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.