pamoate suspension is as a generic copy of Pfizer's NADA 100–237 Nemex-2™ (pyrantel pamoate) suspension. The supplemental ANADA is approved as of June 4, 1997, 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 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 revising paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) *Sponsors.* See Nos. 000069 and 011615 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 023851 for use of 4.54 milligrams per milliliter product.

* * * * *

Dated: June 20, 1997.

Robert C. Livingston,

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

[FR Doc. 97–18459 Filed 7–14–97; 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; 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 Solvay Animal Health, Inc. The supplemental NADA provides for revised conditions of use of sulfaquinoxaline sodium in the drinking water of chickens and turkeys to reflect compliance with the results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Implementation (DESI) evaluation of the product and FDA's conclusions based on that evaluation.

EFFECTIVE DATE: July 15, 1997.

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: Solvay Animal Health, Inc., 1201 Northland Dr., Mendota Heights, MN 55120–1149, filed supplemental NADA 6–707 that provides for use of 28.62-percent sulfaquinoxaline sodium solution to make 0.025- or 0.04-percent solution used in the drinking water of chickens and turkeys for control of coccidiosis, acute fowl cholera, and fowl typhoid.

The supplement is approved as of June 2, 1997, and the regulations are amended by adding new 21 CFR 520.2325a(a)(4) to reflect the approval.

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.

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 520.2325a is amended by adding new paragraph (a)(4) to read as follows:

§ 520.2325a Sulfaquinoxaline drinking water.

(a) * * *

(4) No. 053501 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

* * * * *

Dated: June 20, 1997.

Robert C. Livingston,

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

[FR Doc. 97–18458 Filed 7–14–97; 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; Moxidectin 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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral use of moxidectin tablets for dogs to prevent canine heartworm infections and subsequent development of canine heartworm disease.

EFFECTIVE DATE: July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., P.O. Box 518, Fort Dodge, IA 50501, filed original NADA 141–051 that provides for oral use of ProHeart™ (moxidectin) tablets in dogs to prevent infections by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease. The drug is limited to use by or on the order of a licensed veterinarian.

The NADA is approved as of May 27, 1997, and the regulations are amended by adding new 21 CFR 520.1451 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 27, 1997, because no active ingredient of the drug, including any ester or salt of the active ingredient, has been previously approved in any other application filed under 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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. New § 520.1451 is added to read as follows:

§ 520.1451 Moxidectin.

(a) *Specifications.* Each tablet contains 30, 68, or 136 micrograms of moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.

(2) *Indications for use.* To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

(3) *Limitations.* Use once-a-month in dogs at 8 weeks of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 20, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–18457 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation of Injectable Dosage 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 a change of sponsor for an abbreviated new animal drug application (ANADA) from Phoenix Pharmaceutical, Inc., to Phoenix Scientific, Inc.

EFFECTIVE DATE: July 15, 1997.

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: Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457, has informed FDA that it has transferred ownership of, and all rights and interests in, approved ANADA 200–108 (dexamethasone injection) to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457. Accordingly, FDA is amending the regulations in 21 CFR 522.540 to reflect the change of sponsor.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.540 [Amended]

2. Section 522.540 *Dexamethasone injection* is amended in paragraph (a)(2) by removing ''057319'' and adding in its place ''059130''.

Dated: June 27, 1997.

Robert C. Livingston,

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

[FR Doc. 97–18461 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 32

[OJP(BJA)–1121]

RIN 1121–AA44

Federal Law Enforcement Dependents Assistance Program

AGENCY: Office of Justice Programs, Bureau of Justice Assistance, Public Safety Officers' Benefits Office, Justice.

ACTION: Final rule.

SUMMARY: Regulations are being issued to comply with the Federal Law Enforcement Dependents Assistance (FLEDA) Act of 1996. The FLEDA Program, to be administered by the Bureau of Justice Assistance through a delegation of authority from the Attorney General, will provide financial assistance in the form of awards to the children and spouses of Federal civilian law enforcement officers whose deaths or permanent and total disabilities in the line of duty resulted in the payment of benefits under the Public Safety Officers' Benefits (PSOB) Program. The financial assistance provided through