

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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Certifier	Monica Oliver

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

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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved lasalocid and bacitracin zinc Type A medicated articles to make two-way combination drug Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in broiler 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.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-083 that provides for use of Avatec® (90.7 grams per pound (g/lb) lasalocid as lasalocid sodium) and Baciferm® (50 g/lb bacitracin zinc) Type A medicated articles to make two-way combination drug Type C medicated chicken feeds. The combination Type C medicated feeds are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of April 18, 2001, 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 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.

FDA 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.

2. Section 558.311 is amended in paragraph (e)(1) in the table by redesignating paragraphs (e)(1)(xi) through (e)(1)(xvi) as paragraphs (e)(1)(xii) through (e)(1)(xvii), respectively, and by adding new paragraph (e)(1)(xi) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xi) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin zinc 4 to 50.	Broiler chickens. For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 046573 in § 510.600(c) of this chapter.	046573

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Dated: 5/15/01
May 15, 2001.

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

Moni Oliver

S F Sundlof

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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