in the Dockets Management Branch (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 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for non-food producing animals qualifies for 3 years of marketing exclusivity for the new formulation beginning June 17, 1998, because the supplemental application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for the approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the new milbemycin oxime/lufenuron flavored tablets in three tablet sizes.

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.

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. Section 520.1446 is amended by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraph (d), to read as follows:

§ 520.1446 Milbemycin oxime/lufenuron tablets.

* * * * *

(c) [Reserved]

(d) *Conditions of use*— (1) *Dogs*— (i) *Amount.* 0.5 milligrams of milbemycin and 10 milligrams of lufenuron per kilogram of body weight.

(ii) *Indications for use.* For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, control of adult *Ancylostoma caninum* (hookworm), and removal and control of adult *Toxocara canis, Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations.* Administer tablets once a month, preferably on the same date each time. All dogs in a household should be treated to achieve maximum efficacy. Do not use in dogs less than 4 weeks of age and less than 2 pounds body weight. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: July 14, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–20597 Filed 7–31–98 ; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Florfenicol Solution

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 Schering-Plough Animal Health. The supplemental NADA provides for the subcutaneous use of florfenicol injectable solution in cattle for treatment of bovine respiratory disease, a new dosage, an additional slaughter withdrawal time, and an additional tolerance for residues in food.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1652.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083–1982, is sponsor of NADA 141–063 that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) for intramuscular treatment of cattle for bovine respiratory disease at 20 milligrams per kilogram of body weight, with a second dose after 48 hours, and a 28-day slaughter withdrawal time. Schering-Plough filed a supplemental NADA providing for a single subcutaneous injection at 40 milligrams per kilogram of body weight, and a 38-day slaughter withdrawal time. The supplemental NADA is approved as of June 4, 1998, and the regulations are amended by revising 21 CFR 522.955(d)(1)(i) and (d)(1)(iii) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulation concerning tolerances for residues of florfenicol in food (21 CFR 556.283) is amended to reflect an acceptable daily intake (ADI) of residues of the drug in food and a tolerance for residues in cattle muscle. The ADI is the amount of total drug residue that can be safely consumed daily for a lifetime. Previously, FDA had codified safe concentrations of animal drugs, the ADI corrected for consumption of various food products. Few individuals understood the relationship between safe concentrations, a value representing total drug residues, and tolerance, the part of the drug residue in a given tissue that is detected by an analytical method. To avoid confusion between the tolerance and safe concentration, FDA is codifying ADI's and removing safe concentrations.

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 supplement may be seen in the Dockets Management Branch (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)(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 June 4, 1998, 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 and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to subcutaneous use of the drug in cattle as approved in this supplement.

FDA has determined under 21 CFR 25.33(a)(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.

List of Subjects

21 CFR Part 522
Animal drugs.
21 CFR Part 556
Animal drugs, Foods.

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 parts 522 and 556 are 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: 21 U.S.C. 360b.

2. Section 522.955 is amended by revising paragraph (d)(1)(i) and the first four sentences of paragraph (d)(1)(iii) to read as follows:

§ 522.955 Florfenicol solution.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* For intramuscular injection use 20 milligrams per kilogram of body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later. Alternatively, a single subcutaneous injection of 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) may be used.

* * * * *

(iii) *Limitations.* For intramuscular or subcutaneous use only. Do not inject more than 10 milliliters at each site. Injection should be given in the neck only. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment.

* * *

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PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.283 is revised to read as follows:

§ 556.283 Florfenicol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of florfenicol is 10 micrograms per kilogram of body weight per day.

(b) *Cattle.* A tolerance of 3.7 parts per million (ppm) for florfenicol amine (marker residue) in liver (target tissue) is established. A tolerance of 0.3 ppm for florfenicol amine in cattle muscle is established.

Dated: July 10, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–20534 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Melengestrol Acetate and Oxytetracycline

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 two original new animal drug applications (NADA's) filed by Pharmacia & Upjohn Co. The NADA's provide for the use of separately approved Type A medicated articles containing melengestrol acetate (dry and liquid form) and oxytetracycline (dry form) to make dry combination drug Type C medicated feeds. The Type C medicated feeds are for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus, and reduced incidence of liver abscesses.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed original NADA's 46–718 and 46–719 that provide for combining separately approved melengestrol acetate (MGA) (dry and liquid form) and oxytetracycline (dry form) Type A medicated articles to make dry Type C medicated feeds for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses. The NADA's are approved as of May 6, 1998, and 21 CFR 558.342(d)(8) and 558.450(d)(3)(iii) are added to reflect the approvals.

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.

FDA has determined under 21 CFR 25.33(a)(2) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

2. Section 558.342 is amended by adding paragraph (d)(8) to read as follows:

§ 558.342 Melengestrol acetate.

* * * * *

(d) * * *

(8) *Amount.* Melengestrol acetate, 0.25 to 0.5 milligram per head per day, plus oxytetracycline, 75 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduction of liver condemnation due to liver abscesses.

(ii) *Limitations.* Heifers fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 6 to 10 grams of oxytetracycline per ton; or add at the rate of 0.5 to 2.0 pounds per head per day a dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 37.5 to 150 milligrams of oxytetracycline per pound to provide 0.25 to 0.5 milligram of melengestrol acetate and 75 milligrams of oxytetracycline per head per day. Liquid melengestrol acetate may not be mixed