

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.274 [Amended]

4. Section 558.274 *Hygromycin B* is amended in paragraphs (a)(4) and (c)(1)(i) and (c)(1)(ii) by removing the number "017519,".

§ 558.485 [Amended]

5. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraph (a)(4).

§ 558.625 [Amended]

6. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(53).

§ 558.630 [Amended]

7. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(3) by removing the number "034500" and in paragraph (b)(10) by removing the number "017519,".

Dated: March 13, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97-7541 Filed 3-25-97; 8:45 am]

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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-Geigy Animal Health Corp. The NADA provides for oral administration of lufenuron tablets to cats and kittens 6 weeks of age and older for the control of flea populations.

EFFECTIVE DATE: March 26, 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 Corp., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-062, which provides for oral administration of Program®

(Lufenuron) Cat Flavor Tablets for cats and kittens 6 weeks of age or older, for the control of flea populations. The drug is given orally, once a month, at a minimum of 13.6 milligrams (mg) of lufenuron per pound of body weight (30 mg/kilogram), in tablets containing 135 or 270 mg lufenuron each. Lufenuron has no deleterious effect on adult fleas, but it prevents most flea eggs from hatching or maturing into adults. The NADA is approved as of March 3, 1997, and the regulations are amended in 21 CFR 520.1288(a) and (d) 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, 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)(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 March 3, 1997, because the NADA contains substantial evidence of effectiveness of the drug involved or any studies of animal safety, 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 paragraphs (a), (d) (1), and (d) (3) to read as follows:

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron.

(2) *Cats*. Each regular tablet contains either 90 or 204.9 mg lufenuron, each flavor tablet contains 135 or 270 mg lufenuron.

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(d) *Conditions of use in cats*—(1) *Amount*. Minimum of 13.6 mg lufenuron per pound (lb) of body weight (30 mg per kilogram). Recommended 90 mg regular tablet for cats up to 6 lb of body weight, 204.9 mg regular tablet for 7 to 15 lb, 135 mg flavor tablet for up to 10 lb, 270 mg flavor tablet for 11 to 20 lb. Cats over 15 lb (regular tablet) or over 20 lb (flavor tablet) are provided the appropriate combination of tablets.

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(3) *Limitations*. For oral use in cats or kittens 6 weeks of age or older, once a month, directly or broken and mixed with 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: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-7549 Filed 3-25-97; 8:45 am]

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin and Clorsulon

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 Merck Research Laboratories, Division of Merck & Co., Inc. The supplemental NADA provides for persistent control of gastrointestinal roundworms and lungworms following use of ivermectin and clorsulon injection for cattle.

EFFECTIVE DATE: March 26, 1997.

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.