or at the next ''C'' check, whichever occurs first.

New Requirements of This AD

Modification

(b) For all airplanes: Within 36 months after the effective date of this AD; modify the electrical wires in the cable trough below the cabin floor at Sections X510.00 to X580.50 (including a general visual inspection and any applicable repair) per Part III, paragraphs 1 through 9 and 12 through 20, of the Accomplishment Instructions of Bombardier Service Bulletin 8–53–80, Revision 'A', dated July 25, 2000. Any applicable repair must be done before further flight. Accomplishment of these actions before the effective date of this AD per Bombardier Service Bulletin 8–53–80, dated December 22, 1999, is considered acceptable for compliance with the actions required by this paragraph.

Alternative Methods of Compliance

(c) 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

(d) The actions shall be done in accordance with Bombardier Service Bulletin S.B. 8–53–66, dated March 27, 1998; and Bombardier Service Bulletin 8–53–80, Revision 'A', dated July 25, 2000; as applicable.

(1) The incorporation by reference of Bombardier Service Bulletin 8–53–80, Revision 'A', dated July 25, 2000; 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 Bombardier Service Bulletin S.B. 8–53–66, dated March 27, 1998; was approved previously by the Director of the Federal Register as of October 27, 1998 (63 FR 50501, September 22, 1998).

(3) 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, 1600 Stewart Avenue, Westbury, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 2: The subject of this AD is addressed in Canadian airworthiness directive CF–1998–08R2, dated July 10, 2000.

Effective Date

(e) This amendment becomes effective on March 19, 2004.

Issued in Renton, Washington, on January 29, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–2576 Filed 2–12–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–SW–45–AD; Amendment 39–13471; AD 2004–03–27]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS332C, L, and L1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for the specified Eurocopter France (Eurocopter) model helicopters that requires inspecting the bevel gear for a crack using a borescope. This amendment is prompted by a crack that was detected on a bevel gear during a main gearbox teardown inspection. The actions specified by this AD are intended to prevent failure of the bevel gear, loss of torque to the main rotor system, and subsequent loss of control of the helicopter.

DATES: Effective March 19, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 19, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Uday Garadi, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, Fort Worth, Texas 76193–0110, telephone (817) 222–5123, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Eurocopter Model AS332C, L, and L1 helicopters was published in the **Federal Register** on December 31, 2002 (67 FR 79893). That action proposed to require inspecting the bevel gear for cracks using a borescope within 50 hours TIS, and thereafter at intervals not to exceed 150 hours TIS, for bevel gears with more than 6,600 hours TIS. If a crack was found in the bevel gear, it was proposed that replacing the bevel gear would be required. However, before the final rule was published, we discovered that certain part-numbered bevel gears were omitted from the applicability and one was incorrectly stated in that previous proposal. Also, the manufacturer revised the service information to introduce the new inspection interval of 1,000 cycles for helicopter operations involving a torque application frequency of more than 4 cycles per hour for helicopters that conduct external load operations involving more frequent torque applications. Additionally, we inadvertently included Model AS332C1 helicopters in the ''Applicability'' section of the proposal—those model helicopters are not on the U.S. Registry. Finally, the DGAC issued a revised AD for helicopters operated in France. Therefore, we reopened the comment period by publishing a supplemental notice of proposed rulemaking on September 18, 2003 (68 FR 54686). That action:

- Corrected the basic bevel gear part number (P/N) stated in the ''Applicability'' of the proposal to state ''332A32–2181–00'';
- Added bevel gear P/Ns 332A32–2181–01 and –08 to the ''Applicability'';
- Deleted the Model AS332C1 helicopters from the ''Applicability'';
- Incorporated the latest Eurocopter Alert Telex and referenced the latest DGAC AD;
- Proposed requiring the repetitive inspection at intervals not to exceed 150 hours TIS or 1,000 torque cycles, whichever occurs first; and
- Excluded from the ''Applicability'' any main gearbox (regardless of the P/N of the main reduction gear module or bevel gear) overhauled after December 31, 2002, and any P/N inspected in accordance with AS332 letter to Repair Stations No. 183 or repaired in accordance with Repair Sheet (F.R.) 332A32–2181–ZA or 331A32–3110–ZA.

The Direction Generale De L'Aviation Civile (DGAC), the airworthiness authority for France, notified the FAA that an unsafe condition may exist on Eurocopter Model AS332C, C1, L, and L1 helicopters. The DGAC advises that borescope inspections of the bevel gear are necessary to detect cracks.

Eurocopter has issued Alert Telex No. 05.00.58 R2, dated February 3, 2003, which indicates that as a result of metal particles found on the chip detector of the main gearbox sump on a helicopter, further investigation has revealed a longitudinal crack that grows lengthwise in the shaft, up to the

combiner gear, in the bevel gear where the ring retains the pinion toe bearing. The alert telex specifies inspecting the bevel gear for cracks using a borescope, pending the result of the investigation into the cause of the fatigue crack initiation currently being conducted in France. The DGAC classified this alert telex as mandatory and issued AD 2002–424–081(A) R2, dated March 19, 2003, to ensure the continued airworthiness of these helicopters in France.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that this AD will affect 4 helicopters of U.S. registry, and the required actions will take approximately 4 work hours for the inspections and 16 work hours to replace the bevel gear, if necessary, at an average labor rate of $65 per work hour. Required parts will cost approximately $31,372. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $130,688, assuming that upon the first inspection a crack is detected and the bevel gear will need to be replaced.

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 a new airworthiness directive to read as follows:

2002–SW–45–AD Eurocopter France: Amendment 39–13471. Docket No. 2002–SW–45–AD.

Applicability: Model AS332C, L, and L1 helicopters, with main gearbox bevel gear (bevel gear), part numbers (P/N) 332A32–2027–00 or 332A32–2026–00, containing bevel gears, P/N 332A32–2181–00, –01, –02, –03, or –04, or 331A32–3110–07, –08, –09, or –19, installed, certificated in any category. This AD does not apply to:

- Main gearboxes that were overhauled after December 31, 2002;
- Parts inspected in accordance with AS332 letter to Repair Stations No. 183; or
- Parts repaired in accordance with Repair Sheet (F.R.) 332A32–2181–ZA or 331A32–3110–ZA.

Compliance: Required as indicated, unless accomplished previously.

To detect a bevel gear crack and prevent failure of the bevel gear, loss of torque to the main rotor system, and subsequent loss of control of the helicopter, accomplish the following:

(a) For bevel gears that have more than 6,600 hours time-in-service (TIS), within 50 hours TIS and thereafter at intervals not to exceed 150 hours TIS, or at intervals not to exceed 1,000 frequent torque variation cycles, whichever occurs first, inspect for a crack using a borescope in accordance with the Operational Procedure, paragraph 2.B.1. and 2.B.2. of Eurocopter Telex No. 05.00.58 R2, dated February 3, 2003. A frequent torque variation cycle is each landing or external load operation beginning at the point when there are 4 or more landings, or 4 or more external load operations, or any combination of 4 or more landings and external load operations in any 60 minute time period, and ending when any combination of landings and external load operations is less than 4 in any 60 minute time period.

(b) If a crack is found in the bevel gear, before further flight, replace the bevel gear with an airworthy bevel gear.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) The inspection and replacement, if necessary, shall be done in accordance with Eurocopter Telex No. 05.00.58 R2, dated February 3, 2003. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

(e) This amendment becomes effective on March 19, 2004.

Note: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 2002–424–081(A) R2, dated March 19, 2003.

Issued in Fort Worth, Texas, on January 30, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–2782 Filed 2–12–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 610

[Docket No. 1980N–0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule and final order that appeared in the **Federal Register** of January 5, 2004 (69 FR 255). The document amended the biologics regulations and categorized certain biological products licensed before July 1, 1972, based on their safety, effectiveness, and labeling. The document was published with some typographical errors in the reference section. This document corrects those errors.

DATES: Effective February 13, 2004.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–32255, appearing on page 255, in the