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:

2003–20–08 Boeing: Amendment 39–13326. Docket 2002–NM–106–AD.

Applicability: Airplanes, certificated in any category, as listed in Table 1 of this AD below:

TABLE 1.—APPLICABILITY

Models and series	As listed in the fol- lowing Boeing Serv- ice Bulletins
Model 747SR and 747SP, and 747– 100B, -200B, -200C, -200F, -300, -400, and -400D.	747–25–3244, Revision 4, dated June 26, 2003.
Model 767–200 and –300.	767–25–0288, Revision 3, dated August 1, 2002.

Compliance: Required as indicated, unless accomplished previously.

To prevent detachment of the shoulder restraint harness of the attendant or observer seat from its mounting bracket during service, which could result in injury to the occupant of the seat, accomplish the following:

Inspection and Corrective Action

(a) Within 36 months after the effective date of this AD, do a one-time general visual inspection of the attachment of the shoulder restraint harness of each observer or attendant seat to determine if a C-clip is used in the attachment. Do the inspection according to Boeing Service Bulletin 747–25–3244, Revision 4, dated June 26, 2003; or Boeing Special Attention Service Bulletin 767–25–0288, Revision 3, dated August 1, 2002; as applicable. If the shoulder harness is looped through the bracket and attached to itself with a C-clip, do paragraph (a)(1) or (a)(2) of this AD.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(1) Remove and discard the C-clip, and reattach the shoulder harness to the mounting bracket, according to the service bulletin.

(2) Install a second C-clip with the clip's opening positioned in the opposite direction of the opening of the existing C-clip, according to the optional method described in Steps 19 and 20 of Figure 1 or 2 of the applicable service bulletin.

Acceptable for Compliance

(b) Removing and discarding the C-clip and reattaching the shoulder harness to the mounting bracket; according to Boeing Service Bulletin 747–25–3244, Revision 1, dated May 17, 2001, Revision 2, dated April 4, 2002, or Revision 3, dated August 1, 2002; Boeing Service Bulletin 767–25–0288, Revision 1, dated May 17, 2001, or Revision 2, dated April 4, 2002; as applicable; is acceptable for compliance with the requirements of paragraph (a)(1) of this AD.

Parts Installation

(c) As of the effective date of this AD, do not attach the shoulder restraint harness of an observer or attendant seat on any airplane to the mounting bracket using a C-clip, unless the required actions specified in paragraph (a)(2) of this AD are done.

Alternative Methods of Compliance

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

Incorporation by Reference

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Service Bulletin 747-25-3244, Revision 4, dated June 26, 2003; or Boeing Special Attention Service Bulletin 767-25-0288, Revision 3, dated August 1, 2002; 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,

Effective Date

(f) This amendment becomes effective on October 21, 2003.

Issued in Renton, Washington, on September 26, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 03–24976 Filed 10–3–03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NM-143-AD; Amendment 39-13321; AD 2003-20-03]

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 adopts a new airworthiness directive (AD), applicable to certain Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, that requires revising the airworthiness limitations section of the Instructions for Continued Airworthiness by incorporating new structural inspection intervals for the vertical beams of the pressure bulkheads at fuselage stations 409+128 and 559; repairing the vertical beams if necessary; and submitting inspection findings to the airplane manufacturer. This action is necessary to detect and correct, in a timely manner, fatigue cracks in the vertical beams of the pressure bulkheads at fuselage stations 409+128 and 559, which could result in the reduced structural integrity of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective November 10, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 10, 2003.

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 Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 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:

Serge Napoleon, Aerospace Engineer, Airframe and Propulsion Branch, ANE– 171, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7512; fax (516) 568–2716.

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 Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes was published in the Federal Register on July 9, 2003 (68 FR 40829). That action proposed to require revising the airworthiness limitations section of the Instructions for Continued Airworthiness by incorporating new structural inspection intervals for the vertical beams of the pressure bulkheads at fuselage stations 409+128 and 559; repairing the vertical beams if necessary; and submitting inspection findings to the airplane manufacturer.

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.

Interim Action

This is considered to be interim action. The inspection reports required by this AD will enable the manufacturer to obtain better insight into the cause of the fatigue cracks in the vertical beams of the pressure bulkheads at fuselage stations 409+128 and 559. Once final action has been identified, the FAA may consider further rulemaking.

Cost Impact

The FAA estimates that 533 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is \$65 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$34,645, or \$65 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed 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:

2003–20–03 Bombardier, Inc. (Formerly Canadair): Amendment 39–13321. Docket 2003–NM–143–AD.

Applicability: Model CL–600–2B19 (Regional Jet series 100 & 440) airplanes, serial numbers 7003 through 7999 inclusive; certificated in any category.

Note 1: This AD requires revisions to certain operator maintenance documents to include new inspections. Compliance with these inspections is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by these inspections, the

operator may not be able to accomplish the inspections described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance from the office identified in paragraph (d) of this AD and Sections 39.19 and 39.21 of the Federal Aviation Regulations (14 CFR 39.19 and 39.21). The request should include a description of changes to the required inspections that will ensure the continued damage tolerance of the affected structure. The FAA has provided guidance for this determination in Advisory Circular (AC) 25–1529

Compliance: Required as indicated, unless accomplished previously.

To detect and correct, in a timely manner, fatigue cracks in the vertical beams of the pressure bulkheads at fuselage stations 409+128 and 559, which could result in the reduced structural integrity of the airplane, accomplish the following:

Revise Airworthiness Limitations (AWL) Section

(a) Within 14 days after the effective date of this AD, revise the AWL section of the Instructions for Continued Airworthiness by incorporating the contents of Canadair Temporary Revision (TR) 2B–1566, dated January 31, 2003, to the Canadair Regional Jet Maintenance Requirements Manual, Part 2, Appendix B, "Airworthiness Limitations," into the AWL section. Thereafter, except as provided in paragraph (d) of this AD, no alternative structural inspection intervals may be approved for the vertical beams on the pressure bulkheads at fuselage stations 409+128 and 559.

Note 2: When the contents of TR 2B–1566 have been included in the general revisions of the AWL section, the general revisions may be incorporated into the AWL section, and the TR may be removed from the AWL section.

Repair and Revise AWL Section

(b) If any crack is found during any inspection done according to the AWL section of the Instructions for Continued Airworthiness specified in paragraph (a) of this AD, do the actions specified in paragraphs (b)(1) and (b)(2) of this AD.

(1) Before further flight: Repair per a method approved by either the Manager, New York Aircraft Certification Office (ACO), FAA; or Transport Canada Civil Aviation (TCCA) (or its delegated agent).

(2) Within 14 days after receiving the new AWL associated with a repair: Revise the AWL section of the Instructions for Continued Airworthiness by inserting a copy of the new airworthiness limitation and inspection requirements associated with the FAA- or TCCA-approved repair referred to in paragraph (b)(1) of this AD into the Canadair Regional Jet Maintenance Requirements Manual, Part 2, Appendix B, "Airworthiness Limitations" section. Thereafter, except as provided in paragraph (d) of this AD, no alternative structural inspection intervals specified in the FAA- or TCCA-approved repair may be approved for the vertical beams on the pressure bulkheads at fuselage stations 409+128 and 559.

Reporting

- (c) Submit a report of the findings (both positive and negative) of the inspection required by paragraph (a) of this AD to Bombardier, Inc., Canadair, Aerospace Group, CRJ Technical Help Desk, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada; fax (514) 855-8501; at the applicable time specified in paragraph (c)(1) or (c)(2) of this AD. Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provision of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) and have been assigned OMB Control Number 2120-0056.
- (1) If the inspection was done after the effective date of this AD: Submit the report within 30 days after the inspection.
- (2) If the inspection was done prior to the effective date of this AD: Submit the report within 30 days after the effective date of this

Alternative Methods of Compliance

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

Incorporation by Reference

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with Canadair Temporary Revision 2B-1566, dated January 31, 2003, to the Canadair Regional Jet Maintenance Requirements Manual, Part 2, Appendix B, "Airworthiness Limitations." 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 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, 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 3: The subject of this AD is addressed in Canadian airworthiness directive CF-2003-08, dated April 23, 2003.

Effective Date

(f) This amendment becomes effective on November 10, 2003.

Issued in Renton, Washington, on September 24, 2003.

Ali Bahrami.

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 03-24679 Filed 10-3-03: 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts

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 supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for use of progesterone intravaginal inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

DATES: This rule is effective October 6, 2003.

FOR FURTHER INFORMATION CONTACT:

Harlan J. Howard, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0231, email: hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199 filed a supplement to NADA 141-200 that provides for use of EAZI-BREED CIDR Progesterone Intravaginal Inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus. The NADA is approved as of July 29, 2003, and the regulations are amended in 21 CFR 529.1940 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning July 29, 2003.

The agency has determined under 21 CFR 25.33(c) 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 Subjects in 21 CFR Part 529

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529-CERTAIN OTHER DOSAGE **FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Section 529.1940 is amended in paragraph (e)(3) in the first sentence by removing the phrase "; or in lactating dairy cows"; and by revising paragraphs (d)(1), (d)(2), (e)(1), and (e)(2) to read asfollows:

§ 529.1940 Progesterone intravaginal inserts.

(d) * * *

- (1) Product labeling shall bear the following warnings: "Avoid contact with skin by wearing latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed of in accordance with applicable local, State, and Federal regulations."
- (2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(2)(i) of this section. See § 522.690(c) of this chapter.

- (e) * * *
- (1) Amount. Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(2)(i) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.
- (2) Indications for use—(i) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows,