

Issued in Burlington, Massachusetts, on December 4, 2009.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2009-1124; Directorate Identifier 2009-SW-35-AD; Amendment 39-16128; AD 2009-25-09]

RIN 2120-AA64

Airworthiness Directives; Eurocopter France Model SA 330 F, G, and J Helicopters

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the specified Eurocopter France (Eurocopter) helicopters. This AD results from a mandatory continuing airworthiness information (MCAI) AD issued by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community. The MCAI Emergency AD states that there has been a report of the failure of a flexible coupling on one of the main gearbox (MGB) inputs, which may be the result of loss of the tightening torque load, or insufficient tightening of the nuts on the bolts fixing the discs of the flexible coupling to its sliding and fixed hinges. This condition, if not corrected, could result in failure of the coupling discs, and if this condition develops on both the left-hand (LH) and right-hand (RH) MGB inputs, a complete loss of power to the transmission and subsequent loss of control of the helicopter.

DATES: This AD becomes effective on December 29, 2009.

The incorporation by reference of certain publications is approved by the Director of the Federal Register as of December 29, 2009.

We must receive comments on this AD by February 12, 2010.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting your comments electronically.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053-4005, telephone (800) 232-0323, fax (972) 641-3710, or at <http://www.eurocopter.com>.

Examining the Docket: You may examine the AD docket on the Internet at <http://www.regulations.gov>, or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is stated in the **ADDRESSES** section of this AD. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: DOT/FAA Southwest Region, Ed Cuevas, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone 817-222-5355, fax 817-222-5961.

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Community, has issued EASA AD No. 2008-0049-E, dated March 3, 2008 (Corrected: March 7, 2008), to correct an unsafe condition for Eurocopter Model SA 330 F, G, and J helicopters, all serial numbers, with MGB input flexible coupling sliding and fixed flanges assemblies installed that have been modified per MOD 0752416 and MOD 0752419, but have not been subject to maintenance scheduled inspection per Working Card 65.32.601 since new or since a complete overhaul of the MGB. There has been one report of the failure of a modified flexible coupling assembly on one of the MGB inputs, which EASA has deemed to be the result of the loss of the tightening torque load, or insufficient tightening of the nuts on the bolts attaching the disks of the flexible coupling to its sliding and fixed flanges. This condition, if not

corrected, could result in progressive fatigue failure of the coupling discs, caused by extensive fretting on the faces and in the holes of the flexible coupling discs. If this unsafe condition develops on both the LH and RH MGB inputs, it could result in a complete loss of power to the transmission and subsequent loss of control of the helicopter.

Related Service Information

Eurocopter has issued Emergency Alert Service Bulletin No. 05.95, dated March 3, 2008, which specifies readjusting or checking the tightening torque load of the nuts on the bolts attaching the flexible coupling to the sliding coupling flange and the bolts attaching the flexible coupling to the fixed coupling flange, in order to prevent any damage to the flexible couplings, which, over time, may lead to the loss of input drive to the MGB. The actions described in the MCAI are intended to correct the same unsafe conditions as those identified in the service information.

FAA's Evaluation and Unsafe Condition Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, their Technical Agent, has notified us of the unsafe condition described in the MCAI AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe conditions exist and are likely to exist or develop on other helicopters of these same type designs.

Differences Between This AD and the MCAI AD

The MCAI AD uses the term "flight hours" instead of "hours time-in-service", as we have used in this AD. Also, the MCAI AD allows "use of later approved revisions" of the service information to comply with the MCAI AD. Our AD requires compliance in accordance with the Eurocopter EASB. Additionally, this AD requires "inspections" conducted by a qualified mechanic, instead of "checks", which we allow a pilot to do. Finally, contacting Eurocopter Technical Support is not required by this AD as it is by the MCAI AD.

Costs of Compliance

We estimate that this AD will affect about 14 helicopters of U.S. registry. We also estimate that it will take about:

- 8 work-hours per helicopter to remove the engine, re-adjust the

tightening torque load, and re-install the engine for 10 helicopters in the fleet;

- 10 work-hours per helicopter to remove the engine, measure the tightening torque load, and re-install the engine on 3 helicopters in the fleet; and
- 12 work-hours to remove the engine, inspect and replace a damaged flexible coupling, and re-install the engine on 1 helicopter.

The average labor rate is \$80 per work-hour. Costs to replace a damaged flexible coupling, if necessary, include \$1,018 for 6 nuts, \$838 for 1 flexible coupling, \$71 for 6 (6 each) bolts, and \$624 for 12 washers. Based on these figures, we estimate the cost of this AD on U.S. operators will be \$12,311, assuming that 1 flexible coupling is damaged and needs to be replaced.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. We find that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because loss of the tightening torque load or insufficient tightening of the nuts on the bolts attaching the disks of the flexible coupling to its sliding and fixed flanges could result in a complete loss of power to the transmission, and there are helicopters that will be required to comply with this AD within a short time period because of the criticality of this unsafe condition. Therefore, we have determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. However, we invite you to send us any written data, views, or arguments concerning this AD. Send your comments to an address listed under the **ADDRESSES** section of this AD. Include "Docket No. FAA-2009-1124; Directorate Identifier 2009-SW-35-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov> including any personal information you provide. We

will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD 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, I certify this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the 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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

- Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2009-25-09 Eurocopter France:

Amendment 39-16128. Docket No. FAA-2009-1124; Directorate Identifier 2009-SW-35-AD.

Effective Date

- (a) This airworthiness directive (AD) becomes effective on December 29, 2009.

Other Affected ADs

- (b) None.

Applicability

(c) This AD applies to Model SA 330 F, G, and J helicopters, all serial numbers, with main gearbox (MGB) input flexible coupling flange assemblies, part number (P/N) 330A-32937401, installed that have been modified per MOD 0752416 and MOD 0752419, but have not been subject to a maintenance scheduled inspection per Working Card 65.32.601 since new or since a complete overhaul of the MGB, certificated in any category.

Reason

(d) The mandatory continuing airworthiness information (MCAI) AD states that there has been one report of disks failure of a flexible coupling on one of the MGB inputs, which may be the result of the loss of the tightening torque load, or insufficient tightening of the nuts on the bolts attaching the disks of the flexible coupling to its sliding and fixed flanges. This condition, if not corrected, could result in progressive fatigue failure of the coupling discs, caused by extensive fretting on the faces and in the holes of the flexible coupling discs. If this unsafe condition develops on both the LH and RH MGB inputs, a complete power loss to the transmission could occur, resulting in subsequent loss of control of the helicopter.

Actions and Compliance

- (e) Required as indicated, unless previously accomplished.

(1) For MGB input flexible coupling flange assemblies with less than 50 hours time-in-service (TIS) since new or since a complete overhaul of the MGB, re-adjust the tightening torque load of the 6 nuts on the flexible coupling-to-flange attachment bolts. Accomplish this re-adjustment between 50 hours TIS and 75 hours TIS since new or since a complete overhaul of the MGB in accordance with paragraph 2.B.2.a. of Eurocopter Emergency Alert Service Bulletin No. 05.95, dated March 3, 2008 (EASB).

(2) For MGB input flexible coupling flange assemblies with 50 hours TIS and 75 or less hours TIS since new or since a complete overhaul of the MGB, either:

- (i) Upon or before reaching 75 hours TIS since new or since a complete overhaul of the MGB, re-adjust the tightening torque load of the 6 nuts on the flexible coupling-to-flange attachment bolts in accordance with paragraph 2.B.2.a. of the EASB; or
- (ii) Upon or before reaching 125 hours TIS since new or since a complete overhaul of the

MGB, inspect the tightening torque load of the 6 nuts on the flexible coupling-to-flange attachment bolts in accordance with paragraph 2.B.2.b. of the EASB, except you are not required to contact the manufacturer.

(3) For MGB input flexible coupling flange assemblies that have more than 75 hours TIS since new or since a complete overhaul of the MGB, within the next 50 hours TIS, inspect the tightening torque load of the 6 nuts on the flexible coupling-to-flange attachment bolts, in accordance with paragraph 2.B.2.b. of the EASB, except you are not required to contact the manufacturer.

(4) Prior to installing a MGB that contains an input flexible coupling flange assembly that has been modified per MOD 0752416 and MOD 0752419, you must comply with the provisions of this AD.

Differences Between This AD and the MCAI AD

(f) The MCAI AD uses the term “flight hours” instead of “hours time-in-service”, as we have used in this AD. Also, the MCAI AD allows “use of later approved revisions” of the service information to comply with the MCAI AD. Our AD requires compliance in accordance with Eurocopter Emergency Alert Service Bulletin No. 05.95, dated March 3, 2008. Additionally, this AD requires “inspections” by a qualified mechanic instead of “checks”, which we allow a pilot to do. Finally, this AD does not require you to contact Eurocopter Technical Support, which is required by the MCAI AD.

Other Information

(g) *Alternative Methods of Compliance (AMOCs)*: The Manager, Safety Management Group, Attn: DOT/FAA Southwest Region, Ed Cuevas, Aerospace Engineer, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5355, fax (817) 222-5961, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(h) European Aviation Safety Agency MCAI Airworthiness Directive No. 2009-0049-E, dated March 3, 2008 (Corrected: March 7, 2008), contains related information.

Joint Aircraft System/Component Code

(i) JASC Code 6310: Engine/Transmission Coupling.

Material Incorporated by Reference

(j) You must use the specified portions of Eurocopter Emergency Alert Service Bulletin No. 05.95, dated March 3, 2008, to do the actions required.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053-4005, telephone (800) 232-0323, fax (972) 641-3710, or at <http://www.eurocopter.com>.

(3) You may review copies at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Fort Worth, Texas 76137; or at the National Archives and Records Administration (NARA). For information on the availability of this

material at NARA, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on November 18, 2009.

Gary B. Roach,

*Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.*

[FR Doc. E9-29424 Filed 12-11-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2009-N-0665]

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Schering-Plough Animal Health Corp. to Intervet, Inc., and to change the sponsor's mailing address.

DATES: This rule is effective December 14, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, has informed FDA of a change of name and mailing address to Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Schering-Plough Animal Health Corp.” and alphabetically add a new entry for “Intervet, Inc.”; and in the table in paragraph (c)(2), revise the entry for “000061” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * *
Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068	000061
* * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * *
000061	Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068
* * *	* * *

Dated: December 8, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-29627 Filed 12-11-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2009-N-0665]

Implantation or Injectable Dosage Form New Animal Drugs; Insulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.