059130'' and by adding in its place ''059130, and 061690.''

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–25910 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Narasin and Bacitracin Methylene Disalicylate with 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 supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for using approved narasin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds.

EFFECTIVE DATE: September 29, 1998

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of supplemental NADA 140–852 which provides for combining approved Monteban® (45 grams per pound (g/lb) narasin), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate), and 3–Nitro® (45.4, 90, or 227 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C medicated broiler chicken feed containing 54 to 72 g/t narasin, 50 g/t bacitracin methylene disalicylate, and 22.7 to 45.4 g/t roxarsone is used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *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, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The Type C medicated broiler chicken feed containing 54 to 72 g/t narasin, 100 to 200 g/t bacitracin methylene disalicylate, and 22.7 to 45.4 g/t roxarsone is used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *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, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

The supplemental NADA is approved as of July 29, 1998, and the regulations are amended by adding 21 CFR 558.363(a)(6), (d)(1)(viii), and (d)(1)(ix) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in supplemental NADA 140–852 is limited to manufacture in a licensed feed mill.

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 supplemental 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) 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.

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 558.363 is amended by adding paragraphs (a)(6), (d)(1)(viii), and (d)(1)(ix) to read as follows:

§ 558.363 Narasin.

(a) * * *

(6) To 046573: 45 grams per pound with 10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate and 45.4, 90, or 227 grams per pound roxarsone, paragraphs (d)(1)(viii) and (d)(1)(ix) of this section.

* * * * *

(d) * * *

(1) * * *

(viii) *Amount per ton*. Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 50 grams, with roxarsone, 22.7 to 45.4 grams.

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

(B) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(ix) *Amount per ton*. Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 100 to 200 grams, with roxarsone, 22.7 to 45.4 grams.

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

(B) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do

not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–25913 Filed 9–28–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Bacitracin Methylene Disalicylate and Decoquinate

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 bacitracin methylene disalicylate (BMD) and decoquinate Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: September 29, 1998.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–102 that provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD), and Deccox® (6 percent decoquinate) Type A medicated articles to make Type C medicated feeds for broiler chickens containing 4 to 50 grams per ton (g/t) BMD and 27.2 g/t decoquinate. The Type C medicated broiler feed is used for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of August 3, 1998, and the regulations in 21 CFR 558.76(d)(3) and the table in 21 CFR 558.195(d) 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.

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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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 by adding paragraph (d)(3)(xviii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xviii) Decoquinate as in § 558.195.

3. Section 558.195 is amended in the table in paragraph (d) by adding an entry under ''27.2(0.003 pct)'' before the entry for ''Bacitracin 10 to 50'' to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
27.2 (0.003 pct)				
*	*	* *	* *	*
	Bacitracin 4 to 50	Broiler chickens; for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed continuously as sole ration; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
*	*	* *	* *	*