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Display Date	11-25-98
Publication Date	11-27-98
Certifier	J. W. [Signature]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Chlortetracycline, Salinomycin, 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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved chlortetracycline, salinomycin, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and as an aid in the reduction of mortality due to *Escherichia coli* infections.

EFFECTIVE DATE: (Insert date of publication in the **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301-827-0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200-259 and 200-260 that provide for combining approved ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline), Sacox® or Bio-Cox® (30 or 60 g/lb salinomycin sodium), and 3-Nitro® (10, 20, or 50 percent roxarsone) Type A medicated articles to make Type C medicated broiler feeds containing chlortetracycline 500 grams per ton (g/t), salinomycin 40 to 60 g/t, and roxarsone 45.4 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible

to roxarsone combined with salinomycin than salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200-259 is approved as a generic copy of Hoechst-Roussel's ANADA 200-091. Alpharma Inc.'s ANADA 200-260 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140-867. Alpharma Inc.'s ANADA's 200-259 and 200-260 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is added and paragraph (d)(1)(xv) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

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.

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.

2. Section 558.550 is amended by revising paragraph (a) and the last sentence in paragraph (d)(1)(xv)(c) to read as follows:

§ 558.550 Salinomycin.

(a) *Approvals.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass) as follows:

(1) To 063238 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) To 012799 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), and (d)(3)(i) through (d)(3)(iii) of this section.

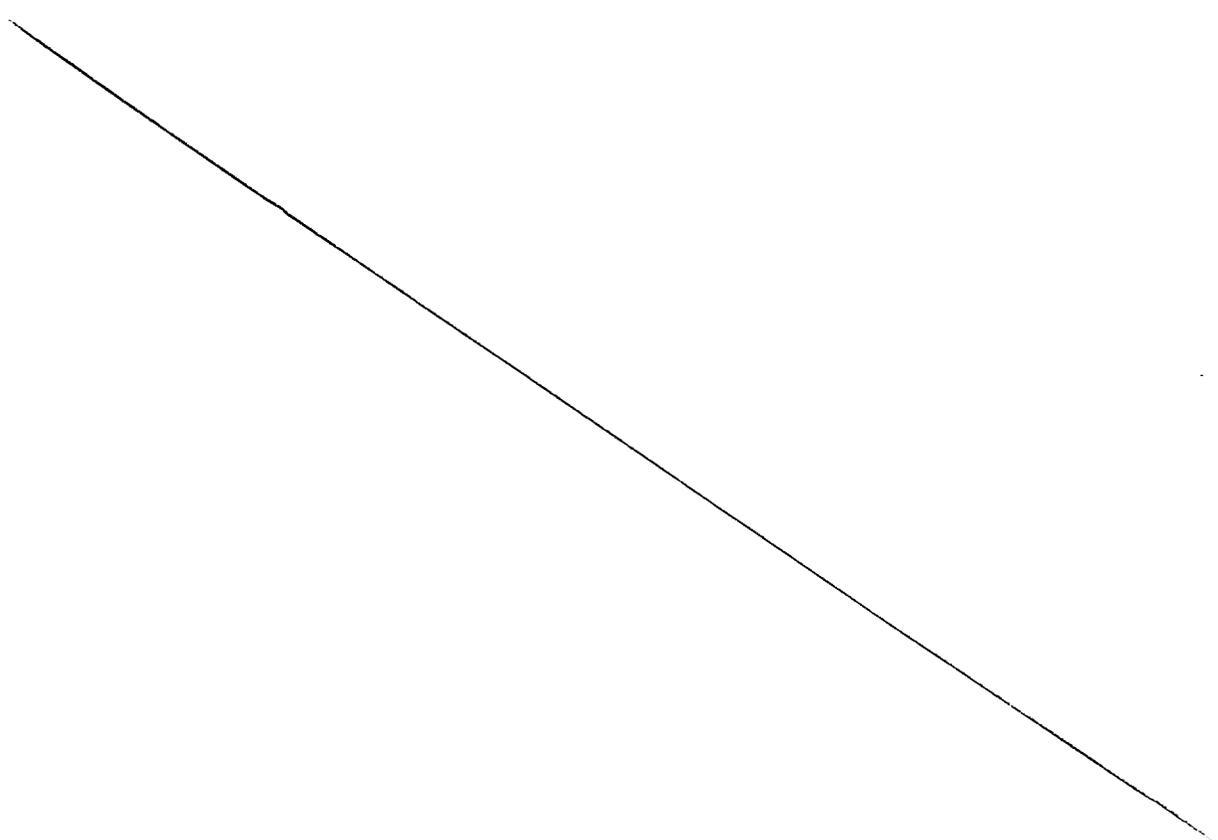
(3) To 046573 for use as in paragraph (d)(1)(xv) of this section.

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(d) * * *

(1) * * *

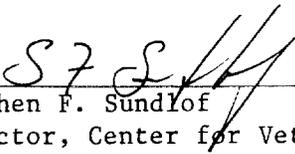
(xv) * * *



(c) * * * Chlortetracycline as provided by Nos. 046573 and 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

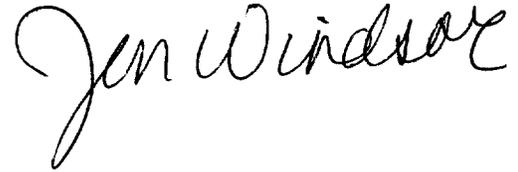
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Dated: 11/12/98
November 12, 1998



Stephen F. Sundlof
Director, Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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