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 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 524.802 is added to read as follows:

§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.

(a) *Specifications*. Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—Dogs*—(1) *Amount*. 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

Dated: October 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–28520 Filed 11–6–00; 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; Decoquinate 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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved decoquinate and chlortetracycline (CTC) Type A medicated articles to make two-way combination Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle used for prevention of coccidiosis, treatment of bacterial enteritis, and treatment of bacterial pneumonia.

DATES: This rule is effective November 7, 2000.

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.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–147 that provides for use of Deccox® (27.2 grams per pound g/lb) and ChlorMax™ (50, 65, or 70 g/lb CTC) Type A medicated articles to make combination drug Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle. The combination Type C feeds are for prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for treatment of bacterial enteritis caused by *Escherichia coli*, and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to CTC. The NADA is approved as of September 29, 2000, and the regulations are amended in the table in 21 CFR 558.195(d) to reflect the approval. The basis of 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)(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 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 558.195 is amended in the table in paragraph (d) by adding an entry following the indication for ''Cattle'' at the 13.6 to 27.2 grams per ton decoquinate dose level and before the entry for ''Cattle'' at the 13.6 to 535.7 grams per ton dose level, to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
	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: prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for treatment of bacterial enteritis caused by *Escherichia coli*, and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Feed Type C feed to provide 22.7 mg decoquinate and 1 g chlortetracycline/100 lb body weight (0.5 mg/kg)/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 decoquinate and 6,700 to 80,000 g/ton chlortetracycline. When consumed, feed 22.7 mg decoquinate/100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food.	046573
*	*	* *	* *	*

Dated: October 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–28524 Filed 11–6–00; 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; Pyrantel Tartrate

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 an abbreviated new animal drug application (ANADA) filed by Farnam Companies, Inc. The ANADA provides for use of pyrantel tartrate in horse feed for the prevention and control of various species of internal parasites.

DATES: This rule is effective November 7, 2000.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928, is sponsor of ANADA 200–282 that provides for use of CONTINUEX™ (pyrantel tartrate) Daily Dewormer. The ANADA provides for use of pyrantel tartrate in horse feed for the prevention and control of various species of internal parasites. The ANADA is approved as a generic copy of Pfizer Inc.'s NADA 140–819 for STRONGID® 48. ANADA 200–282 is approved as of September 26, 2000, and the regulations are amended in 21 CFR 558.485 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)(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 558.485 is amended by adding paragraph (a)(29) to read as follows:

§ 558.485 Pyrantel tartrate.

(a) * * *

(29) To 017135: 48 grams per pound, paragraph (e)(2) of this section.

* * * * *

Dated: October 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–28523 Filed 11–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600 and 606

[Docket No. 97N–0242]

Biological Products: Reporting of Biological Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation requiring licensed