

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.

§ 520.1196 [Amended]

2. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (b) by removing “*Sponsor. See 050604*” and by adding in its place “*Sponsors. See Nos. 050604 and 065274*”.

Dated: June 20, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-17051 Filed 7-6-01; 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; Moxidectin

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 Fort Dodge Animal Health. The NADA provides for veterinary prescription use of a sustained-release injectable moxidectin formulation for prevention of heartworm disease and treatment of existing hookworm infections in dogs.

DATES: This rule is effective July 9, 2001.

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.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141-189 that provides for veterinary prescription use of ProHeart® 6 (moxidectin) Sustained Release Injectable for Dogs for prevention of heartworm disease caused by *Dirofilaria immitis* and treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections. The NADA is approved as of June 6, 2001, and the

regulations are amended in 21 CFR part 522 by adding new § 522.1451 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 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, 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 (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 6, 2001, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

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 522.1451 is added to read as follows:

§ 522.1451 Moxidectin.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the

moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs—(1) Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections.

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

Dated: June 25, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-17049 Filed 7-6-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09-01-035]

RIN 2115-AA97

Safety Zone; Cleveland Harbor, Cleveland, OH

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone encompassing the navigable waters adjacent to the Cleveland Port Authority, on Cleveland Harbor, Lake Erie. The safety zone is necessary to ensure the safety of spectator vessels during a fireworks display launched from a barge in Cleveland Harbor on July 28, 2001. This regulation is intended to restrict vessel traffic from a portion of Lake Erie and Cleveland Harbor.

DATES: This temporary final rule is effective 9 p.m. until 10 p.m. (local time), July 28, 2001.

ADDRESSES: Comments and material received from the public are part of docket CGD09-01-035, and are available for inspection and copying at Coast Guard Marine Safety Office Cleveland, Ohio, 1055 East Ninth Street, Cleveland, Ohio, 44114, between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant John Natale, U.S. Coast Guard Marine Safety Office Cleveland,