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**

(f) This amendment becomes effective on January 22, 2004.

Issued in Renton, Washington, on December 5, 2003.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 03–31061 Filed 12–17–03; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2002–NM–78–AD; Amendment 39–13386; AD 2003–25–03]**

**RIN 2120–AA64**

## Airworthiness Directives; Bombardier Model DHC–8–400, –401, and –402 Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain Bombardier Model DHC–8–400, –401, and –402 airplanes, that requires a one-time inspection of the forward engine mount assemblies on the left and right engine nacelles for installation of pre-production engine mount assemblies, and follow-on corrective actions if necessary. This action is necessary to prevent failure of the forward engine mount, which could result in reduced structural integrity of the nacelle and engine support structure. This action is intended to address the identified unsafe condition.

**DATES:** Effective January 22, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 22, 2004.

**ADDRESSES:** The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, 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:** Douglas G. Wagner, Aerospace Engineer, Systems and Flight Test Branch, ANE–172, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7506; 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 DHC–8–400, –401, and –402 airplanes was published in the **Federal Register** on October 9, 2003 (68 FR 58287). That action proposed to require a one-time inspection of the forward engine mount assemblies on the left and right engine nacelles for installation of pre-production engine mount assemblies, and follow-on corrective actions if necessary.

### 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

We estimate that 11 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per airplane to accomplish the required inspection, 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 $1,430, or $130 per airplane.

The cost impact figure discussed above is 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:

**2003–25–03 Bombardier, Inc.** (Formerly de Havilland, Inc.): Amendment 39–13386. Docket 2002–NM–78–AD.

*Applicability:* Model DHC–8–400, –401, and –402 airplanes; serial numbers 4005, 4006, 4008 through 4016 inclusive, 4018 through 4051 inclusive, and 4053; certificated in any category.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent failure of the forward engine mount, which could result in reduced structural integrity of the nacelle and engine support structure, accomplish the following:

**Inspection**

(a) Within 100 flight cycles after the effective date of this AD: Do a general visual inspection of the forward engine mount assemblies on the left and right engine nacelles for installation of pre-production assemblies (determine the part number and configuration for each assembly), per the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–71–06, Revision ''A,'' dated December 5, 2001. If no pre-production engine mount assembly is installed, no further action is required by 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.''

**Follow-on Corrective Actions**

(b) If any pre-production engine mount assembly is installed, do all the applicable follow-on corrective actions (including repetitive detailed inspections for cracking, and rework or replacement of the pre-production engine mount assembly if necessary), per all the actions specified in the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–71–06, Revision ''A,'' dated December 5, 2001, at the applicable times specified in Paragraph I., Part D., ''Compliance,'' of the service bulletin. Any replacement due to cracking must be done before further flight.

**Note 2:** For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

**Optional Terminating Action for Follow-on Repetitive Inspections**

(c) Installation of production engine mount assemblies on all four forward engine mounts ends the repetitive inspection requirements of paragraph (b) of this AD.

**Part Installation**

(d) As of the effective date of this AD, no person may install an engine mount assembly having a pre-production configuration and/or part number 96042–07 on any airplane, unless the assembly has been reworked per Part B of the Accomplishment Instructions of Bombardier Alert Service Bulletin A84–71–06, Revision ''A,'' dated December 5, 2001.

**Alternative Methods of Compliance**

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

**Incorporation by Reference**

(f) Unless otherwise provided in this AD, the actions shall be done per Bombardier Alert Service Bulletin A84–71–06, Revision ''A,'' dated December 5, 2001. 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., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, 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–2002–07, dated January 21, 2002.

**Effective Date**

(g) This amendment becomes effective on January 22, 2004.

Issued in Renton, Washington, on December 5, 2003.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 03–31062 Filed 12–17–03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 882

**[Docket No. 2002N–0370]**

## Neurological Devices; Classification of Human Dura Mater

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying human dura mater intended to repair defects in human dura mater into class II (special controls). This action is being taken to establish sufficient regulatory control to provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled ''Class II Special Controls Guidance Document: Human Dura Mater'' that will serve as the special control for this device.

**DATES:** This rule is effective January 20, 2004.

**FOR FURTHER INFORMATION CONTACT:** Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of October 22, 2002 (67 FR 64835), FDA issued a proposed rule to classify human dura mater into class II based on new information regarding this device and the recommendation of the Neurological Devices Panel. FDA identified the draft guidance document entitled ''Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA'' as the proposed special control capable of providing reasonable assurance of the safety and effectiveness of the device. The device is intended to repair defects in human dura mater. FDA invited interested persons to comment on the proposed rule by January 21, 2003. FDA received one comment.

### II. Summary of the Comment and FDA's Response

The comment did not express an opinion on the proposed rule. It informed FDA of new research in transgenic mice which suggests that it may be difficult to distinguish whether a patient's cause of death is related to Creutzfeldt-Jakob Disease (CJD) or variant CJD based on neuropathology. FDA appreciates receipt of the information but does not believe it affects the classification of human dura mater. The guidance document ''Class II Special Controls Guidance Document: Human Dura Mater'' recommends clinical and histopathological methods, including next of kin interviews and full brain autopsy, respectively, that are intended to identify and defer potential human dura mater donors who have either CJD or variant CJD.

### III. FDA's Conclusion

Based on a review of the available information in the preamble to the proposed rule and placed on file in FDA's Division of Dockets Management (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device.