

Issued in Burlington, Massachusetts, on May 28, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NE-12-AD; Amendment 39-13168; AD 2003-11-09]

RIN 2120-AA64

Airworthiness Directives; Turbomeca Turmo IV A and IV C Series Turboshaft Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2003-11-09 applicable to Turbomeca Turmo IV A and IV C series turboshaft engines that was published in the **Federal Register** on May 29, 2003 (68 FR 31970). The engine model in the regulatory section, under applicability, is incorrect. This document corrects that model. In all other respects, the original document remains the same.

EFFECTIVE DATE: July 3, 2003.

FOR FURTHER INFORMATION CONTACT: Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7751; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: A final rule AD, FR Doc. 03-13115 applicable to Turbomeca Turmo IV A and IV C series turboshaft engines, was published in the **Federal Register** on May 29, 2003 (68 FR 31970). The following correction is needed:

§ 39.13 [Corrected]

■ On page 31970, in the third column, in the regulatory section, under applicability, in the first paragraph, in the fifth line, "FA 330-PUMA" is corrected to read "SA 330-PUMA".

Issued in Burlington, MA, on June 2, 2003.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NM-311-AD; Amendment 39-13179; AD 2003-11-20]

RIN 2120-AA64

Airworthiness Directives; Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, that currently requires repetitive lubrication of the slide shaft of the input plunger of the brake control valve assembly. This amendment adds requirements for modifying the brake control valve assembly, which terminates the repetitive lubrications required by the existing AD. This amendment also adds subsequent repetitive lubrications of the valve utilizing the grease fittings installed during the modification. This amendment is prompted by reports of temporary loss of braking action upon landing. The actions specified by this AD are intended to prevent temporary loss of braking action due to the freezing of moisture on the input plunger of the brake control valve during steep descent.

DATES: Effective July 11, 2003.

The incorporation by reference of Bombardier Service Bulletin 601R-32-017, dated November 9, 1993, as listed in the regulations, is approved by the Director of the Federal Register as of July 11, 2003.

The incorporation by reference of Canadair Regional Jet Alert Service Bulletin S.B.A601R-32-016, dated October 14, 1993, as listed in the regulations, was approved previously by the Director of the Federal Register as of February 4, 1994 (59 FR 2952, January 20, 1994).

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Aircraft Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 10

Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Parrillo, Aerospace Engineer, Systems and Flight Test Branch, ANE-172, FAA, New York ACO, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256-7505; fax (516) 568-2716.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 93-21-04, amendment 39-8801 (59 FR 2952, January 20, 1994), which is applicable to certain Bombardier Model CL-600-2B19 (Regional Jet series 100) series airplanes, was published in the **Federal Register** on January 13, 2003 (68 FR 1566). The action proposed to require repetitive lubrication of the slide shaft of the input plunger of the brake control valve assembly; modification of the brake control valve assembly, which would terminate the repetitive lubrications required by the existing AD; and subsequent repetitive lubrications of the valve utilizing the grease fittings that are installed during the modification.

Comments

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

Request To Revise Identification of Regional Jet Series 100

One commenter requests that the proposed AD be revised to either remove the reference to "Regional Jet Series 100" in association with the affected airplanes throughout the document or add a reference to series 440 airplanes. The commenter explains that the proposed AD applies to Model CL-600-2B19 airplanes. The type certificate data sheet (TCDS) identifies the affected airplane model as "CL-600-2B19 (Regional Jet Series 100 & 440)." The commenter suggests that the references to this airplane model should be revised to reflect both the 100 and 440 series.

The FAA concurs with the request. After the proposed AD was issued, the TCDS was revised to incorporate this change. The final rule has been revised accordingly to correctly identify the affected airplanes where appropriate.

Request To Incorporate AD Actions Into the Maintenance Program

Paragraph (c) of the proposed AD proposed to require repetitive

lubrication of the brake control valve in accordance with Bombardier Service Bulletin 601R-32-017. One commenter requests that the proposed AD be revised to instead require incorporation of the lubrication task (task 32-43-06-05 of the CL-600-2B19 Maintenance Requirements Manual (MRM)) into the approved maintenance program. The commenter asserts that the lubrication task, if incorporated into the MRM, would be considered a routine task subject to normal maintenance program development and escalation. The commenter adds that incorporating the task into the MRM would terminate the repetitive lubrication requirements specified in the proposed AD.

The FAA does not concur with the request. An AD's requirements are mandated for all affected airplanes, but the applicable section of the MRM (Part 1, CSP A-053) is not approved by the FAA (although it is "accepted"). Consequently, the FAA does not control revisions to Part 1 of the MRM. If a task were to be subsequently altered or deleted, the intent of the AD would then become nullified. However, under the provisions of 14 CFR 39.19 and paragraph (d)(1) of this AD, an operator may request approval of an alternative method of compliance (AMOC) to allow use of a particular task card for this AD. However, the AMOC granted would require adherence to a particular revision of the task card; use of any subsequent revisions would require a new AMOC request and approval to enable the cognizant ACO to determine that the intent of the AD requirement has not been altered. No change to the final rule is necessary regarding this issue.

Clarification of Requirements

Certain portions of the preamble and paragraph (b) of this final rule have been revised to clarify that the modification includes applying grease to the grease fittings that are installed during the modification.

The repetitive lubrication interval was clarified in paragraph (c) of this final rule. Whereas the proposed AD specified that the lubrication be done "at intervals of 1,500 flight hours," this final rule will require that the lubrication be done "at intervals not to exceed 1,500 flight hours."

Paragraph (d)(2) has been revised in this final rule to clarify that AMOCs approved previously in accordance with AD 93-21-04 are approved as alternative methods of compliance with paragraph (a) of this AD only.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

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. Because we have now included this material in part 39, we no longer need to include it in each individual AD; however, the office authorized to approve AMOCs is identified in paragraph (d)(1) of this AD.

Cost Impact

The FAA estimates that 2 airplanes of U.S. registry are affected by AD 93-21-04. The actions that are currently required by that AD 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 the currently required actions is estimated to be \$60 per airplane.

Approximately 194 airplanes of U.S. registry will be affected by this AD.

The modification required by this AD will take approximately 4 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$3,812 per airplane. Based on these figures, the cost impact of the modification on U.S. operators is estimated to be \$786,088, or \$4,052 per airplane.

The lubrication of the brake control valve required by this AD will 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 action on U.S. operators is estimated to be \$11,640, or \$60 per airplane, per lubrication.

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 removing amendment 39-8801 (59 FR 2952, January 20, 1994), and by adding a new airworthiness directive (AD), amendment 39-13179, to read as follows:

2003-11-20 Bombardier, Inc. (Formerly Canadair): Amendment 39-13179. Docket 2000-NM-311-AD. Supersedes AD 93-21-04, Amendment 39-8801.

Applicability: Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent temporary loss of braking action due to the freezing of moisture on the input plunger of the brake control valve during steep descent, accomplish the following:

Requirements of AD 93-21-04

Lubrications

(a) Within 3 days after February 4, 1994 (the effective date of AD 93-21-04, amendment 39-8801), and thereafter at intervals not to exceed 3 days, lubricate, with grease, the sliding shaft of the input plunger of the brake control valve assembly, per Canadair Regional Jet Alert Service Bulletin S.B.A601R-32-016, dated October 14, 1993, until modification of the brake control valve, as required by paragraph (b) of this AD, is accomplished.

New Actions Required by This AD

Modification

(b) Within 12 months after the effective date of this AD: Modify the brake control valve assembly by accomplishing all the actions (including the application of grease to the grease fittings) specified in Bombardier Service Bulletin 601R-32-017, dated November 9, 1993, per the service bulletin. Such modification terminates the repetitive lubrications of the sliding shaft of the input plunger of the brake control valve assembly required by paragraph (a) of this AD.

Repetitive Lubrications

(c) Within 1,500 flight hours after doing the modification required by paragraph (b) of this AD, and thereafter at intervals not to exceed 1,500 flight hours, lubricate with grease the brake control valve per paragraph 2.B.(18) of the Accomplishment Instructions of Bombardier Service Bulletin 601R-32-017, dated November 9, 1993.

Alternative Methods of Compliance

(d)(1) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

(2) Alternative methods of compliance, approved previously in accordance with AD 93-21-04, amendment 39-8801, are approved as alternative methods of compliance with paragraph (a) of this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Canadair Regional Jet Alert Service Bulletin S.B.A601R-32-016, dated October 14, 1993; and Bombardier Service Bulletin 601R-32-017, dated November 9, 1993; as applicable.

(1) The incorporation by reference of Bombardier Service Bulletin 601R-32-017, dated November 9, 1993, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Canadair Regional Jet Alert Service Bulletin S.B.A601R-32-016, dated October 14, 1993, was approved previously by the Director of the Federal Register as of February 4, 1994 (59 FR 2952, January 20, 1994).

(3) Copies of these service bulletins may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in Canadian airworthiness directive CF-93-26R2, dated January 18, 1994.

Effective Date

(f) This amendment becomes effective on July 11, 2003.

Issued in Renton, Washington, on May 28, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 03-13975 Filed 6-5-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Acepromazine Maleate Injection

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of acepromazine maleate injectable solution in dogs, cats, and horses as a tranquilizer.

DATES: This rule is effective June 6, 2003.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200-319 that provides for use of Acepromazine Maleate (acepromazine maleate) Injection as a tranquilizer. Phoenix Scientific's Acepromazine Maleate Injection is approved as a generic copy of Fort Dodge Animal Health's PROMACE

Injectable approved under NADA 015-030. The ANADA is approved as of March 25, 2003, and the regulations are amended in 21 CFR 522.23 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subject in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.23 [Amended]

■ 2. Section 522.23 *Acepromazine maleate injection* is amended in paragraph (b), introductory text, by removing "No. 000856" and by adding in its place "Nos. 000856 and 059130".

Dated: May 27, 2003.

Steven F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 03-14348 Filed 6-5-03; 8:45 am]

BILLING CODE 4160-01-S