

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 520.1263c is amended by revising paragraph (a) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin.

* * * * *

Dated: March 8, 1995.

Robert C. Livingston,

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

[FR Doc. 95-6531 Filed 3-15-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate 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 Sanofi Animal Health, Inc. The ANADA provides for the use of a generic neomycin sulfate soluble powder administered orally in drinking water or in milk for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Sanofi Animal Health, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed ANADA 200-050, which provides for the oral use of neomycin sulfate soluble powder in drinking water or milk for cattle (excluding veal calves), swine, sheep, and goats for the

treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin sulfate.

Approval of ANADA 200-050 is as a generic copy of The Upjohn's approved NADA 11-315 for Neomix® 325 soluble powder. The ANADA is approved as of February 15, 1995, and the regulations are amended by revising § 520.1484(b) (21 CFR 520.1484(b)) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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. Section 520.1484 is amended by revising paragraph (b) to read as follows:

§ 520.1484 Neomycin sulfate soluble powder.

* * * * *

(b) *Sponsors.* See Nos. 000009, 000069, 050604, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: March 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-6530 Filed 3-15-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline 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 oxytetracycline injection in cattle and swine for the treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, has filed ANADA 200-123 which provides for use of oxytetracycline injection as follows: (1) Intramuscular or intravenous use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline; (2) intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*; and (3) intramuscular use in sows for control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

Phoenix Scientific's ANADA 200-123 for oxytetracycline injection (Maxim 200) is approved as a generic copy of Pfizer's NADA 113-232 for oxytetracycline injection (Liquamycin®