under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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:

2002–14–26 Turbomeca S.A.: Amendment 39–12826. Docket No. 2001–NE–35–AD.

Applicability: This airworthiness directive (AD) is applicable to Turbomeca S.A. Arriel models 1A, 1A1, 1B, 1D, and 1D1 turboshaft engines. These engines are installed on, but not limited to, Astar AS350D; Eurocopter AS350B, BA, B1, L1, and B2N; and Fennic AS550U2 helicopters.

Note 1: This AD applies to each engine 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 engines 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: Compliance with this AD is required as indicated, unless already done.

To prevent uncontainment of the free turbine during an overspeed event, resulting in damage to the helicopter, do the following:

(a) For Arriel engine models 1A and 1A1 that have incorporated modification TU 13, but have not incorporated modification TU 99 and modification TU 215, and for Arriel engine models 1B and 1D that have not incorporated modification TU 99 and modification TU 215, do the following within 30 days after the effective date of this AD:

(1) Install containment shield ring in accordance with the Instructions to be Incorporated, paragraphs 2A. through 2C, (modification TU 254) of service bulletin (SB) No. A292 72 0206, Update 2, dated October 23, 2000.

(2) Install double support around the reduction gearbox free turbine bearing housing, in accordance with Instructions for Incorporation, paragraphs 2A. through 2C, (modification TU 259) of SB No. 292 72 0208, Update 2, dated May 13, 1996.

(b) For Arriel engine models 1A and 1A1 that have incorporated modification TU 13 and modification TU 99, but have not incorporated modification TU 215, and Arriel engine models 1B, 1D, and 1D1 that have incorporated modification TU 99, but have not incorporated modification TU 215, do the following within 30 days after the effective date of this AD:

(1) Install additional containment shield ring, in accordance with the Instructions to be Incorporated, paragraphs 2A. through 2C, (modification TU 255) of SB No. A292 72 0207, Update 2, dated October 23, 2000.

(2) Install double support around the reduction gearbox free turbine bearing housing, in accordance with Instructions for Incorporation, paragraphs 2A. through 2C, (modification TU 259) of SB No. 292 72 0208, Update 2, dated May 13, 1996.

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, Engine Certification Office (ECO). Operators must submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

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 helicopter to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated by Reference

(e) The modifications must be done in accordance with the following Turbomeca S.A. mandatory service bulletins (MSB's):

Document No.	Pages	Revision	Date
MSB No. A292 72 0206, Total pages: 8	All	2	Oct. 23, 2000.
MSB No. A292 72 0207, Total pages: 7	All	2	Oct. 23, 2000.
MSB No. 292 72 0208, Total pages: 8	All	2	May 13, 1996.

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 Turbomeca S.A., 40220 Tarnos, France; telephone: (33) 05 59 64 40 00; fax: (33) 05 59 64 60 80. Copies may be inspected, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; 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 Direction Generale de L'Aviation Civile airworthiness directive AD 1995–069(A)R3.

Effective Date

(f) This amendment becomes effective on August 6, 2002.

Issued in Burlington, Massachusetts, on July 8, 2002.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02–18203 Filed 7–19–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–124–AD; Amendment 39–12828; AD 2002–14–28]

RIN 2120–AA64

Airworthiness Directives; de Havilland Inc. Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain de Havilland Inc. (de Havilland) Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes. This AD establishes a life limit for the front fuselage struts and requires you to repetitively replace the front fuselage struts every 15 years or repetitively inspect the struts for corrosion or fatigue damage and replace when the damage exceeds a certain level. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Canada. The actions specified by this AD are intended to prevent structural failure of the front fuselage caused by corrosion or fatigue damage to the struts that develops over time, which could result in reduced or loss of control of the airplane.

EFFECTIVE DATE: This AD becomes effective on September 6, 2002.

ADDRESSES: You may get the service information referenced in this AD from Bombardier Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario, Canada M3K 1Y5; telephone: (416) 633–7310. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–124–AD, 901 Locust, Room 506, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Hjelm, Aerospace Engineer, New York Aircraft Certification Office, 10 Fifth Street, 3rd Floor, Valley Stream, New York 11581–1200; telephone: (516) 256–7523; facsimile: (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

Transport Canada, which is the airworthiness authority for Canada, notified FAA that an unsafe condition may exist on certain de Havilland Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes. Transport Canada reports numerous incidents of corrosion of the front fuselage struts. Further analysis of the front fuselage struts reveals that these parts are not life limited and incur corrosion and fatigue damage over time.

What Is The Potential Impact if FAA Took No Action?

Corrosion damage, if not detected and corrected, could result in failure of the front fuselage and possible reduced or loss of control of the airplane.

Has FAA Taken Any Action to This Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain de Havilland Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on March 28, 2002 (67 FR 14886). The NPRM proposed to establish a life limit for the front fuselage struts and would require you to repetitively replace the front fuselage struts every 15 years or repetitively inspect the struts for corrosion or fatigue damage and replace when the damage exceeds a certain level.

Was the Public Invited To Comment?

The FAA encouraged interested persons to participate in the making of this amendment. We did not receive any comments on the proposed rule or on our determination of the cost to the public.

FAA's Determination

What is FAA's Final Determination on This Issue?

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We have determined that these minor corrections:

—Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and

—Do not add any additional burden upon the public than was already proposed in the NPRM.

Cost Impact

How Many Airplanes Does This AD Impact?

We estimate that this AD affects 354 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the replacement:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. Operators
108 workhours × $60 an hour = $6,480 per airplane.	$2,352 per airplane	$8,832 per airplane per replacement	$3,126,528

Compliance Time of This AD

What Will Be the Compliance Time of This AD?

The replacement compliance time of this AD is ''initially replace upon accumulating 15 years from the date of installation of the front fuselage struts or within the next 12 calendar months after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 15 years.'' If the repetitive inspection option is used, then the repetitive compliance time interval will be at 1 and 5 years depending on the method used (provided certain corrosion or damage limits are not exceeded).

Why Is the Compliance Time Presented in Calendar Time Instead of Hours Time-in-Service (TIS)?

The compliance of this AD is presented in calendar time instead of hours TIS. The need for establishing a life limit for the front fuselage struts as specified in this AD is the result of reports of corrosion found in this area on the affected airplanes. Corrosion can occur regardless of whether the aircraft is in operation. In order to ensure that the unsafe condition specified in this AD does not go undetected if the airplane was not in operation for an extended period of time, the compliance is presented in calendar time instead of hours TIS.

Regulatory Flexibility Determination and Analysis

What Are the Requirements of the Regulatory Flexibility Act?

The Regulatory Flexibility Act of 1980 was enacted by Congress to assure that small entities are not unnecessarily or disproportionately burdened by government regulations. This Act establishes ''as principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational

requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that the rule will, the Agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

What Is FAA's Determination?

The FAA has determined that this AD could have a significant economic impact on a substantial number of small entities. However, we have determined that we should continue with this action in order to address the unsafe condition and ensure aviation safety.

You may obtain a copy of the complete Regulatory Flexibility Analysis (entitled ''Final Regulatory Flexibility Analysis'') that was prepared for this AD from the Docket file at the location listed under the **ADDRESSES** section of this document.

Regulatory Impact

Does This AD Impact Various Entities?

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.

Does This AD Involve a Significant Rule or Regulatory Action?

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) could have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, under 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. FAA amends § 39.13 by adding a new AD to read as follows:

2002–14–28 de Havilland Inc.: Amendment 39–12828; Docket No. 98–CE–124–AD.

(a) *What airplanes are affected by this AD?* This AD affects all serial numbers of Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent structural failure of the front fuselage caused by corrosion or fatigue damage to the struts that develops over time, which could result in reduced or loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Replace each front fuselage strut with a new strut. Part numbers for existing and replacement front fuselage struts parts are presented in paragraph (e) of this AD.	Initially replace upon accumulating 15 years on each front fuselage strut or within the next 12 calendar months after September 6, 2002 (the effective date of this AD), whichever occurs later. Repetitively replace thereafter upon accumulating 15 years on each front fuselage strut.	In accordance with the applicable maintenance manual, as specified in de Havilland Parts Service Manual 1–2–2, Part 5, Temporary Revision 2–22; and de Havilland Parts Service Manual 1–2T–2, Part 5, Temporary Revision 2T–6, both dated August 3, 1998.

Actions	Compliance	Procedures
(2) As an alternative method of compliance to the replacements in paragraph (d)(1) of this AD, you may repetitively inspect each front fuselage strut, as follows:. (i) perform a detailed inspection of each front fuselage strut and all fittings attached to the frame for damage (corrosion, cracks, dents). When fatigue damage is found, you must replace the damaged strut. After each inspection, clean the drain holes around the bottom end fitting and protect the tube with an appropriate corrosion preventive spray. Part numbers for existing and replacement front fuselage struts parts are presented in paragraph (e) of this AD. (ii) perform an ultrasonic thickness measurement of all surface on each front fuselage strut. When minimum thickness is below 0.030 inches, you must replace the affected strut. Part numbers for existing and replacement front fuselage struts parts are presented in paragraph (e) of this AD.	Initially inspect upon accumulating 15 years on each front fuselage strut or within the next 12 calendar months after September 6, 2002 (the effective date of this AD), whichever occurs later. Accomplish the repetitive detailed inspection thereafter at intervals not to exceed 12 months and the ultrasonic thickness measurement at intervals not to exceed 5 years. Accomplish the corrosion prevention work prior to further flight after each inspection. Accomplish the replacement prior to further flight after damage is found or the thickness is found below 0.030 inches. Then, after replacement either replace with a new strut at 15-year intervals thereafter or repetitively inspect as prescribed above beginning at 15 years after each replacement.	For the detailed inspection, use an inspection light, inspection mirror, and 10X magnifying glass. For the ultrasonic inspection, use FAA-approved procedures that follow a similar calibration and measures strut thickness to that detailed in Bombardier Service Bulletin 2/49, Revision C.
(3) Do not install, on any affected airplane, any front fuselage strut unless it has a part number specified in the Replacement Part Number column of the chart presented in paragraph (e) of this AD.	As of September 6, 2002 (the effective date of this AD.	Not Applicable.

(e) *What part number front fuselage struts should I use for replacements?* The following charts presents the part numbers for existing parts and replacement parts for the front fuselage strut replacements:

Installed part No.	Replacement part No.	Description
C2FS209 or C2FS3281A	C2FS3281A	Strut Assembly Front Fuselage, Left.
C2FS210 or C2FS3282A	C2FS3282A	Strut Assembly Front Fuselage, Right.

(f) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, New York Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, 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 (f) 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(g) *Where can I get information about any already-approved alternative methods of compliance?* Contact Jon Hjelm, Aerospace Engineer, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone: (516) 256–7523; facsimile: (516) 256–2716.

(h) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(i) *How do I get copies of the documents referenced in this AD?* You may direct technical questions to or get copies of the documents referenced in this AD from Bombardier Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario, Canada M3K 1Y5; telephone: (416) 633–7310. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in Canadian AD CF–98–37R1, dated August 20, 1999.

(j) *When does this amendment become effective?* This amendment becomes effective on September 6, 2002.

Issued in Kansas City, Missouri, on July 15, 2002.

Dorenda D. Baker,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–18334 Filed 7–19–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol

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 several supplemental applications filed by Pharmacia and Upjohn Co. to their new animal drug applications (NADAs) for the use of single-ingredient Type A medicated