supplement to ANADA 200–292 for IVERSOL (ivermectin) Liquid for Horses for the oral treatment and control of various species of internal parasites or parasitic conditions. The supplement provides for revisions to label indications and to the food safety warning. The supplemental ANADA is approved as of May 30, 2006, and 21 CFR 520.1195 is amended to reflect the approval.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 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. In § 520.1195, in paragraph (b)(1) remove ''No. 050604'' and add in its place ''Nos. 050604 and 054925''; and in paragraph (b)(2) remove ''054925, 058829,'' and add in its place ''058829''.

Dated: June 22, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–10444 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 Vétoquinol NA, Inc. The ANADA provides for use of oxytetracycline soluble powder to prepare medicated drinking water for the treatment of various bacterial diseases of livestock.

DATES: This rule is effective July 5, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Vétoquinol NA, Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J5T 3S5, filed a supplement to ANADA 200–305 that provides for use of Oxytetracycline HCl Soluble Powder to prepare medicated drinking water for the treatment of various bacterial diseases of livestock. Vétoquinol NA, Inc.'s Oxytetracycline HCl Soluble Powder is approved as a generic copy of Alpharma, Inc.'s OXY–TET (oxytetracycline hydrochloride) Soluble approved under NADA 130–435. The ANADA is approved as of June 2, 2006, and the regulations are amended in 21 CFR 520.1660d 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 21 CFR 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 Division of Dockets Management (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 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.

§ 520.1660d [Amended]

■ 2. Amend § 520.1660d as follows:
■ a. Revise the section heading;
■ b. In paragraphs (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), (d)(1)(ii)(C)(*3*), and (d)(1)(iii)(C), remove ''and 061133'' and add in its place ''059320, and 061133''; and
■ c. Add paragraphs (a)(10) and (b)(8).

The revisions read as follows:

§ 520.1660d Oxytetracycline powder.

(a) * * *

(10) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.74 oz; pails: 5 lb).

(b) * * *

(8) No. 059320 for use of OTC concentration in paragraph (a)(10) of this section in chickens, turkeys, and swine as in paragraph (d) of this section.

* * * * *

Dated: June 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–10445 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Griseofulvin

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 (ANADA) filed by IVX Animal Health, Inc. The ANADA provides for veterinary prescription use of griseofulvin powder orally as a systemic antifungal agent in horses.

DATES: This rule is effective July 5, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200–391 that provides for veterinary prescription use of Griseofulvin Powder Microsize, orally as a systemic antifungal agent in horses. IVX Animal Health's Griseofulvin Powder Microsize, is approved as a generic copy of Schering-Plough Animal Health Corp.'s FULVICIN–U/F (griseofulvin) Powder approved under NADA 39–792. The ANADA is approved as of June 1, 2006, and the regulations are amended in 21 CFR 520.1100 to reflect the approval and a current format. 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 21 CFR 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 Division of Dockets Management (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 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. Amend § 520.1100 as follows:

■ a. Revise paragraphs (a), (b), (c), and (d)(1);

■ b. Remove paragraphs (d)(2) and (d)(3)(iii); and

■ c. Redesignate paragraphs (d)(3) introductory text, (d)(3)(i), (d)(3)(i)(*a*), (d)(3)(i)(*b*), and (d)(3)(ii) as paragraphs (d)(2) introductory text, (d)(2)(i), (d)(2)(i)(A), (d)(2)(i)(B), and (d)(2)(ii).

The revisions read as follows:

§ 520.1100 Griseofulvin.

(a) *Specifications*—(1) The powder complies with U.S.P. for griseofulvin, microsize.

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 059130 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount and indications for use*—(A) For equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of this section daily for not less than 10 days as follows: adults, 1 bolus; yearlings, one-half to 1 bolus; and foals, one-half bolus.

(ii) *Limitations.* Not for use in horses intended for food.

* * * * *

Dated: June 23, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–10406 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Copper Naphthenate Solution

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 Farnam Companies, Inc. The supplemental NADA provides for a revised food safety warning on labeling for copper naphthenate topical solution for horse and pony hooves.

DATES: This rule is effective July 5, 2006.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928, filed a supplement to NADA 100–616 for THRUSH-XX (copper naphthenate), a solution approved for topical use on horse and pony hooves as an aid in treating thrush. The supplemental NADA provides for a revised food safety warning on the labeling. The supplemental NADA is approved as of May 30, 2006, and the regulations are amended in 21 CFR 524.463 to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(d)(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.

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 524

Animal drugs.