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-in-service (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*

caninum and *Uncinaria stenocephala*. The supplement is approved as of February 15, 1996, and the regulations are amended in § 520.1196 (21 CFR 520.1196) by revising the limitation in paragraph (c)(1)(iii) as above to reflect the correct limitation as is stated in the approved product labeling. The basis of approval is discussed in the freedom of information summary.

In addition, the heading of § 520.1196 is revised from ''pyrantel (as pamoate salt)'' to ''pyrantel pamoate'' in order to conform with titles of other sections.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 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)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental NADA qualifies for a 3-year marketing exclusivity period beginning February 15, 1996, because new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant. The exclusivity period applies only to use in animals weighing less than 5 pounds.

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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1196 is amended by revising the section heading and in paragraph (c)(1)(iii) by revising the second sentence to read as follows:

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablet.

* * * * *

(c) * * *

(1) * * *

(iii) * * * Recommended for dogs 6 weeks of age and older. * * *

* * * * *

Dated: March 28, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–8362 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 814

[Docket No. 93N–0047]

RIN 0910–AA09

Medical Devices; Temporary Suspension of Approval of a Premarket Approval Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing procedures to order the temporary suspension of approval of a premarket approval application (PMA) for a medical device. This action is being taken under a new authority granted to the agency by the Safe Medical Devices Act of 1990 (the SMDA). Under this new authority, if, after providing an opportunity for an informal hearing, FDA determines there is a reasonable probability that continued distribution of a device would cause serious, adverse health consequences or death, the agency shall, by order, temporarily suspend approval of a PMA, and proceed expeditiously, but within 60 days, to permanently withdraw approval of the PMA. The final rule also clarifies that these procedures apply to an original PMA, as well as any PMA supplement(s), for a medical device.

EFFECTIVE DATE: May 6, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 12, 1993 (58 FR 52729), FDA published a proposed rule to establish procedures to order the temporary suspension of approval of a PMA for a medical device. Interested persons were given until December 13, 1993, to comment on the proposed rule. The agency received four comments, one from a trade association, and three from manufacturers.

II. Summary of the Final Rule

Section 9 of the SMDA (Pub. L. 101–629) amended section 515(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(e)) by adding section 515(e)(3) of the act which provides the agency with the authority to temporarily suspend approval of a PMA. This authority applies to the original PMA, as well as any PMA supplement(s), for a medical device. Section 515(e)(3) of the act and new § 814.47, the implementing regulation, provide the agency with a prompt method of removing dangerous devices from the market pending resolution of permanent PMA or PMA supplement withdrawal proceedings.

Under § 814.47(a), FDA will issue an order temporarily suspending approval of a PMA or a PMA supplement when FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.

Pursuant to § 814.47(b), when FDA makes the requisite determination, FDA shall provide an opportunity for an informal hearing to determine whether to issue an order temporarily suspending approval of a PMA or a PMA supplement. Such an informal hearing is to be initiated and conducted by FDA pursuant to part 16 (21 CFR part 16). Generally, under § 814.47(b)(2), the person provided with notice of an opportunity for an informal hearing will have not less than 3 working days after receipt of the notice to request a hearing. Moreover, the informal hearing ordinarily will not be held less than 2 working days after receipt of the request for the hearing, in order to provide time for preparation. However, in those rare circumstances when FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may waive, suspend, or modify the above-referenced timeframes in accordance with § 10.19 (21 CFR 10.19) and § 16.60(h).

Under § 814.47(b)(3), a PMA holder's or a PMA supplement holder's failure to request a hearing within the timeframe specified by FDA in the notice of opportunity for a hearing, which is generally not less than 3 working days, is deemed a waiver of the hearing.