nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 520.1615 is revised to read as follows:

§ 520.1615 Omeprazole.

(a) *Specifications.* Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use in horses*—(1) *Amount*—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for up to 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use.* (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: March 11, 2004.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 04–6248 Filed 3–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride and Spectinomycin Soluble Powder

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 approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for oral use of lincomycin and spectinomycin soluble powder to make medicated drinking water for administration to chickens up to 7 days of age as an aid in the control of several bacterial respiratory diseases.

DATES: This rule is effective March 22, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; tel: 301–827–8549; e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–345 for Lincomycin-Spectinomycin (lincomycin hydrochloride monohydrate/ spectinomycin dihydrochloride pentahydrate) Water Soluble Powder. The application provides for oral use of lincomycin and spectinomycin soluble powder to make medicated drinking water for administration to chickens up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Phoenix Scientific's Lincomycin-Spectinomycin Water Soluble Powder is approved as a generic copy of Pharmacia & Upjohn's L-S 50 (lincomycin hydrochloride monohydrate/ spectinomycin sulfate tetrahydrate) Water Soluble Powder, approved under NADA 46 109. ANADA 200 345 is approved as of February 5, 2004, and the regulations are amended in part 520 (21 CFR part 520) by removing § 520.1263b and by adding § 520.1265 to reflect the approval and a current format. 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 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 Division of Dockets Management (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.

FDA 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

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.

§ 520.1263b [Removed and Reserved]

■ 2. Section 520.1263b is removed and reserved.

■ 3. Section 520.1265 is added to read as follows:

§ 520.1265 Lincomycin and spectinomycin soluble powder.

(a) *Specifications.* The following salts of lincomycin and spectinomycin are present in a soluble powder in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base:

(1) Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate.

(2) Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000009 for use of product described in paragraph (a)(1) of this section.

(2) No. 059130 for use of product described in paragraph (a)(2) of this section.

(c) *Tolerances.* See §§ 556.360 and 556.600 of this chapter.

(d) *Conditions of use in chickens*—(1) *Amount.* 2 grams of antibiotic activity per gallon of drinking water; administer as the sole source of water for the first 5 to 7 days of life.

(2) *Indications for use.* As an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

Dated: March 11, 2004.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 04–6249 Filed 3–19–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Semduramicin, Virginiamycin, 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 a new animal drug application (NADA) filed by Phibro Animal Health. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing semduramicin, virginiamycin, and roxarsone to formulate three-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective March 22, 2004.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *jmessenh@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rte. 46 East, suite 401, Fairfield, NJ 07004, filed NADA 141–226 that provides for the use of AVIAX (semduramicin sodium), STAFAC (virginiamycin), and 3–NITRO (roxarsone) Type A medicated articles to formulate three-way combination drug Type C medicated feeds for broiler chickens. The Type C medicated feeds contain 22.7 grams per ton (g/ton) semduramicin, 20 g/ton virginiamycin, and 22.7 to 45.4 g/ton roxarsone, and are used for the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*; for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens. The application is approved as of February 23, 2004, and the regulations are amended in 21 CFR 558.555 and 558.635 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 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 Division of Dockets Management (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)(2) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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.

■ 2. Section 558.555 is amended by adding paragraph (d)(8) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(d) * * *

(8) *Amount.* Semduramicin 22.7 grams with virginiamycin 20 grams and roxarsone 22.7 to 45.4 grams/ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*; for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(ii) *Limitations.* Feed continuously as sole ration throughout growing period. Withdraw 5 days before slaughter. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water may result in leg weakness. Roxarsone provided by No. 046573; semduramicin and virginiamycin provided by No. 066104 in § 510.600(c) of this chapter.

■ 3. Section 558.635 is amended by revising paragraph (d)(4)(vii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(d) * * *

(4) * * *

(vii) Semduramicin alone or with roxarsone as in § 558.555.

Dated: March 11, 2004.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 04–6247 Filed 3–19–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN158–1a; FRL–7626–7]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency is approving revisions to particulate matter (PM_{10}) emissions regulations for U.S. Steel-Gary Works and U.S. Steel-Gary Coke Operations, located in Lake County, Indiana. The