

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	<i>11 27 00</i>
Publication Date	<i>11 28 00</i>
Certifier	<i>[Signature]</i>

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Salinomycin 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 salinomycin and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler, roaster, and replacement (breeder and layer) chickens. The Type C medicated feeds are used for prevention of coccidiosis and as an aid in the prevention and control of necrotic enteritis in broiler, roaster, and replacement (breeder and layer) chickens; and for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in roaster and replacement (breeder and layer) chickens. Previously established acceptable daily intakes (ADI's) for total residues of bacitracin and salinomycin are also being codified.

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 141-136 that provides for use of approved BIO-COX® (30 or 60 grams per pound (g/lb) of salinomycin activity) and BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin

methylene disalicylate) Type A medicated articles to make combination drug Type C medicated feeds for use in broiler, roaster, and replacement (breeder and layer) chickens. The combination Type C medicated feeds containing 40 to 60 g/ton salinomycin and 4 to 50 g/ton bacitracin methylene disalicylate are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency in roaster and replacement (breeder and layer) chickens. The combination Type C medicated feeds containing 40 to 60 g/ton salinomycin and 50 g/ton bacitracin methylene disalicylate are used for the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler, roaster, and replacement (breeder and layer) chickens. The combination Type C medicated feeds containing 40 to 60 g/ton salinomycin and 100 to 200 g/ton bacitracin methylene disalicylate are used for the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler, roaster, and replacement (breeder and layer) chickens. The NADA is approved as of September 20, 2000, and the regulations are amended in 21 CFR 558.550 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulations are amended in 21 CFR part 556 to add the previously established ADI's for total residues of bacitracin and salinomycin, and editorially, to reflect current format.

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

21 CFR Part 556

Animal drugs, Food.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.70 is revised to read as follows:

§ 556.70 Bacitracin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.

(b) *Tolerances.* The tolerance for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs is 0.5 part per million.

3. Section 556.592 is added to subpart B to read as follows:

§ 556.592 Salinomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day.

(b) [Reserved]

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 adding paragraphs (a)(3), (d)(1)(xx), and (d)(1)(xxi); by redesignating paragraphs (d)(3)(ii), (d)(3)(iii), and (d)(3)(iv) as paragraphs (d)(3)(iv), (d)(3)(vi), and (d)(3)(vii), respectively; and by adding paragraphs (d)(3)(ii), (d)(3)(iii), and (d)(3)(v) to read as follows:

§ 558.550 Salinomycin.

(a) * * *

(3) To 046573 for use as in paragraphs (d)(1)(xv), (d)(1)(xvi), (d)(1)(xviii) through (d)(1)(xxi), and (d)(3)(ii) through (d)(3)(vii) of this section.

* * * * *

(d) * * *

(1) * * *

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

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

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) in this chapter.

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

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

(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 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) in this chapter.

* * * * *

(3) * * *

(ii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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(v) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 100 to 200 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *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 grams per ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens.

May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 063238; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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Dated: 11/6/00
November 6, 2000



Stephen F. Sundlof
Director
Center for Veterinary Medicine

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



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

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