

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; Salinomycin, Bacitracin Methylene Disalicylate, 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 a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for using approved, single-ingredient salinomycin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make three-way combination Type C medicated feeds used for prevention of coccidiosis, as an aid in the prevention and control of necrotic enteritis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler, roaster, and replacement (breeder and layer) chickens.

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

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-121 that provides for use of approved BIO-COX® (30 or 60 grams per pound (g/lb) of salinomycin activity), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3-NITRO® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds for use in broiler, roaster, and replacement chickens. The combination Type C medicated feeds contain 40 to 60 grams per ton (g/ton) salinomycin, 50 or 100 to 200

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NADA 141.121

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g/ton BMD, and 22.7 to 45.4 g/ton roxarsone and are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, as an aid in the prevention (at 50 g/ton BMD) or control (at 100 to 200 g/ton BMD) of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of December 23, 1999, and the regulation in § 558.550 (21 CFR 558.550) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, due to an error in structuring the regulations, the approval entry in § 558.550(a)(3) is removed. Also, § 558.500(d)(1)(xv) and (d)(1)(xvi) are amended under limitations to reflect the change due to the error.

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 558.550 is amended by removing the phrase “through (d)(3)(iii)” from paragraph (a)(2), by removing paragraph (a)(3), by revising the last sentence of paragraphs (d)(1)(xv)(c) and (d)(1)(xvi)(c), by adding paragraphs (d)(1)(xviii) and (xix), by redesignating paragraphs (d)(3)(i), (d)(3)(ii), and (d)(3)(iii) as paragraphs (d)(3)(i)(A), (d)(3)(i)(B), and (d)(3)(i)(C), respectively, and by adding new paragraphs (d)(3)(ii) and (d)(3)(iii) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(d) * * *

(1) * * *

(xv) * * *

(c) *Limitations.* * * * Chlortetracycline as provided by Nos. 046573 and 063238; roxarsone as provided by No. 046573; and salinomycin as provided by Nos. 012799 and 063238 in § 510.600(c) of this chapter.

(xvi) * * *

(c) *Limitations.* * * * Chlortetracycline as provided by Nos. 046573 and 063238; salinomycin as provided by Nos. 012799 and 063238 in § 510.600(c) of this chapter.

* * * * *

(xviii)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis

caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by Nos. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xix)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary 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 g/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

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(3) * * *

(ii)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

(iii)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

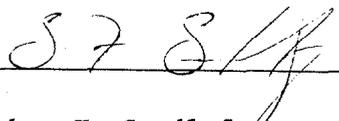
(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug

overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 063238; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

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Dated: June 26, 2000

June 26, 2000



Stephen F. Sundlof
Director
Center for Veterinary Medicine

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

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COPY OF THE ORIGINAL**

