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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Display Date 10-24-07
Publication Date 10-25-07
Certifier Alodin

Oral Dosage Form New Animal Drugs; Spinosad

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 Elanco Animal Health. The NADA provides for veterinary prescription use of spinosad chewable tablets to kill fleas and for the prevention and treatment of flea infestations on dogs for 1 month.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-277 that provides for veterinary prescription use of COMFORTIS (spinosad) Chewable Tablets to kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for 1 month. The NADA is approved as of September 25, 2007, and the regulations in 21 CFR part 520 are amended by adding § 520.2130 to reflect the approval.

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

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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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

FDA 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 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 § 520.2130 to read as follows:

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

(b) *Sponsor.* See No. 000986 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer tablets once a month at a recommended minimum dosage of 13.5 mg per pound (30 mg per kilogram) of body weight.

(2) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for 1 month.

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

Dated: 10/17/07

October 17, 2007.

Bernadette Dunham DVM, PhD.

Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.
[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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10/19/07

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