

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid and Bacitracin

Methylene Disalicylate

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 a 0-day withdrawal period for the use of approved two-way combination drug Type C medicated feeds containing lasalocid and bacitracin methylene disalicylate in broiler and fryer chickens.

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

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600, e-mail: candres@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 107-996 for use of AVATEC (lasalocid sodium) and BMD (bacitracin methylene disalicylate) Type A medicated articles to formulate two-way combination drug Type C medicated chicken feeds. The supplemental NADA provides for a 0-day withdrawal period for broiler and fryer chicken feeds containing 68 grams/ton (g/ton) lasalocid and 10 to 50 g/ton bacitracin methylene disalicylate used

for the prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency; and for broiler chicken feeds containing 68 to 113 g/ton lasalocid and 4 to 50 g/ton bacitracin methylene disalicylate used for the prevention of coccidiosis, and for improved feed efficiency. The NADA is approved as of December 4, 2002, and the regulations are amended in 21 CFR 558.311 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 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.

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.

§ 558.311 [Amended]

2. Section 558.311 *Lasalocid* is amended in the table in paragraph (e)(1)(iv) under the “Limitations” column by removing “withdraw 3 days before slaughter”, and in the table in paragraph (e)(1)(x) under the “Limitations” column by removing “withdraw 3 days before slaughter;”.

Dated: March 21, 2003.

Steven D. Vaughn,

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

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S