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Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs for Use in Animal Feeds; Salinomycin 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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved salinomycin and bacitracin zinc Type A medicated articles to make Type C medicated broiler chicken feeds used for the prevention of coccidiosis and for increased rate of weight gain. This document is also amending the animal drug regulations to reflect the correct sponsor name for Alpharma Inc.

EFFECTIVE DATE: November 13, 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's 200–204 and 200–210 that provide for combining approved salinomycin and bacitracin zinc Type A medicated articles to make Type C medicated broiler feeds containing salinomycin 40 to 60 grams per ton (g/t) and bacitracin zinc 10 to 50 g/t. The Type C medicated feed is used for the 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.

ANADA 200–204, filed by Alpharma Inc., provides for using approved BIO–COX® (Hoffmann-LaRoche Inc.'s salinomycin NADA 128–686) and ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223) Type A medicated articles to make the combination drug Type C medicated feeds. ANADA 200–210, also filed by Alpharma Inc., provides for using approved SACOX® (Hoechst-Roussel Vet's salinomycin ANADA 200–075) and ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200–204 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 139–235. Alpharma Inc.'s ANADA 200–210 is approved as a generic copy of Hoechst-Roussel Vet's ANADA 200–089. The ANADA's are approved as of September 19, 1997, and the regulations are amended in 21 CFR 558.550(b)(1)(vii)(*c*) to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

FDA is also amending the animal drug regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the correct firm name for Alpharma Inc.

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 these applications 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.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''ALPHARMA INC.'' and in paragraph (c)(2) in the entry for ''046573'' by removing the name ''ALPHARMA INC.'' and adding in its place ''Alpharma Inc.''

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.550 [Amended]

4. Section 558.550 *Salinomycin* is amended in paragraph (b)(1)(vii)(*c*) by removing ''No. 000004'' and adding in its place ''Nos. 000004 and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–29905 Filed 11–12–97; 8:45 am]

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DEPARTMENT OF THE TREASURY

Departmental Offices

31 CFR Part 1

Privacy Act of 1974; Implementation

AGENCY: Departmental Offices, Treasury.

ACTION: Final Rule.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Department of the Treasury gives notice of an amendment to exempt the system of records entitled, ''Integrated Data Retrieval System (IDRS) Security Files—Treasury/IRS 34.018,'' from certain provisions of the Privacy Act.

EFFECTIVE DATE: November 13, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Sincavage, Director, 6103/Privacy Operations, Governmental Liaison & Disclosure, Internal Revenue Service at (202) 622–6240.

SUPPLEMENTARY INFORMATION: The Department of the Treasury published a notice of a proposed rule exempting a system of records from certain provisions of the Privacy Act of 1974, as Amended, at 60 FR 40797, dated August 10, 1995. The Internal Revenue Service published an alteration to the system notice on July 31, 1995, at 60 FR 30972.

Under 5 U.S.C. 552a(k)(2), the head of an agency may promulgate rules to exempt any system of records within the agency from certain provisions of the