

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

SMB

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Certifier	SARullo

New Animal Drugs for Use in Animal Feeds; Decoquinatone and Chlortetracycline

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 a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved decoquinatone and chlortetracycline (CTC) Type A medicated articles to make two-way combination Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle used for prevention of coccidiosis, treatment of bacterial enteritis, and treatment of bacterial pneumonia.

DATES: This rule is effective [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-147 that provides for use of Deccox® (27.2 grams per pound g/lb) and ChlorMax™ (50, 65, or 70 g/lb CTC) Type A medicated articles to make combination drug Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle. The combination Type C feeds are for prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for treatment of bacterial enteritis caused by *Escherichia coli*, and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to CTC. The NADA is approved

as of September 29, 2000, and the regulations are amended in the table in 21 CFR 558.195(d) to reflect the approval. The basis of 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, 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)(2) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

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 558.195 is amended in the table in paragraph (d) by adding an entry following the indication for "Cattle" at the 13.6 to 27.2 grams per ton decoquinate dose level and before the entry for "Cattle" at the 13.6 to 535.7 grams per ton dose level, to read as follows:

§ 558.195 Decoquinatc.

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(d) * * *

Decoquinatc in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline approximately 400, varying with body weight and feed consumption to provide 10 mg/lb of body weight per day.	Calves, beef and nonlactating dairy cattle: prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> , for treatment of bacterial enteritis caused by <i>Escherichia coli</i> , and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline.	Feed Type C feed to provide 22.7 mg decoquinatc and 1 g chlortetracycline/100 lb body weight (0.5 mg/kg)/day for not more than 5 days. Type C feed may be prepared from Type B feed containing 535.8 to 5,440 g/ton decoquinatc and 6,700 to 80,000 g/ton chlortetracycline. When consumed, feed 22.7 mg decoquinatc/100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food.	046573

Dated: 10/26/00
October 26, 2000.

cv9996

SFS/A

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

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