trimethylene carbonate tripolymer absorbable sutures for general surgery.

FDA gave interested persons until May 26, 1998, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of April 23, 1998, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the April 23, 1998, final rule. Accordingly, the amendments issued thereby became effective May 27, 1998.

Dated: August 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23106 Filed 8–27–98; 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; Neomycin Sulfate Soluble Powder and Oral Solution

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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for revised withdrawal times for oral solution as a drench and in drinking water for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

EFFECTIVE DATE: August 28, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, is the sponsor of ANADA 200–118 that provides for the use of neomycin sulfate soluble powder and oral solution as a drench in milk, or in drinking water for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats. The sponsor filed a supplement that provides for the revised withdrawal periods for the use of the generic product to be identical to that of the pioneer product.

The supplemental ANADA is approved as a generic copy of Pharmacia & Upjohn's NADA 011–315 Neomix®. Supplemental ANADA 200–118 is approved as of July 14, 1998, and the regulations are amended in 21 CFR 520.1485 to reflect the approval for the neomycin sulfate solution. 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(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.

§ 520.1485 [Amended]

3. Section 520.1485 *Neomycin sulfate oral solution* is amended in paragraph (d)(3) by removing ''For sponsor 059130: 30 days for cattle and goats, and 20 days for swine and sheep; for sponsors 000009 and 050604:''.

Dated: August 17, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–23108 Filed 8–27–98; 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; 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 Phoenix Scientific, Inc. The ANADA provides for use of pyrantel pamoate suspension for removal of large roundworms and hookworms and to prevent reinfections of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

EFFECTIVE DATE: August 28, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457 has filed ANADA 200–248 that provides for oral use of pyrantel pamoate suspension for removal of large roundworms (*T. canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping.

The ANADA is approved as a generic copy of Pfizer, Inc.'s NADA 100–237 Nemex™ and Nemex-2™ (pyrantel pamoate) suspension. ANADA 200–248 is approved as of July 16, 1998, and the regulations are amended in 21 CFR 520.2043(b)(2) 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(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 to read 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.

§ 520.2043 [Amended]

2. Section 520.2043 *Pyrantel pamoate suspension* is amended in paragraph (b)(2) by removing ''Nos. 000069 and 011615'' and adding in its place ''Nos. 000069, 011615, and 059130''.

Dated: August 20, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–23107 Filed 8–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Progesterone and Estradiol Benzoate

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 Fort Dodge Animal Health. The supplemental NADA provides for reimplantation of steers fed in confinement for slaughter with a progesterone-estradiol implant 70 days following an initial implant of a lower dose implant.

EFFECTIVE DATE: August 28, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St., NW., P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 9–576 that provides for use of Synovex® S (200 milligrams (mg) progesterone and 20 mg estradiol benzoate) implanted in the ear of steers fed in confinement for slaughter at approximately day 70 following initial implant of Synovex® C (100 mg progesterone and 10 mg estradiol benzoate) when used as part of a reimplant program for increased rate of weight gain. The supplemental NADA is approved as of July 14, 1998, and the regulations in 21 CFR 522.1940 are amended by adding paragraph (d)(3) 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(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 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: 21 U.S.C. 360b.

2. Section 522.1940 is amended by adding paragraph (d)(3) to read as follows:

§ 522.1940 Progesterone and estradiol benzoate in combination.

* * * * *

(d) * * *

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* Reimplant 200 milligrams of progesterone and 20 milligrams of estradiol benzoate on approximately day 70 following an initial implant of 100 milligrams of progesterone and 10 milligrams of estradiol benzoate or 200 milligrams of progesterone and 20 milligrams of estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation.

Dated: August 18, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–23109 Filed 8–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 359

Offering Regulations for United States Savings Bonds, Series I

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury (''Department'' or ''Treasury'') is publishing in final form an amendment to the offering circular for United States Series I savings bonds. The amendment is a technical change to accommodate the first Series I savings bond offering, effective September 1, 1998.

EFFECTIVE DATE: September 1, 1998.

ADDRESSES: Copies of this final rule are available for downloading from the Bureau of the Public Debt at the following World Wide Web address: <http://www.savingsbonds.gov> or may be obtained from the Bureau of the Public Debt, Division of Staff Services, 200 3rd St., Parkersburg, WV 26106–1328.

FOR FURTHER INFORMATION CONTACT: Wallace L. Earnest, Director, Division of Staff Services, at (304) 480–6319 or by e-mail at <wearnest@bpd.treas.gov>; Edward C. Gronseth, Deputy Chief Counsel, at (304) 480–5192 or by e-mail at <egronset@bpd.treas.gov>; or Dean A. Adams, Assistant Chief Counsel, Office of the Chief Counsel, at (304) 480–5192 or by e-mail at <dadams@bpd.treas.gov>.