

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bambermycins

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 Intervet, Inc. The supplemental NADA provides for use of bambermycins Type A medicated articles to make Type B and Type C medicated feeds used to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when consumed free-choice or hand-fed at a rate of not less than 10 milligrams (mg) nor more than 40 mg bambermycins per head per day.

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

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 141-034 that provides for use of GAINPRO (bambermycins) Type A medicated articles to make Type B and Type C medicated feeds used to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)

when consumed free-choice or hand-fed at a rate of not less than 10 mg nor more than 40 mg bambarmycins per head per day. The supplemental NADA is approved as of February 10, 2003, and the regulations are amended in 21 CFR 558.95 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 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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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.

§ 558.95 [Amended]

2. Section 558.95 *Bambermycins* is amended by:

a. In paragraphs (d)(4)(ii)(b) and (d)(4)(iv)(a) by removing “20” and by adding in its place “40”;

b. In paragraph (d)(4)(iii)(d) by adding “cattle, and dairy and beef replacement heifers” after “feeder”, and by removing “5.33” and “10- to 20-milligrams” and by adding in their respective places “10.66” and “10 to 40 milligrams”; and

c. In paragraphs (d)(4)(ii)(b), (d)(4)(iii)(d), and (d)(4)(iv)(c) by adding “Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.” at the end of the paragraph.

Dated: May 8, 2003.

Steven D. Vaughn,

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

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