Issued in Fort Worth, Texas, on December 23, 2003.

Kim Smith,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service. [FR Doc. 04–268 Filed 1–8–04; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–SW–41–AD; Amendment 39–13428; AD 2004–01–14]

RIN 2120-AA64

Airworthiness Directives; Eurocopter France Model EC130B4 Helicopters

AGENCY: Federal Aviation Administration, DOT. **ACTION:** Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for Eurocopter France (Eurocopter) Model EC130B4 helicopters with a certain air intake cowling attachment fitting (fitting) installed. This action requires inspecting for broken or cracked forward fittings. If a broken or cracked fitting is found, inspecting the four center and aft fittings for cracks is required. Replacing broken fittings or certain cracked fittings is also required. This amendment is prompted by reports of cracked and broken fittings; one fitting failed after only 418 hours timein-service (TIS). This condition, if not corrected, could result in failure of a forward fitting, an excess load on the other fittings, which could cause them to crack and break, which could result in loss of the air intake cowling in flight, and subsequent damage or loss of control of the helicopter, or both. DATES: Effective January 26, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 26, 2004.

Comments for inclusion in the Rules Docket must be received on or before March 8, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2003–SW– 41–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: 9-asw-adcomments@faa.gov. 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: Ed Cuevas, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5355, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: 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 EC130B4 helicopters with fittings, part number (P/N) 350A25–0405–00, –01, –02, –03, –04, and –05, installed. The DGAC advises that there have been cases of cracks and failures of fittings.

Eurocopter France has issued Eurocopter Alert Service Bulletin No. 53A004, dated September 11, 2003, which specifies inspecting the fittings for cracks and replacing failed fittings or those with more than 2 cracks or 1 crack that exceeds 10 mm in length. The alert service bulletin permits operators to stop-drill up to two cracks provided that no crack exceeds 10 mm in length and that the fitting is inspected every 20 flying hours, at the lastest. The DGAC classified this alert service bulletin as mandatory and issued AD 2003-358(A), dated October 15, 2003, to ensure the continued airworthiness of these helicopters in France.

This helicopter model is manufactured in France and is type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

This unsafe condition is likely to exist or develop on other helicopters of the same type design registered in the United States. Therefore, this AD is being issued to prevent failure of a forward fitting, an excess load on the other fittings, which could cause them to crack and break, which could result in loss of the air intake cowling in flight, and subsequent damage or loss of control of the helicopter, or both. This AD requires:

• For helicopters with less than 100 hours TIS, inspecting the forward fittings no later than 110 hours TIS, then at intervals not to exceed 110 hours TIS;

• For helicopters with 100 or more hours TIS, inspecting the forward fittings within the next 10 hours TIS, then at intervals not to exceed 110 hours TIS;

• If one or two forward fittings are broken or cracked, inspecting the center and aft fittings for breaks or cracks before further flight;

• If any fitting is broken, has a crack that exceeds 10 mm in length, or has more than 2 cracks, replacing the fitting with an airworthy fitting before further flight; and

• For helicopters with one or more cracked fitting with no more than two cracks on each fitting, and each crack length is less than or equal to 10mm, stop-drilling the cracks and inspecting the fitting at intervals not to exceed 20 hours TIS.

The actions must be done in accordance with the alert service bulletin described previously. The unsafe condition must be corrected in a very short time period because loss of an air intake cowling in flight can adversely affect the controllability or structural integrity of the helicopter. Therefore, the previously described actions are required, and this AD must be issued immediately. This AD is an interim action; Eurocopter is investigating to determine the cause of the cracked and failed fittings. Upon completion of that investigation, we may issue another AD with terminating action for the requirements of this AD.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

The FAA estimates that this AD will affect 28 helicopters and will take approximately 1 work hour to inspect the two forward fittings. If cracked or broken fittings are found, an additional 2 work hours will be required to inspect the center and aft fittings, and an additional 0.5 work hour will be required to replace each cracked or broken fitting. We estimate that the average labor rate will be \$65 per work hour. We estimate that forward fittings cost \$240 each and center and aft fittings cost \$225 each. The estimated total cost of the AD for each year will be approximately \$11,995, assuming that (1) The entire fleet is inspected 5 times per year, (2) cracked forward fittings are found on two helicopters during 2 inspections, (3) 2 forward and 2 center fittings are replaced on one helicopter, and (4) 2 forward, 2 center, and 2 aft fittings are replaced on the other helicopter.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption ADDRESSES. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2003–SW– 41–AD." The postcard will be date stamped and returned to the commenter.

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.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to

correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation 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 a new airworthiness directive to read as follows:

2004–01–14 Eurocopter France: Amendment 39–13428. Docket No.

2003–SW–41–AD.

Applicability: Eurocopter France Model EC130B4 helicopters with an air intake cowling forward attachment fitting (fitting), part number (P/N) 350A25–0405–00, –01, –02, –03, –04, and –05, installed, certificated in any category.

Compliance: Required as indicated. To prevent failure of a forward fitting, an excess load on the other fittings, which could cause them to crack and break, which could result in loss of the air intake cowling in flight, and subsequent damage or loss of control of the helicopter, or both, accomplish the following:

(a) Visually inspect the forward fittings for breaks or cracks by following paragraph 2.B.1. of the Operational Procedure in Eurocopter Alert Service Bulletin No. 53A004, dated September 11, 2003 (ASB).

(1) For helicopters with less than 100 hours time-in-service (TIS), inspect before the helicopter reaches 110 hours TIS, unless accomplished previously, and thereafter, at intervals not to exceed 110 hours TIS.

(2) For helicopters with 100 or more hours TIS, inspect within 10 hours TIS, unless accomplished previously, and thereafter at intervals not to exceed 110 hours TIS.

(b) If one or two forward fittings are broken or cracked, inspect the center and aft fittings for breaks or cracks before further flight by following paragraph 2.B.2.b. of the ASB.

(c) Before further flight, replace any fitting that is broken or has more than two cracks, or any fitting with a crack that exceeds 10 mm in length by following paragraph 2.B.2.c. of the Operational Procedure in the ASB.

(d) For any cracked fitting that has no more than two cracks, and neither crack exceeds 10 mm in length, you are not required to replace that cracked fitting provided that you stop-drill each crack and re-inspect that fitting at intervals not to exceed 20 hours TIS. During a later inspection, if you discover that the fitting has failed, another crack has developed, or a stop-drilled crack has grown to exceed 10mm in length, replace the fitting before further flight.

(e) 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.

(f) The inspections and replacements, if necessary, shall be done using Eurocopter Alert Service Bulletin No. 53A004, dated September 11, 2003. 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 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, DĈ.

(g) This amendment becomes effective on January 26, 2004.

Note: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 2003–358(A), dated October 15, 2003.

Issued in Fort Worth, Texas, on December 31, 2003.

Kim Smith,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–368 Filed 1–8–04; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the