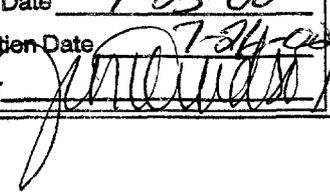


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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

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 Elanco Animal Health. The supplemental NADA provides for use of monensin Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding for the prevention and control of coccidiosis, and increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). A technical correction is also being made.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95-735 that provides for use of RUMENSIN® 80 (80 grams per pound (g/lb) of monensin as monensin sodium) Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding to pasture cattle. The free-choice medicated mineral granules contain 1,620 g/ton monensin and are used for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and

beef replacement heifers). The supplemental NADA is approved as of July 7, 2000, and the regulations are amended in § 558.355(f)(3)(x) (21 CFR 558.355(f)(3)(x)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.355(d)(6) is revised to reflect current precautionary statements regarding the ingestion of monensin-containing formulations by unapproved species.

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
July 18, 2000

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

J. McDonald

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug
Evaluation
Center for Veterinary
Medicine
[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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