

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 (b) 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 failure of the spoiler actuator, which could result in the spoiler panel floating and inducing an uncommanded roll of the airplane, accomplish the following:

Inspection and Replacement

(a) Within 150 flight hours after the effective date of this AD, perform a visual inspection to determine the serial number of the spoiler actuators, in accordance with Learjet Service Bulletins SB 31-27-19, dated December 14, 1998 (for Model 31 and 31A airplanes); SB 35-27-36, dated December 14, 1998 (for Model 35 and 35A airplanes); or SB 60-27-21, dated December 14, 1998 (for Model 60 airplanes); as applicable.

(1) If the serial number is not listed in the applicable service bulletin, no further action is required by this AD.

(2) If the serial number is listed in the applicable service bulletin, prior to further flight, replace the spoiler actuators with new actuators in accordance with the Accomplishment Instructions of the applicable service bulletin.

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, Wichita Aircraft Certification Office (ACO), FAA, Small 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, Wichita ACO.

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

Special Flight Permits

(c) 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.

Incorporation by Reference

(d) The actions shall be done in accordance with Learjet Service Bulletin SB 31-27-19, dated December 14, 1998, Learjet Service Bulletin SB 35-27-36, dated December 14, 1998, or Learjet Service Bulletin SB 60-27-21, dated December 14, 1998, as applicable. 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 Learjet, Inc., One Learjet Way, Wichita, Kansas 67209-2942. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on December 21, 1999.

Issued in Renton, Washington, on October 28, 1999.

D.L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99-29470 Filed 11-15-99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

RIN 2120-AA64

[Docket No. 99-NM-101-AD; Amendment 39-11417; AD 99-23-21]

Airworthiness Directives; Boeing Model 757 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 757 series airplanes, that requires a modification of the reverse thrust lever assemblies and replacement of the spring bumper assemblies of the thrust reverser sleeves with new assemblies. This amendment is prompted by an FAA review of the thrust reverser system on all transport category airplanes including the Boeing Model 757 series airplane. The actions specified by this AD are intended to prevent operation with an energized sync lock or malfunctioning sleeve locking devices, which could result in the deployment of a thrust reverser in flight and subsequent reduced controllability of the airplane.

DATES: Effective December 21, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 21, 1999.

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:

Kathrine Rask, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-1547; 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 757 series airplanes was published in the **Federal Register** on August 23, 1999 (64 FR 45927). That action proposed to require a modification of the reverse thrust lever assemblies and replacement of the spring bumper assemblies of the thrust reverser sleeves with new assemblies.

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 308 airplanes of the affected design in the worldwide fleet.

The FAA estimates that the modification of the reverse thrust lever assemblies will be required to be accomplished on 169 U.S. registered airplanes. It will take approximately 8 work hours per airplane to accomplish the required modification at an average labor rate of \$60 per work hour. Required parts will cost approximately \$29 per airplane. Based on these figures, the cost impact of this required modification on U.S. operators is estimated to be \$86,021, or \$509 per airplane.

The FAA estimates that the replacement of the spring bumper assemblies will be required to be accomplished on 92 U.S. registered airplanes. It will take approximately 10 work hours per airplane to accomplish the required replacement at an average labor rate of \$60 per work hour. Required parts will cost approximately

\$5,178 per airplane. Based on these figures, the cost impact of this required replacement on U.S. operators is estimated to be \$531,576, or \$5,778 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.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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:

99-23-21 **Boeing:** Amendment 39-11417. Docket 99-NM-101-AD.

Applicability: Model 757 series airplanes, as listed in Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998, or Boeing Service Bulletin 757-78-0012, dated August 31, 1989; 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 operation with an energized sync lock or malfunctioning sleeve locking devices, which could result in deployment of a thrust reverser in flight and subsequent reduced controllability of the airplane, accomplish the following:

(a) For airplanes listed in Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998: Within 2 years after the effective date of the AD, replace the reverse thrust switches and actuators with improved switches and actuators, and modify the reverse lever links and thrust control levers in accordance with the service bulletin.

Note 2: Modifications accomplished prior to the effective date of this AD in accordance with Boeing Service Bulletin 757-76-0009, dated November 8, 1990, are considered acceptable for compliance with the applicable action specified in this amendment.

(b) For airplanes listed in Boeing Service Bulletin 757-78-0012, dated August 31, 1989: Within 2 years after the effective date of the AD, replace the spring bumper assemblies of the thrust reverser sleeve with improved assemblies in accordance with the service bulletin.

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, Seattle Aircraft Certification Office (ACO), 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, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(d) 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.

Incorporation by Reference

(e) The actions shall be done in accordance with Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998, or Boeing Service Bulletin 757-78-0012, dated August 31, 1989, as applicable. 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.

(f) This amendment becomes effective on December 21, 1999.

Issued in Renton, Washington, on November 4, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99-29471 Filed 11-15-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 99N-0188]

Progestational Drug Products for Human Use; Requirements for Labeling Directed to the Patient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulation requiring patient labeling for progestational drug products. Patient labeling had been required to inform patients of an increased risk of birth defects reported to be associated with the use of these drugs during the first 4 months of pregnancy. FDA concluded that, based on a review of the scientific data, such labeling for all progestogens is not warranted. In addition, the diversity of drugs that can be described as progestational and the diversity of conditions these drugs may be used to treat make it inappropriate to consider these drugs a single class for labeling purposes. This action is intended to provide consumers with more