

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.

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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]

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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

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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.
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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.