(B) Swine: African swine fever, brucellosis, foot-and-mouth disease, hog cholera, pseudorabies, rinderpest, swine vesicular disease, tuberculosis, and vesicular stomatitis.

\* \* \* \* \*

- (8) (i) Between the time the embryos were collected and all examinations and tests required by this subpart were completed, no animals in the embryo collection unit with the donor dam, or in the donor dam's herd of origin, exhibited any clinical evidence of:
- (A) Ruminant: Bovine spongiform encephalopathy, brucellosis, contagious bovine pleuropneumonia, foot-and-mouth disease, Rift Valley fever, rinderpest, tuberculosis, and vesicular stomatitis; or
- (B) Swine: African swine fever, brucellosis, foot-and-mouth disease, hog cholera, pseudorabies, rinderpest, swine vesicular disease, tuberculosis, and vesicular stomatitis.

\* \* \* \*

- 9. Section 98.16 is amended as follows:
- a. In the introductory paragraph, the first sentence, by removing the word "Cattle" and adding the words "Ruminant and swine" in its place.
- b. In the introductory paragraph, by revising the second sentence to read as set forth below.
- c. In paragraph (b), the first sentence, by removing the word "cattle" and adding the words "embryo donors" in its place.

## § 98.16 The embryo collection unit.

\* \* The embryo collection unit may be located on the premises where the donor dam's herd of origin is kept, or at any other location, provided that the embryo collection unit has been inspected and approved by an APHIS veterinarian and that the following requirements are met:

\* \* \* \* \*

- 10. Section 98.17 is amended as follows:
- a. By revising paragraph (b)(1) to read as set forth below.
- b. In paragraph (g), by adding, at the end of the first and second sentences: "under the personal supervision of an APHIS veterinarian".
- c. By adding at the end of the section the following: "(Approved by the Office of Management and Budget under control number 0579–0040)".

### § 98.17 Procedures.

(a) \* \* \*

(b) Oversight and supervision. (1) All procedures associated with the production of embryos for importation into the United States, including

artificial insemination, natural breeding, and cleaning and disinfection, must be performed under the oversight of an APHIS veterinarian. Collecting test samples, and collecting, processing, and storing embryos, must be supervised in person by an APHIS veterinarian.

## § 98.35 [Amended]

11. Section 98.35 is amended by adding at the end of the section the following:

(Approved by the Office of Management and Budget under control number 0579–0040)

Done in Washington, DC, this 2nd day of April 1996.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–8471 Filed 4–4–96; 8:45 am] BILLING CODE 3410–34–P

# **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 39

[Docket No. 95-SW-26-AD; Amendment 39-9561; AD 96-07-12]

Airworthiness Directives; Bell Helicopter Textron, Inc., Model 214ST Helicopters

**AGENCY:** Federal Aviation Administration, DOT. **ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) applicable to Bell Helicopter Textron, Inc. (BHTI) Model 214ST helicopters with certain tailboom assemblies and a certain emergency float kit installed, that requires initial and repetitive inspections of the tailboom for cracks until modifications of the tailboom are accomplished. This amendment is prompted by several reports of cracks in the lower aft skin of the tailboom assembly. The actions specified by this AD are intended to prevent cracks in the tailboom assembly, which could result in structural failure of the tailboom and subsequent loss of control of the helicopter.

DATES: Effective May 10, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 10, 1996.

**ADDRESSES:** The service information referenced in this AD may be obtained from Bell Helicopter Textron, Inc., Attention: Customer Support, P.O. Box

482, Fort Worth, Texas 76101. This information may be examined at the FAA, Office of the Assistant Chief Counsel, 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. Charles Harrison, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5447, fax (817) 222–5959.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to BHTI Model 214ST helicopters, serial numbers (S/N) 28101 through 28132, with a tailboom assembly, part number (P/N) 214-031-003-111 or 214-031-003-277, and with an emergency float kit, P/N 214-706-120, installed, was published in the Federal Register on November 1, 1995 (60 FR 55495). That action proposed to require inspections of the tailboom assembly for cracks within 250 hours time-in-service (TIS) or at the next 180day float inspection, and thereafter, at each 180-day float inspection until certain modifications of the tailboom are accomplished. The modifications, which are to be accomplished if any crack is found in the tailboom or on or before accumulating an additional 500 hours TIS after the effective date of this AD, whichever occurs first, include installing stiffeners and doublers in the tailboom, and replacing the access door frame with a thicker access door frame.

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 six helicopters of U.S. registry will be affected by this AD, that it will take approximately 20 work hours per helicopter to accomplish the modifications, approximately 3 work hours per helicopter to accomplish the 250 hours TIS inspection, and that the average labor rate is \$60 per work hour. Required parts will cost approximately \$1,100 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$14,880.

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.

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:

AD 96-07-12 Bell Helicopter Textron, Inc. (BHTI): Amendment 39-9561. Docket No. 95-SW-26-AD.

Applicability: Model 214ST helicopters, serial number (S/N) 28101 through 28132, with a tailboom assembly, part number (P/N) 214–031–003–111 or 214–031–003–277 and with an emergency float kit, P/N 214–706–120, installed, 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 (d) 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 prevent cracks in the tailboom assembly, structural failure of the tailboom and subsequent loss of control of the helicopter, accomplish the following:

- (a) Within the next 250 hours time-inservice (TIS) or at the next 180-day float inspection, whichever occurs first, and thereafter at intervals not to exceed each 180-day float inspection, visually inspect the tailboom assembly for cracks in accordance with the maintenance procedures contained in Part 1 of the Accomplishment Instructions of BHTI Alert Service Bulletin 214ST-95-72, dated July 24, 1995.
- (b) Upon discovery of a crack or on or before accumulating an additional 500 hours TIS after the effective date of this AD, whichever occurs first, modify the tailboom assembly in accordance with Part 2 of the Accomplishment Instructions of BHTI Alert Service Bulletin No. 214ST-95-72, dated July 24, 1995.
- (c) Modification of the tailboom assembly in accordance with paragraph (b) constitutes terminating action for the requirements of this AD.
- (d) An alternative methods of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Rotorcraft Certification Office. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Certification Office.

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

- (e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.
- (f) The inspections and modifications shall be done in accordance with Bell Helicopter Textron, Inc. Alert Service Bulletin 214ST-95-72, dated July 24, 1995. 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 Bell Helicopter Textron, Inc., Attention: Customer Support, P.O. Box 482, Fort Worth, Texas 76101. Copies may be inspected at the FAA, Office of the Assistant Chief Counsel, 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.

(g) This amendment becomes effective on May 10, 1996.

Issued in Fort Worth, Texas, on March 26, 1996.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 96–8384 Filed 4–4–96; 8:45 am] BILLING CODE 4910–13–M

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 520

# Oral Dosage Form New Animal Drugs; Ivermectin with Pyrantel Pamoate

**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 supplemental new animal drug application (NADA) filed by Merck Research Laboratories, Division of Merck & Co., Inc., for a chewable tablet containing ivermectin in combination with pyrantel pamoate. The product is used to prevent canine heartworm disease and to treat and control ascarid and hookworm infections in dogs. The supplemental NADA provides for extending the use in dogs to those weighing less than 5 pounds and for revising the limitation in the regulation concerning use in dogs under 6 weeks of age.

**EFFECTIVE DATE:** April 5, 1996. **FOR FURTHER INFORMATION CONTACT:** Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA 140-971, which provides for extending the use of Heartgard-30® Plus (ivermectin with pyrantel pamoate) to dogs weighing less than 5 pounds. In addition, the limitation in the regulation, "Not to be used in dogs under 6 weeks of age.", is being corrected to read "Recommended for dogs 6 weeks of age and older." The product is used to prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for 30 days after infection, and for the treatment and control of adult ascarids Toxocara canis and Toxascaris leonina, and adult hookworms Ancylostoma