NOT APPLY. THIS IS VOR/DME OR TACAN RWY 26, AMDT 10A.

[FR Doc. 97–29726 Filed 11–10–97; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline 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 Phoenix Scientific, Inc. The ANADA provides for oral use of chlortetracycline hydrochloride soluble powder in the drinking water of swine for control and treatment of certain diseases caused by pathogens susceptible to chlortetracycline and chickens and turkeys for control of certain diseases caused by pathogens susceptible to chlortetracycline.

EFFECTIVE DATE: November 12, 1997.

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

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–236 that provides for oral use of chlortetracycline hydrochloride soluble powder in animal drinking water as follows: (1) Swine: Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.) and *Klebsiella* spp.; (2) Chickens: Control of infectious synovitis caused by *Mycoplasma synoviae*, and chronic respiratory disease (CRD) and air-sac infections caused by *M. gallisepticum* and *E. coli*; and (3) Turkeys: Control of infectious synovitis caused by *M. synoviae* and complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

Approval of Phoenix Scientific Inc.'s ANADA 200–236 chlortetracycline hydrochloride soluble powder is as a generic copy of ADM Animal Health & Nutrition Div.'s NADA 65–256 Chlortet™-Soluble-O chlortetracycline hydrochloride soluble powder. ANADA 200–236 is approved as of September 24, 1997, and the regulations are amended in 21 CFR 520.445b(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 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 25.33(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.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfite)* is amended in paragraph (b) by removing ''No. 017519'' and adding in its place ''Nos. 017519 and 059130.''

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–29650 Filed 11-10-97; 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; Neomycin Sulfate 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 Pharmacia & Upjohn Co. The supplemental ANADA provides for a shorter withdrawal period following use of neomycin sulfate oral solution in the drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis.

EFFECTIVE DATE: November 12, 1997.

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

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental ANADA 200–113 that provides for a shorter withdrawal period following use of neomycin sulfate oral solution in the drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

Approval of supplemental ANADA 200–113 is as a generic copy of the sponsor's approved supplemental NADA 11–315. The supplemental ANADA is approved as of February 7, 1997, and the regulations are amended in § 520.1485(d)(3) (21 CFR 520.1485(d)(3)) to reflect the approval.

The previously approved supplement to NADA 11–315 included data to support revised tolerances for residues of neomycin in the edible tissues of cattle, swine, sheep, and goats. Based on evaluation of the data as provided in the ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals Guidelines,'' tolerances of 1.2 parts per million (ppm) in muscle, 3.6 ppm in liver, and 7.2 ppm in kidney and fat, and withdrawal times of 1 day for cattle, 2 days for sheep, and 3 days for swine and goats were established. The revised withdrawal times were established in 21

CFR 520.1484(c)(3) and now for ANADA 200–113 in § 520.1485(d)(3).

No additional effectiveness or safety studies were required for this approval. Therefore, a freedom of information summary is not required. A summary of data and information submitted to support the original ANADA approval 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 25.33(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.

2. Section 520.1485 is amended by revising the last sentence of paragraph (d)(3) to read as follows:

§ 520.1485 Neomycin sulfate oral solution.

* * * * *

(d) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: For sponsor 059130: 30 days for cattle and goats, and 20 days for swine and sheep; for sponsors 000009 and 050604: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

Dated: October 10, 1997.

Robert C. Livingston,

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

[FR Doc. 97–29654 Filed 11-10-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Medicated Feed Applications; Lasalocid; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct assay limits for lasalocid in Type A medicated articles. Although a supplement to the new animal drug application (NADA) was approved, the regulations had not been previously amended to reflect that approval. At this time the regulations are amended to reflect the current assay limits in the approved NADA.

EFFECTIVE DATE: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Mary G. Leadbetter, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1662.

SUPPLEMENTARY INFORMATION: FDA is amending the regulation concerning use of animal drugs in medicated feeds in § 558.4(d) (21 CFR 558.4(d)) to reflect that the assay limit for lasalocid Type A medicated articles is 95 to 115 percent of the labeled amount. Although the original approval for NADA 96–298 Hoffmann-LaRoche, Inc., provided for a 10 percent overage (an assay limit of 100 to 120 percent), a supplemental approval dated August 25, 1992, revised that overage to 5 percent (95 to 115 percent). The regulation in § 558.4(d) is amended in the table entitled ''Category I,'' in the entry for ''Lasalocid,'' accordingly.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category I,'' in the entry for ''Lasalocid,'' in the second column by removing ''100–120'' and adding in its place ''95–115''.

Dated: October 21, 1997.

Robert C. Livingston,

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

[FR Doc. 97–29649 Filed 11-10-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Amprolium Plus Ethopabate With Bacitracin Zinc and Roxarsone

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 Alpharma Inc. The ANADA provides for using approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used as an aid in the prevention of coccidiosis and improved feed efficiency or improved feed efficiency and improved pigmentation.

EFFECTIVE DATE: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed ANADA 200–214 that provides for combining approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler feeds. The Type C medicated feed containing amprolium 113.5 grams per ton (g/t) plus ethopabate 36.3 g/t with bacitracin zinc 10 to 50 g/t and roxarsone 15.4 to 45.4 g/t is used as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina*, *E. maxima*, and *E. brunetti* is likely to occur, and for improved feed efficiency. The Type C medicated feed containing amprolium 113.5 g/t plus ethopabate