

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2006-26647; Directorate Identifier 2006-NM-194-AD]

RIN 2120-AA64

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

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. This proposed AD would require repetitive inspections of the bolts that attach the exhaust nozzle to the aft engine flange to determine if any bolts are missing or fractured, and replacement of the existing bolts with new, improved bolts. This proposed AD results from reports of the engine exhaust nozzle and fairing departing from the airplane in flight due to missing attachment bolts. We are proposing this AD to detect and correct missing or fractured attachment bolts, which could lead to the loss of an engine exhaust nozzle during flight and consequent structural damage to the airplane and hazard to people or property on the ground. Damage to the airplane could cause the airplane to yaw and result in reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by January 25, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL-401, Washington, DC 20590.

- *Fax:* (202) 493-2251.

- *Hand Delivery:* Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087,

Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT:

Rocco Viselli, Aerospace Engineer, Airframe and Propulsion Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228-7331; fax (516) 794-5531.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number "FAA-2006-26647; Directorate Identifier 2006-NM-194-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to <http://dms.dot.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78), or you may visit <http://dms.dot.gov>.

Examining the Docket

You may examine the AD docket on the Internet at <http://dms.dot.gov>, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Discussion

Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, notified us that an

unsafe condition may exist on certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. TCCA advises that there have been three reported incidents of the engine exhaust nozzle and fairing departing from the airplane. One incident occurred in flight and the two other incidents occurred on the ground. TCCA has also received numerous ground reports of missing and loose bolts. Investigation has revealed that the bolts that attach the engine exhaust nozzle to the engine flange provide less than the necessary stress margins, which could lead to failure of the bolts. Missing or fractured attachment bolts could lead to loss of the engine exhaust nozzle during flight. This condition, if not corrected, could cause structural damage to the airplane when the engine exhaust nozzle departs from the airplane and could create a hazard to people or property on the ground. Damage to the airplane could cause the airplane to yaw and result in reduced controllability of the airplane.

Relevant Service Information

Bombardier has issued Service Bulletin 601R-78-021, dated June 2, 2006. The service bulletin describes procedures for doing repetitive detailed visual inspections of the bolts that attach the exhaust nozzle to the aft engine flange to determine if any bolts are missing or fractured. If any bolt is missing or fractured, the service bulletin specifies replacing the existing bolts that attach the exhaust nozzle to the aft engine flange with new, improved bolts. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. TCCA mandated the service information and issued Canadian airworthiness directive CF-2006-19, dated July 28, 2006, to ensure the continued airworthiness of these airplanes in Canada.

Bombardier Service Bulletin 601R-78-021 refers to Short Brothers Service Bulletin CF34-NAC-78-024, Revision 4, dated November 10, 2005, as an additional source of service information for accomplishment of the replacement.

FAA's Determination and Requirements of the Proposed AD

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCCA has kept the FAA informed of the situation described above. We have

examined TCCA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require accomplishing the

actions specified in the service information described previously.

Clarification of Inspection Terminology

The "detailed visual inspection" specified in the Bombardier service bulletin and Canadian airworthiness directive is referred to as a "detailed inspection" in this proposed AD. We

have included the definition for a detailed inspection in a note in the proposed AD.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection, per inspection cycle.	2	\$80	None	\$160, per inspection cycle.	686	\$109,760, per inspection cycle.
Replacement	4	\$80	\$513	\$833	686	\$571,438.

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

For the reasons discussed above, I certify that the 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. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the ADDRESSES section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc. (Formerly Canadair):
Docket No. FAA-2006-26647;
Directorate Identifier 2006-NM-194-AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 25, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category; serial numbers (S/Ns) 7003 through 7067 inclusive and S/Ns 7069 through 7947 inclusive.

Unsafe Condition

(d) This AD results from reports of the engine exhaust nozzle and fairing departing from the airplane in flight due to missing attachment bolts. We are issuing this AD to

detect and correct missing or fractured attachment bolts, which could lead to the loss of an engine exhaust nozzle during flight and consequent structural damage to the airplane and hazard to people or property on the ground. Damage to the airplane could cause the airplane to yaw and result in reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Repetitive Inspections

(f) Within 1,500 flight hours after the effective date of this AD: For the left and right engine exhaust nozzles, do a detailed inspection of the bolts that attach the exhaust nozzle to the aft engine flange to determine if any bolts are missing or fractured, in accordance with part A of the Accomplishment Instructions of Bombardier Service Bulletin 601R-78-021, dated June 2, 2006. If no bolt of an engine exhaust nozzle is missing or fractured, repeat the detailed inspection for that engine exhaust nozzle thereafter at intervals not to exceed 1,500 flight hours, until the replacement specified in paragraph (g) or (h) of this AD is accomplished.

Note 1: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

Corrective Action, if Necessary

(g) If any bolt of an engine exhaust nozzle is found missing or fractured during any inspection required by

paragraph (f) of this AD, before further flight, replace the existing bolts that attach the exhaust nozzle to the aft engine flange with new improved bolts, in accordance with part B of the Accomplishment Instructions of Bombardier Service Bulletin 601R-78-021, dated June 2, 2006. Accomplishing the bolt replacement for an engine exhaust nozzle terminates the repetitive inspections required by paragraph (f) of this AD for that engine exhaust nozzle only.

Note 2: Bombardier Service Bulletin 601R-78-021, dated June 2, 2006, refers to Short Brothers Service Bulletin CF34-NAC-78-024, Revision 4, dated November 10, 2005, as an additional source of service information for accomplishment of the replacement.

Terminating Action

(h) Within 4,000 flight hours after the effective date of this AD: For the left and right engine exhaust nozzles, replace the existing bolts that attach the exhaust nozzle to the aft engine flange with new, improved bolts, in accordance with part B of the Accomplishment Instructions of Bombardier Service Bulletin 601R-78-021, dated June 2, 2006. Accomplishing the replacement for the left and right engine exhaust nozzles terminates all of the inspections required by paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(j) Canadian airworthiness directive CF-2006-19, dated July 28, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on December 14, 2006.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6-22043 Filed 12-22-06; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. 1977N-0094L]

RIN 0910-AF36

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its over-the-counter (OTC) labeling regulations and the tentative final monograph (TFM) for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include new warnings and other labeling requirements advising consumers about potential risks and when to consult a doctor. FDA is also proposing to remove the alcohol warning in its regulations and add new warnings and other labeling for all OTC IAAA drug products. The new labeling would be required for all OTC drug products containing an IAAA active ingredient whether marketed under an OTC drug monograph or an approved new drug application (NDA). FDA is issuing this proposal as part of its ongoing review of OTC drug products after considering the advice of its Nonprescription Drugs Advisory Committee (NDAC) and other available information. FDA is proposing these labeling changes because it has tentatively concluded they are necessary for these ingredients to be considered generally recognized as safe and effective and not misbranded for OTC use. FDA will address information about the cardiovascular risks of nonsteroidal anti-inflammatory drugs (NSAIDs) that was discussed at a February 16-18, 2005, FDA advisory committee meeting, and the "Allergy alert" warning for NSAID products, in a future issue of the **Federal Register**.

DATES: Submit written or electronic comments, including comments on FDA's economic impact determination, by May 25, 2007. The specified comment period is longer than is normally provided for proposed rules. Because of the complexity of the proposed rule, FDA is providing an additional 60 days (beyond the normal

comment period) for comments to be submitted and does not plan to extend the comment period beyond this date. Please see section XV of this document for the proposed effective and compliance dates of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 1977N-0094L and Regulatory Information Number (RIN) 0910-AF36 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. and RIN for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marina Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993-0002, 301-796-2090.