

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, both before and after the closing date for comments, 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 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. 97-SW-44-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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:

97-26-02 Eurocopter Deutschland GmbH (ECD) and Eurocopter Canada LTD.:
Amendment 39-10245. Docket No. 97-SW-44-AD.

Applicability: Eurocopter Deutschland GmbH Model BO-105A, BO-105C, BO-105S, BO-105LS A-1, and BO-105LS A-3 helicopters and Eurocopter Canada Ltd. BO-105LS A-3 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detect cracks in the main rotor mast flange (flange), which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1. and 2.A.2. of the Accomplishment Instructions of Eurocopter Deutschland GmbH Alert Service Bulletin No. ASB-BO 105-10-110, dated August 27, 1997, or Eurocopter Canada Alert Service Bulletin No. ASB-BO 105 LS-10-9, dated September 11, 1997, as applicable.

(b) If a crack is found, remove the cracked main rotor mast and replace it with an airworthy main rotor mast.

(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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 2: Information concerning the existence of approved alternative methods of

compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits will not be issued.

(e) The inspection shall be done in accordance with Eurocopter Deutschland GmbH Alert Service Bulletin No. ASB-BO 105-10-110, dated August 27, 1997, or Eurocopter Canada Alert Service Bulletin No. ASB-BO 105 LS-10-9, dated September 11, 1997, as applicable. These incorporations by reference were 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 Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 31, 1997.

Note 3: The subject of this AD is addressed in Luftfahrt-Bundesamt (Germany) AD 97-275, dated September 25, 1997, and in Transport Canada AD CF-97-18, dated September 30, 1997.

Issued in Fort Worth, Texas, on December 5, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97-32720 Filed 12-15-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97-SW-45-AD; Amendment 39-10246; AD 97-26-03]

RIN 2120-AA64

Airworthiness Directives; Eurocopter Deutschland GmbH (ECD) (Eurocopter Deutschland) Model MBB-BK 117 A-1, A-3, A-4, B-1, B-2, and C-1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Eurocopter Deutschland Model MBB-BK 117 A-1, A-3, A-4, B-1, B-2, and C-1 helicopters. This action requires visual inspections for cracks in the ribbed area of the main rotor mast flange (flange). This amendment is prompted by one report of cracks in a flange. The actions specified in this AD are intended to detect cracks in the

flange, which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter.

DATES: Effective December 31, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 31, 1997.

Comments for inclusion in the Rules Docket must be received on or before February 17, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of Regional Counsel, Southwest Region, Attention: Rules Docket No. 97-SW-45-AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

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 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: Mr. Richard Monschke, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5116, (817) 222-5961.

SUPPLEMENTARY INFORMATION: The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for the Federal Republic of Germany recently notified the FAA that an unsafe condition may exist on Eurocopter Deutschland Model MBB-BK 117 A-1, A-3, A-4, B-1, B-2, and C-1 helicopters. The LBA advises that a main rotor mast was found to have cracks of critical magnitude in the area of the flange. The cause of the cracks is under investigation. Until the cause of the cracks has been determined, the flange must be subjected to immediate and repetitive visual crack inspections until further notice.

Eurocopter Deutschland has issued Eurocopter Deutschland GmbH Alert Service Bulletin MBB-BK 117 No. ASB-MBB-BK 117-10-114, dated August 27, 1997, which specifies visually inspecting the area of the holes on the underside of the flange for cracks, especially in the ribbed area between the holes, and if cracks are found, contacting Eurocopter Deutschland before further flight for advice on how to proceed. The LBA classified this service bulletin as mandatory and

issued LBA AD 97-276, effective September 25, 1997, in order to assure the continued airworthiness of these helicopters in the Federal Republic of Germany.

This helicopter model is manufactured in the Federal Republic of Germany and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, 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.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter Deutschland Model MBB-BK 117 A-1, A-3, A-4, B-1, B-2, and C-1 helicopters of the same type design registered in the United States, this AD is being issued to detect cracks in the flange, which, if not detected could result in failure of the flange and subsequent loss of control of the helicopter. This AD requires, before further flight, a visual inspection of the ribbed area of the flange for cracks using a 5-power or higher magnifying glass, and thereafter, repeated visual inspections at intervals not to exceed 100 hours time-in-service. The actions are required to be accomplished in accordance with the service bulletin described previously. This flange is a part of the main rotor mast assembly and therefore a critical component of the flight control system. Due to the criticality of the flange to the continued safe flight of the affected helicopters, and the required inspection before further flight, this rule must be issued immediately to correct an unsafe condition in the affected helicopters.

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.

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, both before and after the closing date for comments, 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 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. 97-SW-45-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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:

97-26-03 Eurocopter Deutschland:

Amendment 39-10246. Docket No. 97-SW-45-AD.

Applicability: Model MBB-BK 117 A-1, A-3, A-4, B-1, B-2, and C-1 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detect cracks in the main rotor mast flange (flange), which, if not detected, could result in failure of the flange and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight, and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1. and 2.A.2. of the Accomplishment Instructions in Eurocopter Deutschland GmbH Alert Service Bulletin MBB-BK 117 No. ASB-MBB-BK 117-10-114, dated August 27, 1997.

(b) If a crack is found as a result of the inspections specified in paragraph (a) of this AD, remove the cracked main rotor mast and replace it with an airworthy main rotor mast.

(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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits will not be issued.

(e) The inspection shall be done in accordance with Eurocopter Deutschland GmbH Alert Service Bulletin MBB-BK 117 No. ASB-MBB-BK 117-10-114, dated August 27, 1997. 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 Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 31, 1997.

Note 3: The subject of this AD is addressed in Luftfahrt-Bundesamt (Germany) AD 97-276, effective September 25, 1997.

Issued in Fort Worth, Texas, on December 5, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97-32721 Filed 12-15-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 524****Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin**

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 new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for topical use of doramectin for treatment and control of certain worm, grub, lice, and mite infections of cattle.

EFFECTIVE DATE: December 16, 1997.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, is sponsor of NADA 141-095 that provides for the use of Dectomax® (doramectin) 0.5 percent pour-on solution for beef cattle and female dairy cattle less than 20 months of age for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, to control infections and protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment. The NADA is approved as of September 16, 1997, and the regulations are amended by adding new § 524.770 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 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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 16, 1997, because the NADA contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under