Related Information

(l) Rolls-Royce plc MSB No. RB.211–72–D339, Revision 2, dated June 20, 2003, pertains to the subject of this AD.

Issued in Burlington, Massachusetts, on June 18, 2004.

Francis A. Favara,

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

[FR Doc. 04–14317 Filed 6–24–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–SW–15–AD; Amendment 39–13687; AD 2001–24–07 R1]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A. Model A109C, A109E, and A109K2 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment revises an existing airworthiness directive (AD), for the Agusta S.p.A. (Agusta) Model A109C, A109E, and A109K2 helicopters, that currently requires inspecting the main rotor blade (blade) tip cap for bonding separation and a crack, and also requires a tap inspection of the tip cap for bonding separation in the blade bond area and a dye-penetrant inspection of the tip cap leading edge along the welded joint line of the upper and lower tip cap skin shells for a crack. This amendment requires those same actions, but corrects a blade part number (P/N) that was stated incorrectly in the Applicability section of the existing AD. This amendment is prompted by the need to correct a blade P/N. The actions specified by this AD are intended to prevent failure of a blade tip cap, excessive vibration, and subsequent loss of control of the helicopter.

DATES: Effective July 30, 2004.

The incorporation by reference of certain publications listed in the regulations was approved previously by the Director of the Federal Register as of January 7, 2002.

ADDRESSES: The service information referenced in this AD may be obtained from Agusta, 21017 Cascina Costa di Samarate (VA) Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605–222595. 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 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/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5116, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend 14 CFR part 39 by revising AD 2001–24–07, Amendment 39–12523 (66 FR 60144, December 3, 2001), for the specified Agusta helicopters, was published in the **Federal Register** on January 27, 2004 (69 FR 3859). The action proposed to correct a P/N that was stated incorrectly in the previous AD, and to require:

- A tap inspection of the upper and lower sides of the tip cap for bonding separation and in the tip cap to blade bond area;
- A visual inspection of the upper and lower side of the blade tip cap for swelling or deformation; and
- A dye-penetrant inspection of the tip cap leading edge along the welded joint line of the upper and lower tip cap skin shells for a crack.

AD 2001–24–07 superseded AD 98–19–04, Amendment 39–11039 (64 FR 7494, February 16, 1999), Docket No. 98–SW–40–AD. AD 98–19–04 required inspecting between the metal shells and honeycomb core for bonding separation, visually inspecting the blade tip for swelling or deformation, and visually inspecting the welded bead along the leading edge of the blade tip cap for a crack. AD 2001–24–07 retained those requirements, and added a requirement for a tap inspection of the tip cap for bonding separation in the blade bond area, and a dye-penetrant inspection of the tip cap leading edge along the welded joint line of the upper and lower tip cap skin shells for a crack. Installing a tip cap, P/N 709–0103–29–109, on an affected blade is a terminating action for the requirements of the existing AD for that blade.

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 44 helicopters of U.S. registry, and the actions will take approximately 6 work hours per helicopter to accomplish the initial and repetitive inspection at an average labor rate of $65 per work hour. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $17,160, assuming that no blade will need to be replaced as a result of these inspections.

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 removing Amendment 39–12523 (66 FR 60144), and by adding a new airworthiness directive (AD), Amendment 39–13687, to read as follows:

2001–24–07 R1 Agusta S.p.A.: Amendment 39–13687. Docket No. 2001–SW–15–AD. Revises AD 2001–24–07, Amendment 39–12523.

Applicability: Model A109C, A109E, and A109K2 helicopters, with main rotor blade

(blade), part number (P/N) 709–0103–01—all dash numbers, having a serial number (S/N) up to and including S/N 1428 with a prefix of either ''EM–'' or ''A5–'' installed, certificated in any category.

Compliance: Required within 10 hours time-in-service (TIS), unless accomplished previously, and thereafter at intervals not to exceed 25 hours TIS.

To prevent failure of a blade tip cap, excessive vibration, and subsequent loss of control of the helicopter, accomplish the following:

(a) Tap inspect the upper and lower sides of each tip cap for bonding separation between the metal shells and the honeycomb core using a steel hammer, P/N 109–3101–58–1, or a coin (quarter) in the area indicated as honeycomb core on Figure 1 of Alert Bollettino Tecnico Nos. 109–106, 109K–22, or 109EP–1, all Revision B, and dated December 19, 2000 (ABT), as applicable. Also, tap inspect for bonding separation in the tip cap to blade bond area (no bonding voids are permitted in this area).

(b) Visually inspect the upper and lower sides of each blade tip cap for swelling or deformation.

(c) Dye-penetrant inspect the tip cap leading edge along the welded joint line of the upper and lower tip cap skin shells for a crack in accordance with the Compliance Instructions, paragraph 3, of the applicable ABT.

(d) If any swelling, deformation, crack, or bonding separation that exceeds the prescribed limits in the applicable maintenance manual is found, replace the blade with an airworthy blade.

(e) Replacement blades affected by this AD must comply with the repetitive inspection requirements of this AD. Replacing an affected blade with a blade having an airworthy blade tip cap, P/N 709–0103–29–109, is terminating action for the requirements of this AD for that blade.

(f) 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 Office, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(g) The tap inspection and dye-penetrant inspection shall be done in accordance with Agusta Alert Bollettino Tecnico Nos. 109–106, 109K–22, or 109EP–1, all Revision B, and all dated December 19, 2000, as applicable. 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 as of January 7, 2002 (66 FR 60144, December 3, 2001). Copies may be obtained from Agusta, 21017 Cascina Costa di Samarate (VA) Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605–222595. 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 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/code_of_federal_ regulations/ibr_locations.html.*

(h) This amendment becomes effective on July 30, 2004.

Note: The subject of this AD is addressed in Ente Nazionale per l'Aviazionne Civile (Italy) AD Nos. 2000–571, 2000–572, and 2000–573, all dated December 22, 2000.

Issued in Fort Worth, Texas, on June 16, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–14316 Filed 6–24–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; N-Butylscopolammonium Bromide

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 Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of a solution of N-butylscopolammonium bromide by intravenous injection for the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions in horses.

DATES: This rule is effective June 25, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed NADA 141–228 for the veterinary prescription use of BUSCOPAN (N-butylscopolammonium bromide) Injectable Solution by intravenous injection for the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions in horses. The NADA is approved as of May 3, 2004, and 21 CFR part 522 is amended by adding § 522.275 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 21 CFR 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 3, 2004.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.275 is added to read as follows:

§ 522.275 N-Butylscopolammonium bromide.

(a) *Specifications*. Each milliliter of solution contains 20 milligrams (mg) N-butylscopolammonium bromide.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.3 mg per kilogram of body weight (0.14 mg per pound) slowly intravenously.

(2) *Indications for use*. For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.