

or her spouse), the resource limit for an individual and spouse applies.) In addition to the exclusions listed in § 416.1210, pension funds which the ineligible parent or spouse of a parent may have are also excluded. "Pension funds" are defined in paragraph (a) of this section. As used in this section, the term "parent" means the natural or adoptive parent of a child and "spouse of a parent" means the spouse (as defined in § 416.1806) of such natural or adoptive parent.

(2) *Disabled child under age 18.* In the case of a disabled child under age 18 who is living in the same household with his or her parents, the deeming provisions of paragraph (b)(1) of this section shall not apply if such child—

(i) Previously received a reduced SSI benefit while a resident of a medical facility for which Medicaid paid more than 50 percent of the cost of the individual's care;

(ii) Is eligible for medical assistance under a Medicaid State home care plan approved by the Secretary under the provisions of section 1915(c) or authorized under section 1902(e)(3) of the Act; and

(iii) Would otherwise be ineligible because of the deeming of his or her parents' resources or income.

* * * * *

[FR Doc. 95-115 Filed 1-3-95; 8:45 am]

BILLING CODE 4190-29-P

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron 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 a new animal drug application (NADA) filed by Ciba Animal Health, Ciba-Geigy Corp. The NADA provides for oral administration of lufenuron tablets to dogs for the prevention and control of flea populations.

EFFECTIVE DATE: January 4, 1995.

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 Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-035, which

provides for oral administration of Program® tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron per (1) tablet. Once a month, Program® tablets are administered to dogs, 6 weeks of age and older, at a minimum dosage of 10 mg of lufenuron/kilogram (4.5 mg/pound) of body weight for the prevention and control of flea populations. The drug has no deleterious effect on adult fleas, but it prevents most flea eggs from maturing into adults. The NADA is approved as of November 23, 1994, and the regulations are amended in part 520 (21 CFR part 520) by adding new § 520.1288 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act provides a 5-year period of exclusivity to this original NADA beginning November 23, 1994, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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. New § 520.1288 is added to read as follows:

§ 520.1288 Lufenuron tablets.

(a) *Specifications.* Each tablet contains either 45, 90, 204.9, or 409.8 milligrams of lufenuron.

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

(c) *Conditions of use—*(1) *Amount.* 10 milligrams of lufenuron per kilogram (4.5 milligrams per pound) of body weight.

(2) *Indications for use.* For use in dogs, 6 weeks of age and older, for the prevention and control of flea populations.

(3) *Limitations.* Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. Because the drug has no effect on adult fleas, the concurrent use of insecticides that kill adults may be required depending on the severity of the infestation. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 23, 1994.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-164 Filed 1-3-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Animal Health, Inc. The ANADA provides for the use of oxytetracycline injection in cattle and swine for the treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: January 4, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health,