(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