

**§ 385.2011 Procedures for filing on electronic media (Rule 2011).**

(a) \* \* \*  
(9) FERC Form No. 60, Annual report of centralized service companies.

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(c) *What to file.* \* \* \*

(3) With the exception of the Form Nos. 1, 2, 2-A, 6 and 60, the electronic media must be accompanied by the traditional prescribed number of paper copies.

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[FR Doc. E6-18061 Filed 11-6-06; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs; Ivermectin, Pyrantel, and Praziquantel Tablets**

**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 an original new animal drug application (NADA) filed by Virbac AH, Inc. The NADA provides for veterinary prescription use of chewable tablets in dogs containing ivermectin, pyrantel pamoate, and praziquantel for the treatment and control or prevention of various internal parasites.

**DATES:** This rule is effective November 7, 2006.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed NADA 141-257 for IVERHART MAX (ivermectin, pyrantel pamoate, praziquantel) Chewable Tablets that provides for veterinary prescription use of chewable tablets in dogs containing ivermectin, pyrantel pamoate, and praziquantel for the treatment and control or prevention of various internal parasites. The NADA is approved as of October 13, 2006, and 21 CFR part 520 is amended by adding new § 520.1199 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)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning October 13, 2006.

FDA has determined under 21 CFR 25.33 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 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:** 21 U.S.C. 360b.

■ 2. Add § 520.1199 to read as follows:

**§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.**

(a) *Specifications.* Each chewable tablet contains:

(1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;

(2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;

(3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or

(4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.

(b) *Sponsors.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer monthly according to body weight as follows:

(i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.

(ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.

(iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(3) of this section.

(iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(4) of this section.

(v) Greater than 100 lb: use the appropriate combination of tablets.

(2) *Indications for use.* Prevents canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis*, *Toxascaris leonina*), hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*) and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections.

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

Dated: October 23, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E6-18684 Filed 11-6-06; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Lincomycin; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) that appeared in the **Federal Register** of September 1, 2006 (71 FR 51995). FDA is correcting the date of approval of an ANADA for a generic lincomycin injectable solution which was drafted in error. This correction is being made to improve the accuracy of the **Federal Register**.  
**DATES:** This rule is effective November 7, 2006.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).