

Poulenc, Inc.'s NADA 49-934. The ANADA is approved as of November 20, 1997 and the regulations are amended in § 558.175 (21 CFR 558.175) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, § 558.175 is amended to reflect the approval by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by amending newly redesignated paragraph (d)(1)(iv)(b).

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(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.

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

The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.175 [Amended]

2. Section 558.175 *Clopidol* is amended by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and in newly redesignated paragraph (d)(1)(iv)(b) by removing "No. 000061" and adding in its place "Nos. 000061 and 046573".

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-30408 Filed 11-19-97; 8:45 am]

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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 and Bacitracin Zinc With 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 monensin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and increased rate of weight gain, or for prevention of coccidiosis and improved feed efficiency and improved pigmentation.

EFFECTIVE DATE: November 20, 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, is sponsor of ANADA 200-211 that provides for combining approved monensin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler feeds containing: Monensin 90 to 110 grams per ton (g/t) and bacitracin zinc 10 g/t with roxarsone 15 g/t 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, or; monensin 90 to 110 g/t and bacitracin zinc 4 to 50 g/t with roxarsone 15 to 45.4 g/t for prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for improved feed efficiency and improved pigmentation by enhancing carotenoid and xanthophyll utilization.

ANADA 200-211, sponsored by Alpharma Inc., is approved as a generic copy of Hoffmann-La Roche's NADA 123-154. The ANADA is approved as of November 20, 1997 and the regulations are amended in 21 CFR 558.355(f)(1) to reflect the approval. The basis for 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, 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(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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraphs (f)(1)(xv)(b) and (f)(1)(xvi)(b) by removing "No. 000004" and adding in its place "Nos. 000004 and 046573".

Dated: November 7, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-30483 Filed 11-19-97; 8:45 am]

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 357

[Department of the Treasury Circular, Public Debt Series, No. 2-86]

Regulations Governing Book-Entry Treasury Bonds, Notes, and Bills; Determination Regarding State Statutes

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Determination of substantially identical state statutes.