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: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (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 sponsor name for ''Fort Dodge Laboratories, Division of American Home Products Corp.'' and by adding in its place a new entry for ''Fort Dodge Animal Health, Division of American Home Products Corp.''; and in the table in paragraph (c)(2) in the entry for ''000856'' by removing the sponsor name ''Fort Dodge Laboratories, Division of American Home Products'' and adding in its place ''Fort Dodge Animal Health, Division of American Home Products Corp.''

Dated: November 21, 1996.

Robert C. Livingston,

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

[FR Doc. 96–30588 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfaquinoxaline Drinking Water

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 I. D. Russell Co. Laboratories. The supplement provides for a revised formulation of sulfaquinoxaline liquid used in animal drinking water.

EFFECTIVE DATE: December 2, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501, filed supplemental NADA 6–891 that provides for reformulation of the 34-percent sulfaquinoxaline solution to a 31.92-percent sulfaquinoxaline solution (as sodium and potassium salts) used in animal drinking water. The supplement is approved as of October 22, 1996, and the regulations are amended in § 520.2325a(a) (21 CFR 520.2325a(a)) to reflect the approval.

In addition, § 520.2325a(a) is revised to specify the base and salt content of several other approved sulfaquinoxaline drinking water products.

The supplemental approval is for a revised formulation of an approved product and does not affect the basis of approval or conditions of use in the currently approved application. No additional safety or effectiveness data were required. Therefore, a freedom of information summary is not required for this approval.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of this supplemental NADA does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or new human food safety studies (other than bioequivalence or residue studies) essential to the 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 520.2325a is amended by revising paragraph (a) to read as follows:

§ 520.2325a Sulfaquinoxaline drinking water.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) To No. 050749 for use of a 25-percent sulfaquinoxaline soluble powder and a 20-percent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To No. 060594 for use of 3.44- and 12.85-percent sulfaquinoxaline sodium solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) To No. 017144 for use of a 31.92-percent sulfaquinoxaline solution (sodium and potassium salts) as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

* * * * *

Dated: November 18, 1996.

Robert C. Livingston,

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

[FR Doc. 96–30651 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

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 an abbreviated new animal drug application (ANADA) filed by Happy Jack, Inc. The ANADA provides for oral use of pyrantel pamoate suspension for removal of large roundworms and hookworms in puppies and dogs and to prevent reinfections of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

EFFECTIVE DATE: December 2, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Happy Jack, Inc., P.O. Box 475, Highway 258 South, Snow Hill, NC 28580, filed ANADA 200–007, which provides for oral use of Liqui-Vict 2X™ (pyrantel pamoate) oral suspension for removal of large roundworms (*T. canis and Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria*