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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Bacitracin Methylene Disalicylate

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, single-ingredient chlortetracycline (CTC) and bacitracin methylene disalicylate Type A medicated articles to make two-way combination Type C medicated feeds used for control of porcine proliferative enteropathies (ileitis) and for increased rate of weight gain and improved feed efficiency in swine.

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

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7574.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-059 that provides for use of ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline as chlortetracycline hydrochloride) and BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds for use in growing and finishing swine. The Type C medicated feeds contain approximately 400 g/ton CTC (to provide 10 milligrams/lb body weight) and 10 to 30 g/ton bacitracin methylene disalicylate, and they are used for the control of porcine proliferative

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NADA-141-059

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enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of July 7, 2000, and the regulations in 21 CFR 558.76 are amended 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, 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 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 558.76 is amended in the table in paragraph (d)(1) by adding an entry under item (iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

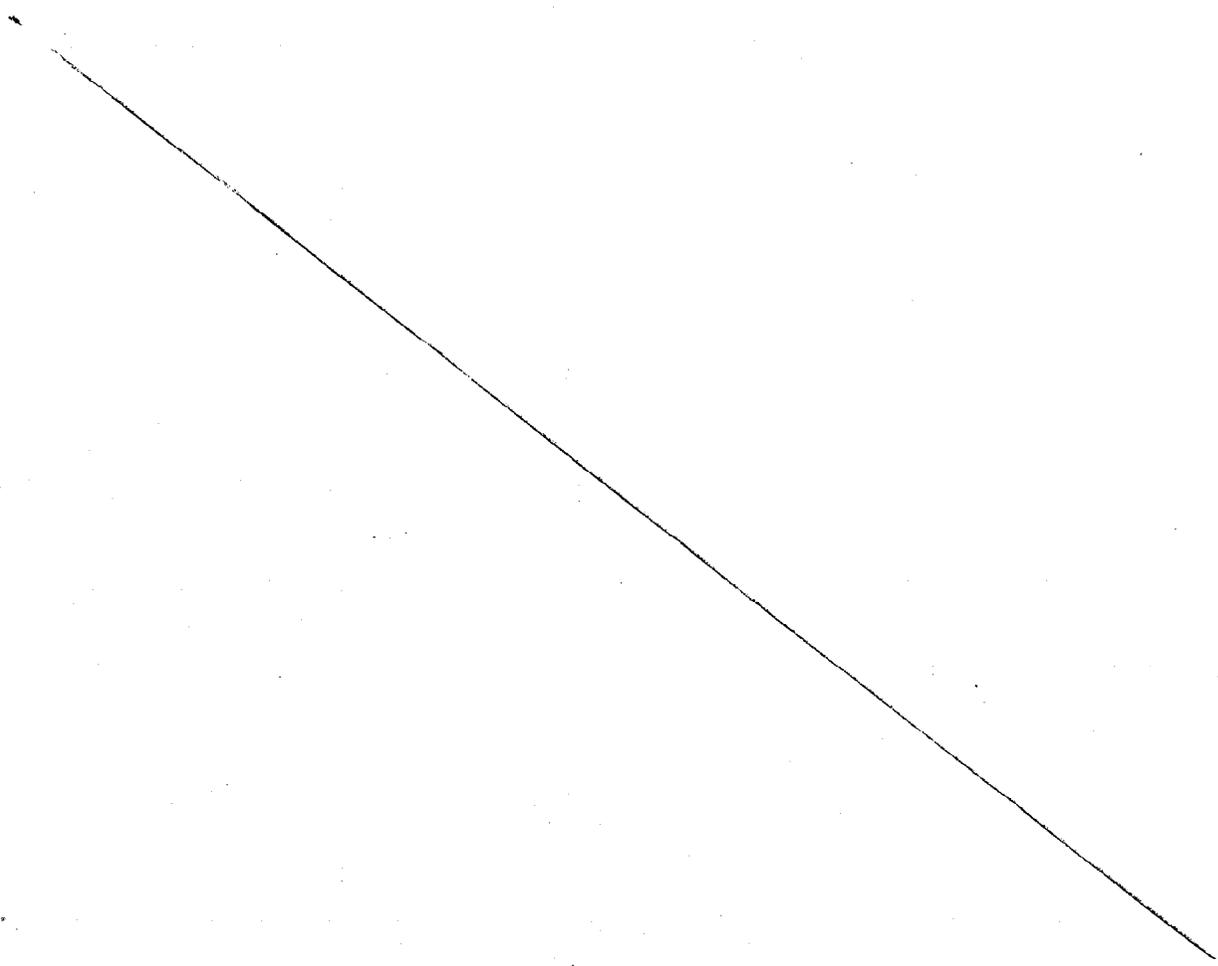
* * * * *

(d) * * *

(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * * * * (iv) * * * * * * * * * *	* * * * * * * * * * * * * * *	* * * * * * * * * * Swine; for control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline. * * * * *	* * * * * * * * * * Feed for not more than 14 days; chlortetracycline and BMD® as provided by 046573 in § 510.600(c) of this chapter. * * * * *	* * * * * * * * * * 046573 * * * * *

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Dated: 8/23/00

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August 23, 2000

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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