FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300, filed supplemental NADA 140–915 that provides for veterinary prescription use of 2.3- and 5.75-milligram (mg) SAFEHEART™ (milbemycin oxime) tablets in dogs and puppies 4 weeks of age or older and 2 pounds (lb) body weight or greater for the prevention of heartworm disease caused by *Dirofilaria immitis* at a minimum dosage of 0.1 mg milbemycin oxime/kilogram (kg) of body weight (0.05 mg/lb). The supplement is approved as of June 4, 1998. FDA is amending the regulations in 21 CFR 520.1445(c) 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, 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 beginning June 4, 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 milbemycin oxime tablets at 0.1 mg/kg for prevention of canine heartworm disease.

The agency 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 520.1445 is amended by removing and reserving paragraph (c) and by revising paragraph (d) to read as follows:

§ 520.1445 Milbemycin oxime tablets.

* * * * *

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and puppies*—(i) *Amount.* For hookworm, roundworm, and whipworm, use 0.23 milligram per pound of body weight (0.5 milligram per kilogram). For heartworm, use 0.05 milligram per pound of body weight (0.1 milligram per kilogram).

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.

(iii) *Limitations.* Do not use in puppies less than 4 weeks of age and less than 2 pounds of body weight. Administer once a month. First dose given within 1 month after first exposure to mosquitoes and continue regular use until at least 1 month after end of mosquito season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats and kittens*—(i) *Amount.* 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 10, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–20533 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 520

Oral Dosage Form New Animal Drugs; Milbemycin Oxime/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 supplemental new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The supplemental NADA provides for use of a milbemycin oxime/lufenuron flavored tablet formulation for dogs not less than 4 weeks of age and not less than 11 pounds of body weight for prevention of heartworm disease, for prevention and control of flea populations, for control of hookworm, and for removal and control of roundworms and whipworms.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300, filed supplemental NADA 141–084 that provides for veterinary prescription use of Sentinel™ (milbemycin oxime/lufenuron) flavor tablets (5.75 and 115 milligrams (mg), 11.5 and 230 mg, and 23 and 460 mg) for dogs not less than 4 weeks of age and not less than 11 pounds of body weight. The tablets are used for the prevention of heartworm disease, for prevention and control of flea populations, for control of adult hookworm, and removal and control of adult roundworm and whipworm infections when used at a minimum dosage of 0.5 milligram/kilogram of body weight (mg/kg) milbemycin with a minimum of 10 mg/kg lufenuron. The supplement is approved as of June 17, 1998. To reflect the approval, FDA is redesignating 21 CFR 520.1446(c) as paragraph (d), reserving paragraph (c), and revising newly redesignated paragraph (d). 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, 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,