The Commission is also amending Rule 4.10(e) of its Rules, 16 C.F.R. 4.10(e), which provides that other materials that are designated confidential by their submitters may not be disclosed, except as provided therein, unless the Commission: (1) determines that they are neither trade secrets nor confidential commercial information; and (2) provides ten days' pre-disclosure notice to the submitter. These provisions implement and expand upon protections in sections 6(f) and 21 of the FTC Act, 15 U.S.C. 46(f), 57b–2. The amendments adopted herein conform the Commission's rules to its authority and obligations under agreements entered pursuant to the International Antitrust Enforcement Assistance Act (''IAEAA''), 15 U.S.C 6201 *et. seq.*

The IAEAA authorizes the Commission and the Department of Justice (''the agencies'') to enter into mutual assistance agreements with foreign antitrust authorities for the purpose of providing reciprocal assistance in antitrust investigations. In accordance with the IAEAA's terms, 15 U.S.C. 6206, the agencies have published for comment the first proposed IAEAA agreement.[1]

Pursuant to requests under IAEAA agreements, the agencies may collect information on behalf of foreign antitrust authorities. 15 U.S.C. 6202. The agencies may also share information with those authorities, including both information collected at their behest and certain information already in the agencies' files. As reflected in these amendments, the IAEAA expressly authorizes disclosures of materials notwithstanding sections 6(f) and 21 of the FTC Act. 15 U.S.C. 6205.

The amendments adopted herein will reconcile the Commission's rules with the agency's obligations to provide assistance under IAEAA agreements. Because failure to make these amendments could impair the Commission's ability to meet its obligations, the amendments are exempt from notice and comment under the Administrative Procedure Act by virtue of the foreign affairs exemption to the Act. 5 U.S.C. 553(a)(1). They are also exempt from the notice and comment requirements of the APA and the Commission's rules by virtue of the good cause exemptions in 5 U.S.C. 553(b)(3) and 16 CFR 1.26(b), respectively. Except for non-substantive stylistic changes, the amendments merely implement agreements that are themselves subject to public comment, and comment on the amendments is therefore unnecessary.[2]

This action does not entail a collection of information for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* It is not subject to the requirements of the Regulatory Flexibility Act because it concerns a foreign affairs function of the United States. *See* 5 U.S.C. 601(2), Section 1(a)(2) of E.O. 12291, 46 FR 13193 (1981).

List of Subjects in 16 CFR Part 4

Administrative practice and procedure, Freedom of Information Act, Privacy Act, Sunshine Act.

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, Chapter 1, Subchapter A of the Code of Federal Regulations, as follows:

PART 4—MISCELLANEOUS RULES

1. The authority citation for Part 4 continues to read as follows:

Authority: Sec. 6, 38 Stat. 721; 15 U.S.C. 46.

2. Amend § 4.10 by revising paragraphs (d) and (e) to read as follows:

§ 4.10 Nonpublic material.

* * * * *

(d) Except as provided in paragraphs (f) or (g) of this section, in § 4.11(b), (c), or (d), or as contemplated by agreements under the International Antitrust Enforcement Assistance Act (15 U.S.C. 6201 *et seq.*), no material that is marked or otherwise identified as confidential and that is within the scope of § 4.10(a)(8), and no material within the scope of § 4.10(a)(9) that is not otherwise public, will be made available, without the consent of the person who produced the material, to any individual other than a duly authorized officer or employee of the Commission or a consultant or contractor retained by the Commission who has agreed in writing not to disclose the information. All other Commission records may be made available to a requester under the procedures set forth in § 4.11 or may be disclosed by the Commission except where prohibited by law.

(e) Except as provided in paragraphs (f) or (g) of this section, in § 4.11(b), (c), or (d), or as contemplated by agreements under the International Antitrust Enforcement Assistance Act (15 U.S.C. 6201 *et seq.*), material not within the scope of § 4.10(a)(8) or § 4.10(a)(9) that is received by the Commission and is marked or otherwise identified as confidential may be disclosed only if it is determined that the material is not within the scope of § 4.10(a)(2), and the submitter is provided at least ten days' notice of the intent to disclose the material.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–19213 Filed 7–16–98; 8:45 am]

BILLING CODE 6750–01–P

[1] ''Request for Comments on Proposed Agreement Between the Government of the United States of America and the Government of Australia on Mutual Antitrust Enforcement Assistance,'' 62 FR 20022 (Apr. 24, 1997) (comment period closed June 9, 1997).

[2] See *International Brotherhood of Teamsters* v. *Peña*, 17 F.3d 1478, 1486 (D.C. Cir. 1994) (APA foreign affairs exemption and good cause exception of agency rule); *WBEN* v. *United States*, 396 F.2d 601, 616 (2d Cir. 1968) (APA foreign affairs exemption).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 Phoenix Scientific, Inc. The ANADA provides for veterinary prescription use of ivermectin oral liquid in horses to treat and control parasites and parasitic conditions.

EFFECTIVE DATE: July 17, 1998.

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: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–202 that provides for veterinary prescription use of Phoenectin™ Liquid (10 milligram per milliliter (mg/mL) ivermectin oral liquid) for horses for the treatment and control of infections of large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*S. vulgaris*), (adult and migrating tissue stages) (*S. endentatus*), (adult) (*Triodontophorus* spp.); small strongyles, including those resistant to some benzimidizole class compounds (adults and fourth-stage larvae) (*Cyathostomum* spp.,

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