

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 65406, has informed FDA of a change of sponsor name to Boehringer Ingelheim Vetmedica, Inc. 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 “Boehringer Ingelheim Animal Health, Inc.” and by alphabetically adding a new entry for “Boehringer Ingelheim Vetmedica, Inc.”; and in the table in paragraph (c)(2) in the entry for “000010” by removing the sponsor name “Boehringer Ingelheim Animal Health, Inc.” and adding in its place “Boehringer Ingelheim Vetmedica, Inc.”

Dated: May 22, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98-15481 Filed 6-9-98; 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; Fenbendazole Paste

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 Hoechst Roussel Vet. The supplemental NADA provides for expanding the indications to include treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae.

EFFECTIVE DATE: June 10, 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:

Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 120-648 that provides for oral administration of Panacur® and Safe-Guard® (fenbendazole 10 percent) paste to horses. The product is currently approved for use concomitantly with an approved form of trichlorfon.

Trichlorfon is approved for the treatment of stomach bots (*Gasterophilus spp.*) in horses. The supplemental NADA provides for expanding the indications to include treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae when administered at 10 milligrams per kilogram per day for 5 consecutive days. The supplemental NADA is approved as of April 20, 1998, and the regulations are amended in 21 CFR 520.905c(d)(1)(iii) 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, this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning April 20, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

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 520.905c is amended by adding paragraph (d)(1)(iii) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(d) * * *

(1) * * *

(iii)(a) *Amount.* 4.6 milligrams per pound of body weight (10 milligrams per kilogram) daily for 5 consecutive days.

(b) *Indications for use.* For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae in horses.

(c) *Limitations.* (Consult your veterinarian for assistance in the diagnosis, treatment, and control of encysted mucosal cyathostomes). Do not use in horses intended for food.

* * * * *

Dated: May 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-15480 Filed 6-9-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 982

[Docket No. FR-4054-C-03]

RIN 2577-AB63

Section 8 Certificate and Voucher Programs Conforming Rule; Correction

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.