4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Milbemycin Oxime, Lufenuron, and Praziquantel

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 Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of milbemycin oxime, lufenuron, and praziquantel for the prevention of heartworm disease, for prevention and control of fleas, and for the treatment and control of various internal parasites in dogs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-333 that provides for the veterinary prescription use of SENTINEL SPECTRUM (milbemycin oxime/lufenuron/praziquantel) Tablets for the prevention of heartworm disease, for the prevention and control of flea populations, and for the treatment and control of adult roundworm, adult hookworm, adult whipworm, and adult tapeworm infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older. The NADA is approved as of December 8, 2011, and 21 CFR part 520 is amended by adding new § 520.1447 to reflect the approval.

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 (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency 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 § 520.1447 to read as follows:

§ 520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.

(a) Specifications. Each tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime, 46 mg lufenuron, and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime, 115 mg lufenuron, and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime, 230 mg lufenuron, and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime, 460 mg lufenuron, and 228 mg praziquantel.

(b) Sponsor. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use--(1) Dogs--(i) Amount. 0.5 mg milbemycin oxime, 10 mg lufenuron, and 5 mg of praziquantel per kilogram of body weight, once a month.

(ii) Indications for use. For the prevention of heartworm disease caused by Dirofilaria immitis; for the prevention and control of flea populations (Ctenocephalides felis); and for the treatment and control of adult roundworm (Toxocara canis, Toxascaris leonina), adult hookworm (Ancylostoma caninum), adult whipworm (Trichuris vulpis), and adult tapeworm (Taenia pisiformis, Echinococcus multilocularis, and E. granulosus) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

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

(2) [Reserved]

Dated: January 23, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

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