

ENG 1(2) OIL FILTER CLOG

In-service reports have shown that this ECAM warning is frequently a symptom of engine bearing damage that could potentially lead to smoke entering the cabin via the pack of the affected side. This procedure aims to avoid air conditioning smoke, while continuing normal engine operation.

ENG BLEED (affected side)—OFF

(Prevents possible bleed contamination by engine oil.)

PACK (affected side)—OFF

(Switching off one pack enables the remaining pack to operate at 120 percent without any risk of remaining bleed misbehavior. Keep the pack on in case of an MEL dispatch with one pack inoperative.

The pack that has been switched off remains available with the crossbleed valve open. Therefore, switch it on in case of a subsequent independent malfunction affecting the operating pack.)

CROSSBLEED—OPEN

(Opening the crossbleed valve enables the wing anti-ice to be used when needed.)

CLOSELY MONITOR ENGINE PARAMETERS FOR SURGE/STALL, OIL PRESSURE FLUCTUATIONS, OR ABNORMAL ENGINE VIBRATIONS; AND, WHEN NECESSARY, APPLY THE ASSOCIATED PROCEDURE.

If, after the oil filter clog, the engine experiences or has already experienced a surge/stall possibly accompanied by a yaw-effect on the aircraft:

ENG (AFFECTED) THRUST LEVER—IDLE—

(Reducing the thrust of the affected engine minimizes further damage to the engine rotary machinery, but will not necessarily prevent more oil from entering the gas path. Maintain engine at idle, and consider engine shutdown if high vibration occurs or oil quantity/oil pressure drops low.)

''Oil Filter Clog'' ECAM warnings occurring on the ground during engine start are frequently due to low oil viscosity and may be self-recoverable. In the event of an ''Oil Filter Clog'' warning during engine start, please refer to FCOM 3.02.70 page 2.''

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Effective Date.

(c) This amendment becomes effective on July 8, 2003.

Issued in Renton, Washington, on June 16, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15595 Filed 6–20–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–02–AD; Amendment 39–13197; AD 2003–12–12]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–120 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 series airplanes, that requires 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: Effective July 28, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 28, 2003.

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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

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 series airplanes was published in the **Federal Register** on March 5, 2003 (68 FR 10415). That action proposed to 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.

Comments

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

Request To Revise Maximum Operating Altitude

The commenter requests that the proposed AD be revised to allow for flight above 30,000 feet if a first-row, right-hand aisle seat is reserved for the flight attendant. By way of justification, the commenter explains that this altitude is the cruise phase of the flight, when the flight attendant is usually serving passengers in the cabin. In the event of rapid depressurization of the airplane, the attendant could use one of the extra masks in the cabin. The flight attendant, although unable to reach the interphone from the first-row, right-hand aisle seat to communicate with the flight crew or passengers, could unlatch the seatbelt and move to the flight attendant station to operate the interphone.

The FAA does not concur with the request. During a rapid depressurization of the airplane, the flightcrew would conduct an emergency descent to lower altitudes. The appropriate procedures for the flight attendant during an emergency descent include returning to the flight attendant station, buckling the seatbelt, and establishing communication with the flightcrew or passengers. Therefore, during an emergency descent, seatbelt removal by a flight attendant seated in the first-row, right-hand aisle seat would be inappropriate, and the interphone would not be readily accessible. No change to the final rule is necessary.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that 150 airplanes of U.S. registry will be affected by this AD.

If required, the AFM revision (maximum operating altitude of 25,000 feet) would take approximately 1 work hour per airplane, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this AFM revision is estimated to be $60 per airplane.

If required, the modification or rework would take approximately 8 work hours per airplane, 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 modification/rework is estimated to be $4,440 per airplane.

If required, the AFM revision (maximum operating altitude of 30,000 feet) would take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this AFM revision 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 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:

2003–12–12 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–13197. 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.

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.

[FR Doc. 03–15323 Filed 6–20–03; 8:45 am]

BILLING CODE 4910–13–P

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