of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1193 is amended by revising paragraphs (b) and (d)(2) to read as follows:

§ 524.1193 Ivermectin pour-on.

* * * * *

(b) *Sponsors.* (1) See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) See No. 059130 for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

* * * * *

(d) * * *

(2) *Indications for use.* (i) For cattle: It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia* spp., *Oesophagostomum radiatum;* (adults) *O. venulosum, Strongyloides papillosus, Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus;* cattle grubs (parasitic stages) *Hypoderma bovis, H. lineatum;* mites *Chorioptes bovis, Sarcoptes scabei* var. *bovis;* lice *Linognathus vituli, Haematopinus eurysternus, Damalina bovis, Solenoptes capillatus;* horn flies *Haematobia irritans.*

(ii) For cattle: It is also used to control infections of gastrointestinal roundworms *O. ostertagi, O. radiatum, H. placei, T. axei, Cooperia punctata,* and *C. oncophora* for 14 days after treatment.

* * * * *

Dated: August 3, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–22226 Filed 8–18–98; 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; Bacitracin Methylene Disalicylate and Chlortetracycline

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 (BMD) and chlortetracycline (CTC) Type A medicated articles to make Type B medicated feeds used to make Type C medicated swine feeds.

EFFECTIVE DATE: August 19, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1652.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 141–059 that provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD) and CTC® (50, 65, or 70 g/lb CTC) Type A medicated articles to make Type B medicated feed. The Type B medicated feed containing 1 to 3 g/lb BMD and 40 g/lb CTC is used to make Type C medicated swine feed containing 10 to 30 g per ton (g/t) BMD and 400 g/t CTC. The Type C medicated swine feeds are used for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, and bacterial pneumonia caused by *Pasteurella multocida* susceptible to CTC, and for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of June 24, 1998, and the regulations are amended in the table in 21 CFR 558.76(d)(1) 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.

The agency has determined under 21 CFR 25.33(a)(3) 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 in the table in paragraph (d)(1) by revising entry (iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	*	* *	*
(iv) 10 to 30	.....	Swine: for increased rate of weight gain and improved feed efficiency.	For growing and finishing swine.	000004 and 046573

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed for not more than 14 days to provide 10 milligrams of chlortetracycline per pound of body weight per day; as chlortetracycline provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter. Type C feed may be prepared from Type B feed containing 1 to 3 grams per pound BMD with 400 grams per pound CTC, to 046573 in § 510.600(c).	000004 and 046573
* *	*	*	* *	*

* * * * *

Dated: August 1, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–22227 Filed 8–18–98; 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; Bambermycins

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 Hoechst Roussel Vet. The supplement provides revised limitations for using bambermycins Type A medicated articles to make a bambermycins Type B and Type C medicated feeds for feedlot cattle and for pasture cattle, including dairy and beef replacement heifers.

EFFECTIVE DATE: August 19, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 141–034 that provides for revised limitations for using 10-grams-per-pound Gainpro® (bambermycins) Type A medicated articles to make Type B and Type C medicated feeds for feedlot cattle and for pasture cattle, including dairy and beef replacement heifers. The Type C medicated feeds are fed to provide 10 to 20 milligrams bambermycins per head per day to feedlot cattle for increased rate of weight gain and improved feed efficiency and to pasture cattle for increased rate of weight gain. The supplement is approved as of June 29, 1998, and the regulations are amended in § 558.95(d)(4) to reflect the approval by deleting the statement ''Not for use in animals intended for breeding'', and amending the phrase ''slaughter, stocker, and feeder'' to read ''slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers.''

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning June 29, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the use of bambermycins Type C medicated feeds for dairy and beef replacement heifers.

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.

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.

§ 558.95 [Amended]

2. Section 558.95 *Bambermycins* is amended in paragraphs (d)(4)(i)(*b*), (d)(4)(ii)(*b*), (d)(4)(iii)(*d*), and (d)(4)(iv)(*c*) by removing the statement ''Not for use in animals intended for breeding.'' and in paragraphs (d)(4)(ii)(*b*), (d)(4)(iii), and (d)(4)(iv), by removing the phrase ''(slaughter, stocker, and feeder)'' and by adding in its place the phrase ''(slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers).''