

(3) A statement that a solution containing an additive drug should not be stored.

(d) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

§ 310.510 [Removed]

14. Section 310.510 *Use of aerosol drug products containing zirconium* is removed.

§ 310.513 [Removed]

15. Section 310.513 *Chloroform, use as an ingredient (active or inactive) in drug products* is removed.

§ 310.525 [Removed]

16. Section 310.525 *Sweet spirits of nitre drug products* is removed.

§ 310.526 [Removed]

17. Section 310.526 *Camphorated oil drug products* is removed.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy
Coordination.

[FR Doc. 97-6411 Filed 3-13-97; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Tablet

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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for oral administration of lufenuron tablets at a minimum dose of 30 milligrams per kilogram (mg/kg) for the control of flea populations on cats.

EFFECTIVE DATE: March 14, 1997.

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: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, filed supplemental NADA 141-035, which provides for oral administration of Program® (lufenuron) tablets to cats 6 weeks of age or older. The drug is approved in 90- or 204.9-mg

tablets, given once a month, directly or broken and mixed into wet food, for the control of flea populations. Lufenuron has no deleterious effect on adult fleas but it prevents most flea eggs from hatching or maturing into adults. The supplemental NADA is approved as of January 23, 1997, and the regulations are amended in 21 CFR 520.1288 by revising the heading for paragraph (c) and by adding new paragraph (d) to reflect the approval. The basis for 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, 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 (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning January 23, 1997, because the application contains substantial evidence of effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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.

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 520.1288 is amended by revising the heading for paragraph (c) and by adding new paragraph (d) to read as follows:

§ 520.1288 Lufenuron tablets.

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(c) *Conditions of use in dogs—*

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(d) *Conditions of use in cats—*(1) *Amount.* 90-milligram tablet for cats up to 6 pounds of body weight, 204.9-milligram tablet for cats 7 to 15 pounds, a combination of tablets for cats over 15 pounds (a minimum of 13.6 milligrams per pound (30 milligrams per kilogram)).

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, directly or broken and mixed into wet food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no effect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

Dated: February 11, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-6412 Filed 3-13-97; 8:45 am]

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21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline and Tiamulin

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 Fermenta Animal Health Co. The NADA provides for the use of separately approved Type A medicated articles containing chlortetracycline and tiamulin in making Type C combination medicated feed. The feed is used in swine for treatment of bacterial enteritis and bacterial pneumonia and for control of swine dysentery. The regulations are also amended to increase the tolerance for tiamulin residue in swine liver.

EFFECTIVE DATE: March 14, 1997

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153-2314, filed NADA 141-011,