

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Decoquinatate

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 the use of decoquinatate Type A medicated articles to make Type C medicated feeds for cattle, sheep, and goats at a broader range of concentrations for the prevention of coccidiosis.

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, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 39-417 that provides for use of DECCOX (decoquinatate) Type A medicated articles to make Type C medicated feeds for cattle, sheep, and goats at a broader range of concentrations for the prevention of coccidiosis caused by various *Eimeria* species. The NADA is approved as of September 4, 2002, and the regulations are amended in 21 CFR 558.195 to reflect the approval. Section 558.195 is also revised to reflect a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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)(1) 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 558.195 is revised to read as follows:

§ 558.195 Decoquate.

(a) *Specifications.* Type A medicated article containing 6 percent decoquate.

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

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Special considerations.* (1) Bentonite should not be used in decoquate feeds.

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

(3) Type C cattle feeds may be manufactured from decoquinatate liquid Type B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

(e) *Conditions of use.* It is used as follows:

(1) *Chickens.*

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2		Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> .	Do not feed to laying chickens.	046573
(ii) 27.2	Bacitracin methylene disalicylate 4 to 50	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(iii) 27.2	Bacitracin zinc 10 to 50	Broiler chickens: As in paragraph (e)(1)(ii) of this section.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(iv) 27.2	Bacitracin zinc 12 to 50 plus roxarsone 11 to 45	Broiler chickens: As in paragraph (e)(1)(ii) of this section.	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic. Bacitracin zinc and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(v) 27.2	Bacitracin methylene disalicylate 50 and roxarsone 22.7 to 45.4	Broiler chickens: As in paragraph (e)(1)(ii) of this section; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; and for improved pigmentation.	Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days before slaughter. Not for use in breeder chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of drinking water may result in leg weakness or paralysis. Bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(vi) 27.2	Chlortetracycline 100 to 200	Chickens: As in paragraph (e)(1)(i) of this section; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption.	046573
(vii) 27.2	Chlortetracycline 200 to 400	Chickens: As in paragraph (e)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline.	As in paragraph (e)(1)(vi) of this section.	046573
(viii) 27.2	Lincomycin 2	Broiler chickens: As in paragraph (e)(1)(ii) of this section.	Feed as sole ration; do not feed to laying chickens; lincomycin provided by No. 000009 in § 510.600(c) of this chapter.	000009 046573
(ix) 27.2	Roxarsone 45.4	Broiler chickens: As in paragraph (e)(1)(ii) of this section; and for improving pigmentation.	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	046573

(2) Cattle.

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed Type C feed or milk replacer at a rate to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kilogram (kg)) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. May be prepared from dry or liquid Type B feed containing 0.0125 to 0.5 percent decoquinatate. See paragraph (d)(3) of this section.	046573
(ii) 90.9 to 535.7		Cattle (including ruminating and nonruminating calves and veal calves): As in paragraph (e)(2)(i) of this section.	Feed as a top dress at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. May be prepared from dry or liquid Type B feed containing 0.0125 to 0.5 percent decoquinatate. See paragraph (d)(3) of this section.	046573
(iii) 13.6	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: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>E. 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 decoquinatate and 1 gram (g) chlortetracycline per 100 lb body weight (0.5 mg/kg) per 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 decoquinatate and 6,700 to 80,000 g/ton chlortetracycline. When consumed, feed 22.7 mg decoquinatate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food.	046573
(iv) 13.6	Monensin 5 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for improved feed efficiency.	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinatate per 100 lb body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and §558.355(d)(8). Monensin as provided by No. 000986 in §510.600(c) of this chapter.	046573

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(v) 13.6	Monensin 5 to 30 plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for improved feed efficiency; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Actinomyces (Corynebacterium) pyogenes</i> .	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinatate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and § 558.355(d)(8). Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	046573

(3) *Minor species.*

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		<p>1. Young sheep: For the prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i>, <i>E. crandallii</i>, <i>E. parva</i>, and <i>E. bakuensis</i>.</p> <p>2. Young goats: For the prevention of coccidiosis caused by <i>E. christenseni</i> and <i>E. ninakohlyakimovae</i>.</p>	<p>Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food.</p> <p>Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food.</p>	046573
(ii) 90.9 to 535.7		<p>1. Young sheep: As in item 1 of paragraph (e)(3)(i) of this section.</p> <p>2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section.</p>	<p>Feed as a top dress at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food.</p> <p>Feed as a top dress at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food.</p>	046573

Dated: November 25, 2002.

Steven D. Vaughn,

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

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