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]

BILLING CODE 4160–01–F

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.

* * * * *

(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.

* * * * *

(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 affect 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]

BILLING CODE 4160–01–F

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.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is sponsor of NADA 140–833, which provides for the use of Ivomec® Plus Injection (1 perecent ivermectin and 10 percent clorsulon) for cattle for the treatment and control of gastrointestinal roundworm, lungworm, grub, lice, and mange mites. The supplement provides for control of infections of *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment. The supplement is approved as of February 24, 1997, and the regulations are amended in 21 CFR 522.1193(d)(2) 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 24, 1997, because the supplement contains substantial evidence of effectiveness of the drug involved, any 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 of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the additional indications.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.1193 is amended by adding a new sentence to the end of paragraph (d)(2) to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) * * * It is also used to control infections of *D. viviparus* and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

* * * * *

Dated: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–7544 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride 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 a supplemental new animal drug application (NADA) filed by Boehringer Ingelheim Animal Health, Inc. The supplemental NADA provides for the subcutaneous use (in addition to the approved intravenous and intramuscular use) of 100 milligrams/milliliter (mg/mL) of oxytetracycline hydrochloride injection in cattle for the treatment of diseases caused by oxytetracycline susceptible organisms, for a 2-day withdrawal period following the subcutaneous use, and for a 13-day withdrawal period following the intramuscular and intravenous use.

EFFECTIVE DATE: March 26, 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: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64502, is the sponsor of NADA 97–452, formerly sponsored by Fermenta Animal Health Co. The firm has filed a supplement to NADA 97–452, which provides for subcutaneous use of 100 mg/mL of oxytetracycline hydrochloride injection in addition to the approved intravenous and intramuscular use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., caused by organisms susceptible to oxytetracycline. In cattle, a 2-day withdrawal period is required following subcutaneous use, and a 13-day withdrawal period is required following intramuscular and intravenous use. The product is also approved for intramuscular and intravenous use in swine. The supplemental NADA is approved as of February 21, 1997, and the regulations are amended in 21 CFR 522.1662a(g)(3)(i)(*c*) 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 for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 21, 1997, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any 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 of the supplement and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 522

Animal drugs.