

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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

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 supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for using approved single-ingredient bacitracin methylene disalicylate and zoalene Type A medicated articles to make two-way combination drug Type C medicated feeds used for the management of necrotic enteritis and coccidiosis in replacement and broiler chickens.

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

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 141-085 that provides for combining approved BMD (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) and ZOAMIX (113.5 g/lb zoalene) Type A medicated articles to make two-way combination drug Type C medicated chicken feeds containing 50 or 100 to 200 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 or 113.5 g/ton zoalene. The combination Type C feeds containing 50 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 g/ton zoalene are used as an aid in the prevention of

necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the development of active immunity to coccidiosis in replacement chickens. The combination Type C feeds containing 100 to 200 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 g/ton zoalene are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the development of active immunity to coccidiosis in replacement chickens. The combination Type C feeds containing 50 g/ton bacitracin methylene disalicylate and 113.5 g/ton zoalene are used as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the prevention and control of coccidiosis in broiler chickens. The combination Type C feeds containing 100 to 200 g/ton bacitracin methylene disalicylate and 113.5 g/ton zoalene are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the prevention and control of coccidiosis in broiler chickens. The supplemental NADA is approved as of November 30, 2001, and the regulations are amended in 21 CFR 558.680 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.

FDA 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 558.680 is amended by redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively; by adding new paragraph (a); by revising newly redesignated paragraph (b); and in the table in paragraph (d)(1) by adding in item (i) after the entry for “Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50” the entries for “Bacitracin methylene disalicylate 50” and “Bacitracin methylene disalicylate 100 to 200”, and by adding in item (ii) after the entry for “Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%)” the entries for “Bacitracin methylene disalicylate 50” and “Bacitracin methylene disalicylate 100 to 200” to read as follows:

§ 558.680 Zoalene.

(a) *Specifications.* Type A medicated article containing 25 percent zoalene.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

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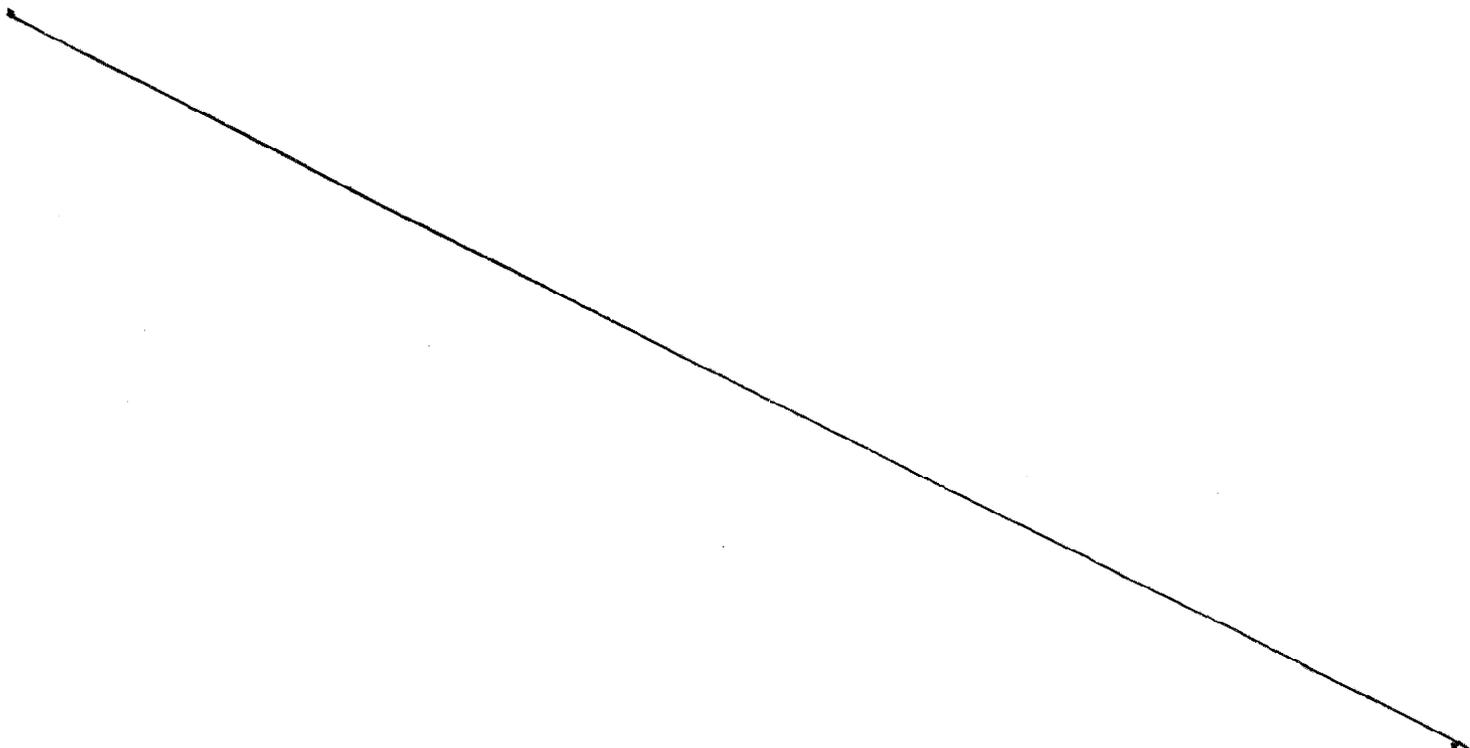
(d) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) 36.3–113.5 (0.004–0.0125%)	***	***	***

Zoaene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Bacitracin methylene disalicylate 50	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in this item (i); grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter.
(ii) 113.5 (0.0125%)	Bacitracin methylene disalicylate 100 to 200	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in this item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter.
	Bacitracin methylene disalicylate 50	Broiler chickens; prevention and control of coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter.
	Bacitracin methylene disalicylate 100 to 200	Broiler chickens; prevention and control of coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter.

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Dated: 2/1/02

February 1, 2002.

Claire M. Lathers

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

[FR Doc. 01-⁰²????? Filed ??-??-01⁰²; 8:45 am]

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2/1/02

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