

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, International Branch, ANM-116, FAA, Transport Airplane Directorate. 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

(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 CASA Service Bulletin SB-235-53-48, dated December 11, 1997. 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 Construcciones Aeronauticas, S.A., Getafe, Madrid, Spain. 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 Spanish airworthiness directive 02/2000, dated January 31, 2000.

Effective Date

(e) This amendment becomes effective on February 28, 2001.

Issued in Renton, Washington, on January 11, 2001.

Donald L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01-1661 Filed 1-23-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NM-380-AD; Amendment 39-12085; AD 2001-02-01]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737-300, -400, and -500 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 737-300, -400, and -500 series airplanes, that requires repetitive inspections to detect cracking of certain areas of the forward pressure bulkhead, and repair, if necessary. This amendment also requires certain preventive modifications, which, when accomplished, terminate the repetitive inspections for the affected areas. This action is necessary to prevent fatigue cracking on critical areas of the forward pressure bulkhead, which could result in rapid decompression of the airplane fuselage. This action is intended to address the identified unsafe condition.

DATES: Effective February 28, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 28, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. 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:

Nenita K. Odesa, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2557; fax (425) 227-1181.

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 Boeing Model 737-300, -400, and -500 series airplanes was published in the **Federal Register** on October 18, 2000 (65 FR 62313). That action proposed to require repetitive inspections to detect cracking of certain areas of the forward pressure bulkhead, and repair, if necessary. That action also proposed to require certain preventive modifications, which, when accomplished, would terminate the repetitive inspections for the affected areas.

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

There are approximately 330 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 115 airplanes of U.S. registry will be affected by this AD.

It will take approximately 2 work hours per airplane to accomplish the required inspection, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$13,800, or \$120 per airplane, per inspection cycle.

It will take approximately 38 work hours per airplane to accomplish the required modification of the vertical chords, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$2,789 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$582,935, or \$5,069 per airplane.

It will take approximately 274 work hours per airplane to accomplish the required modification of the side chord areas, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$6,629 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$2,652,935, or \$23,069 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:

2001-02-01 Boeing: Amendment 39-12085. Docket 99-NM-380-AD.

Applicability: Model 737-300, -400, and -500 series airplanes, certificated in any category; as listed in Boeing Alert Service Bulletin 737-53A1208, dated May 6, 1999.

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 (d) 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 detect fatigue cracking of the forward pressure bulkhead, which could result in

rapid decompression of the airplane fuselage, accomplish the following:

Initial and Repetitive Inspections

(a) Before the accumulation of 20,000 total flight cycles, or within 3,000 flight cycles after the effective date of this AD, whichever occurs later: Perform the applicable inspections of the vertical and side chord areas of the forward pressure bulkhead to detect cracking, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1208, dated May 6, 1999. Thereafter, repeat the inspections at intervals not to exceed 6,000 flight cycles until the preventive modifications required by paragraph (c) of this AD have been accomplished.

Repair

(b) If any cracking is detected during any inspection required by paragraph (a) of this AD, before further flight, repair the area in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1208, dated May 6, 1999.

Terminating Action

(c) Before the accumulation of 75,000 total flight cycles, or within 12,000 flight cycles after the effective date of this AD, whichever occurs later: Accomplish preventive modifications of the vertical and side chord areas of the forward pressure bulkhead, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737-53A1208, dated May 6, 1999. Accomplishment of these modifications constitutes terminating action for the repetitive inspections required by paragraph (a) of this AD.

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(d) 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, Seattle 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, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(e) 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

(f) The actions shall be done in accordance with Boeing Alert Service Bulletin 737-53A1208, dated May 6, 1999. 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 Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. 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.

Effective Date

(g) This amendment becomes effective on February 28, 2001.

Issued in Renton, Washington, on January 12, 2001.

Donald L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 01-1660 Filed 1-23-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Blue Ridge Pharmaceuticals, Inc. The NADA provides for veterinary prescription use of ivermectin otic suspension for the treatment of adult ear mite infestations in cats and kittens.

DATES: This rule is effective January 24, 2001.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed NADA 141-174 that provides for veterinary prescription use of ACAREXX® (0.01% ivermectin) Otic Suspension for the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven. The NADA provides for use of one 0.5-milliliter tube per ear. The NADA is approved as of December 5, 2000, and the regulations are amended by adding 21 CFR 524.1195 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, Blue Ridge Pharmaceuticals, Inc., has not been