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*

stenocephala) in puppies and dogs and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping. The product contains pyrantel pamoate equivalent to 4.54 milligrams of pyrantel base.

Approval of ANADA 200–007 for Happy Jack, Inc.'s, pyrantel pamoate suspension is as a generic copy of Pfizer's NADA 100–237 Nemex-2™ (pyrantel pamoate). The ANADA is approved as of October 30, 1996, and the regulations are amended in 21 CFR 520.2043(b)(2) 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 21 CFR 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.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 520.2043 is amended by adding a new sentence at the end of paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) * * * See No. 023851 for use of 4.54 milligrams per milliliter product.

* * * * *

Dated: November 22, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–30653 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; 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) for Biocraft Laboratories, Inc., and A. H. Robins Co.

EFFECTIVE DATE: December 2, 1996.

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: A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501–0518, and Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, are no longer cosponsors of NADA 140–889. This arrangement was terminated sometime ago, but the agency failed to reflect the change in the regulations. Biocraft Laboratories, Inc., now exclusively owns NADA 140–889 and A. H. Robins Co. is the sponsor of new NADA 141–003. A. H. Robins Co. filed a supplement to NADA 140–889 to provide for the establishment of a new NADA. Therefore, the agency is amending 21 CFR 524.1600a to reflect the change of sponsorship.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1600a [Amended]

2. Section 524.1600a *Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment* is amended in paragraph (b) by removing ''See Nos. 000031/000332 (cosponsors), 000069, 025463, 051259, and 053501 in § 510.600(c) of this chapter'' and by adding in its place ''See Nos. 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter''.

Dated: November 21, 1996.

Robert C. Livingston,

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

[FR Doc. 96–30589 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 318

[DSWA Instruction 5400.11B]

Privacy Program

AGENCY: Defense Special Weapons Agency, DOD.

ACTION: Final rule.

SUMMARY: The Defense Special Weapons Agency (DSWA) is revising its procedural and exemptions rules for the DSWA Privacy Program.

EFFECTIVE DATE: November 9, 1996.

FOR FURTHER INFORMATION CONTACT: Mrs. Sandy Barker at (703) 325–7681.

SUPPLEMENTARY INFORMATION: The proposed rule was previously published on September 9, 1996 at 61 FR 47467. No comments were received, therefore, DSWA is adopting the rule as final.

Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.