

Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

\* \* \* \* \*

30. Section 5.90 is revised to read as follows:

**§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

31. Section 5.91 is revised to read as follows:

**§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

32. Section 5.92 is revised to read as follows:

**§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

Dated: December 16, 1997.

**William K. Hubbard,**

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33482 Filed 12-23-97; 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; Decoquinatate 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 decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

**EFFECTIVE DATE:** December 24, 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 200-206 that provides for combining approved decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds for broilers containing decoquinatate 27.2 grams per ton (g/t) and bacitracin zinc 12 to 50 g/t with roxarsone 11 to 45 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. mivati*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency.

ALPHARMA INC.'s, ANADA 200-206 is approved as a generic copy of Rhone Poulenc Inc.'s NADA 91-326. The ANADA is approved as of December 24, 1997 and the regulations are amended in 21 CFR 558.195(d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, 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 a Type C medicated feed from a

Category II drug. Under section 512(m) of the 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 decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in NADA 200-206 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.

**§ 558.195 [Amended]**

2. Section 558.195 *Decoquinatate* is amended in the table in paragraph (d) in the entry for "27.2 (0.003 pct), Roxarsone 11 to 45 (0.0012-0.005 pct.) plus Bacitracin 12 to 50" under "Limitations" by removing "No. 011716" and adding in its place "Nos. 011716 and 046573".

Dated: October 30, 1997.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

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