2 (Type) of the Automated Export Reporting Program (AERP) record layout. This indicator code should be used in lieu of the domestic (D) or foreign (F) indicator code required in those fields on the SED Form, the AES record, and the AERP record. The FMS indicator code will serve to identify more accurately that segment of U.S. exports that represent FMS deliveries in the U.S. export statistics.

* * * * *

Dated: July 16, 1998.

Bradford R. Huther,

Deputy Director, Bureau of the Census.

[FR Doc. 98–20616 Filed 7–31–98; 8:45 am]

BILLING CODE 3510–07–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for an approved new animal drug application (NADA) from Ohmeda Pharmaceutical Products Division, Inc., to Baxter Pharmaceutical Products, Inc.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Ohmeda Pharmaceutical Products Division, Inc., Liberty Corner, NJ 07938–0804, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved NADA 135–773 (isoflurane) to Baxter Pharmaceutical Products, Inc., 110 Allen Rd., P.O. Box 804, Liberty Corner, NJ 07938. The new sponsor will retain the drug labeler code for Ohmeda, Pharmaceutical Products, Inc. The agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the new sponsor name.

List of Subject in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Ohmeda Pharmaceutical Products Division, Inc.,'' and by alphabetically adding an entry for ''Baxter Pharmaceutical Products, Inc., 110 Allen Rd., Liberty Corner, NJ 07938''; and in the table in paragraph (c)(2) in the entry for ''010019'' by removing the sponsor name ''Ohmeda Pharmaceutical Products Division, Inc.,'' and adding in its place ''Baxter Pharmaceutical Products, Inc., 110 Allen Rd.,''.

Dated: July 10, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–20531 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 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor name from Rhone-Poulenc Chemicals, Ltd., to Rhodia Limited.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS119YF, England, UK, has informed FDA of a change of sponsor name to Rhodia, Limited. Accordingly, the agency is amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Rhone-Poulenc Chemicals, Ltd.,'' and by alphabetically adding an entry for ''Rhodia Limited''; and in the table in paragraph (c)(2) in the entry for ''059258'' by removing the sponsor name for ''Rhone-Poulenc Chemicals, Ltd.,'' and adding in its place ''Rhodia Limited''.

Dated: July 10, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–20532 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 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 lower dose of milbemycin oxime in treating dogs and puppies for the prevention of heartworm disease.

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 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