DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Robenidine 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 an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for using approved robenidine and bacitracin zinc Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–28), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is the sponsor of ANADA 200–212 which provides for combining approved robenidine and bacitracin zinc Type A medicated articles to make Type C medicated broiler feeds containing robenidine hydrochloride 30 grams per ton (g/t) and bacitracin zinc 4 to 50 g/t for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and with bacitracin zinc 4 to 30 g/t, for increased rate of weight gain, and with bacitracin zinc 27 to 50 g/t, for improved feed efficiency.

Alpharma Inc.'s ANADA 200–212 is approved as a generic copy of Hoffmann-La Roche, Inc.'s NADA 96–933. The ANADA is approved as of December 23, 1997, and the regulations are amended in 21 CFR 558.515(d)(1)(vi)(*b*) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of two single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, robenidine, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of robenidine and bacitracin zinc Type A medicated articles to make Type C medicated feeds as provided in NADA 200–212 is limited to manufacture in a licensed feed mill.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 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.

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.

§ 558.515 [Amended]

2. Section 558.515 *Robenidine hydrochloride* is amended in paragraph (d)(1)(vi)(*b*) by removing ''000004 and 000061'' and adding in its place ''000004, 000061, and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, 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; Amprolium Plus Ethopabate With Bacitracin Zinc and Roxarsone

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 an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for using approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used as an aid in the prevention of coccidiosis and increased rate of weight gain in broiler chickens raised in floor pens.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed ANADA 200–217 that provides for combining approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler feeds. The Type C medicated feed containing amprolium 113.5 grams per ton (g/t) plus ethopabate 36.3 g/t with bacitracin zinc 5 to 35 g/t and roxarsone 34 g/t, is used as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, and for increased rate of weight gain in broiler chickens raised in floor pens.

Alpharma Inc.'s ANADA 200–217 provides for using approved AMPROL HI–E® (Merck's amprolium and ethopabate NADA 13–461), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200–217 is approved as a generic copy of Swisher Feed Div.'s NADA 39–284. The ANADA is approved as of December 23, 1997, and the regulations are amended in 21