IV. Opportunity for Comments

Interested persons may submit written comments to the Dockets Management Branch (address above). Such comments will be considered in determining whether further amendments or revisions to this policy are warranted. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

(Secs. 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act and under authority of the Commissioner of Food and Drugs)

Dated: April 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–11116 Filed 4–29–97; 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; Oxytetracycline Hydrochloride Soluble Powder

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 the Pennfield Oil Co. The ANADA provides for the use of a generic oxytetracycline hydrochloride soluble powder for the drinking water of cattle, swine, sheep, chickens, and turkeys.

EFFECTIVE DATE: April 30, 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: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed ANADA 200–026, which provides for use of 102.4-gram (g) oxytetracycline hydrochloride per 4.78-ounce (135.5-g) packet for making medicated drinking water for cattle, swine, sheep, chickens, and turkeys for control and treatment of bacterial infections caused by oxytetracycline susceptible organisms.

ANADA 200–026 for Pennfield Oil Co.'s oxytetracycline hydrochloride water soluble powder is approved as a generic copy of Pfizer's NADA 8–622 Terramycin-343 (oxytetracycline hydrochloride) soluble powder. The ANADA is approved as of March 13, 1997, and the regulations are amended in 21 CFR 520.1660d by adding new paragraphs (a)(8) and (b)(6) 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.

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 520.1660d is amended by adding new paragraphs (a)(8) and (b)(6) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl.

(b) * * *

(6) No. 053389 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

* * * * *

Dated: April 2, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11079 Filed 4–29–97; 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; Sulfadimethoxine 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of sulfadimethoxine oral solution for chickens, turkeys, and cattle for treatment of certain bacterial infections.

EFFECTIVE DATE: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–192, which provides for use of sulfadimethoxine 12.5 percent oral solution for chickens, turkeys, and cattle. The oral solution is used to make medicated drinking water for broiler and replacement chickens for the treatment of outbreaks of coccidiosis, fowl cholera, and infectious coryza; meat-producing turkeys for disease outbreaks of coccidiosis and fowl cholera; dairy calves, dairy heifers, and beef cattle (in drinking water and as a drench) for shipping fever complex, bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine, calf diphtheria and foot-rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

Approval of Phoenix's ANADA 200–192 for sulfadimethoxine oral solution is as a generic copy of Pfizer's NADA 31–205 for Albon® (sulfadimethoxine) 12.5 percent concentrated solution. The ANADA is approved as of March 24, 1997, and the regulations are amended by revising 21 CFR 520.2220a(b) 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).

§ 520.2220a [Amended]

–2. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (b) by removing ''000069, 054273, and 057561'' and adding in its place ''000069, 054273, 057561, and 059130''.

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11084 Filed 4–29–97; 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; Amikacin Sulfate Injection

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 the use of amikacin sulfate injection for the treatment of the following conditions in dogs: genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

EFFECTIVE DATE: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–178, which provides for the use of amikacin sulfate injection for the treatment of the following conditions in dogs: genitourinary tract infections (cystitis) caused by susceptible strains of *E. coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

–The ANADA is approved as a generic copy of Fort Dodge Laboratories, Inc., NADA 127–892, Amiglyde-V® Injection (amikacin sulfate 50 milligrams per milliliter). ANADA 200–178 is approved as of March 14, 1997, and the regulations are amended in 21 CFR 522.56 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.

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 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).

§ 522.56 [Amended]

–2. Section 522.56 *Amikacin sulfate injection* is amended in paragraph (b) by removing ''000856'' and adding in its place ''Nos. 000856 and 059130''.

Dated: April 7, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11085 Filed 4–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Amikacin Sulfate 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intrauterine use of amikacin sulfate solution in horses for the treatment of uterine infections.

EFFECTIVE DATE: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–181, which provides for intrauterine use of amikacin sulfate solution for the treatment of uterine infections (endometritis, metritis, and pyometra) in mares, when caused by susceptible