Cylicocyclus spp., *Cylicodontophorus* spp., (*Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); large-mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and forth-stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

Approval of ANADA 200–202 for Phoenix Scientific, Inc.'s, ivermectin oral liquid is as a generic copy of Merial Ltd.'s, NADA 140–439 Eqvalan ® (ivermectin) liquid for horses. The ANADA is approved as of June 5, 1998, and the regulations are amended in 21 CFR 520.1195(b) 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)(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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1195 [Amended]

2. Section 520.1195 *Ivermectin liquid* is amended in paragraph (b) by removing ''No. 050604'' and adding in its place ''Nos. 050604 and 059130''.

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19028 Filed 7–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Bacitracin Methylene Disalicylate Soluble

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 soluble bacitracin methylene disalicylate (BMD) powder to make a medicated drinking water for growing quail for prevention of ulcerative enteritis.

EFFECTIVE DATE: July 17, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 65–470 that provides for use of BMD® Soluble (BMD soluble powder) to make a medicated drinking water for growing quail containing the equivalent of 400 milligrams of bacitracin per gallon used for prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to BMD. The supplemental NADA is approved as of May 27, 1998, and the regulations in 21 CFR 520.154a 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.

The agency has determined under 21 CFR 25.33(d)(4) 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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.154a is amended in paragraph (a) by removing the phrase ''paragraph (d)(3)'' and by adding in its place the phrase ''paragraphs (d)(3) and (d)(4)'' and by adding paragraph (d)(4) to read as follows:

§ 520.154a Soluble bacitracin methylene disalicylate.

* * * * *

(d) * * *

(4) *Growing quail*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19026 Filed 7–16–98; 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, Decoquinate, and Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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