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, 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)(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 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 558.355 is amended by revising paragraphs (d)(6), (f)(3)(x)(*a*), and (f)(3)(x)(*c*) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(6) The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

* * * * *

(f) * * *

(3) * * *

(x) * * *

(*a*) *Indications for use.* For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

* * * * *

(*c*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. Do not feed to lactating dairy cattle. The product's effectiveness in cull cows and bulls has not been established. Consumption by unapproved species may result in toxic reactions. A feed manufacturing facility must possess a medicated feed mill license issued under § 515.20 of this chapter in order to manufacture this free-choice Type C feed.

* * * * *

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18821 Filed 7–25–00; 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; Penicillin; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect a previously approved 227 grams per pound (g/lb) strength of penicillin G Type A medicated article for use in the feed of several domestic species which was omitted from the regulation in the 1998 notice of approval.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 046–668 that provides for use of Penicillin 100 (100 g/lb penicillin G procaine) and Penicillin 50 (227 g/lb penicillin G procaine) Type A medicated articles to make Type C medicated feeds used for increased rate of weight gain and improved feed efficiency in poultry and swine. In its approval letter of April 10, 1998, to Pfizer, Inc., the Center for Veterinary Medicine approved the use of these products to make Type C medicated feeds, but did not codify the approval of the 227 g/lb strength of Type A medicated article for this sponsor (63 FR 36179, July 2, 1998). At this time, 21 CFR 558.460(b) is amended by adding the 227 g/lb strength of Type A medicated article to reflect the 1998 approval.

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.

§ 558.460 [Amended]

2. Section 558.460 *Penicillin* is amended in the first sentence in paragraph (b) by adding ''and 227'' after ''To 000069, 100''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18872 Filed 7–25–00; 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; Neomycin Sulfate

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 new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for the use of neomycin sulfate Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats in a broader range of concentrations.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, has filed a supplemental application to NADA 140–976 that provides for use of Neomix® (neomycin sulfate) Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats used for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin. The supplemental NADA requested that the approved range of concentrations for neomycin Type C medicated feeds of 400 to 1,600 grams per ton (g/ton) be broadened to 250 to 2,250 g/ton. The approved daily dose of 10 milligrams per pound of body weight remains unchanged. The supplemental NADA is approved as of June 28, 2000, and the regulations are amended in 21 CFR 558.364 to reflect the approval.

Approval of this supplemental NADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary is not required.

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.

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 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.

§ 558.364 [Amended]

2. Section 558.364 *Neomycin sulfate* is amended in the table in paragraph (d) in entry ''(1)'' under ''Neomycin sulfate'' by removing ''400 to 1,600'' and by adding in its place ''250 to 2,250''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18826 Filed 7–25–00; 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; Chlortetracycline

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 new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for use of approved chlortetracycline (CTC) Type A medicated articles to make Type C medicated feeds used for control of porcine proliferative enteropathies (ileitis) in swine.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7574.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., PO Box 1399, Fort Lee, NJ 07024, filed a supplement to approved NADA 046–699 that provides for use of CHLORMAX™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline as chlortetracycline hydrochloride) Type A medicated articles to make Type C medicated feeds for use in growing and finishing swine. The Type C medicated feeds contain approximately 400 g per ton CTC (to provide 10 milligrams/lb body weight) and are used for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. The supplemental NADA is approved as of July 7, 2000, and the regulations are amended in 21 CFR 558.128 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 supplemental application may be seen in the Dockets Management Branch (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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on July 7, 2000, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new claim for which the supplemental application was approved.

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.

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: