DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Cyclosporine

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 Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of cyclosporine by oral capsule for the control of atopic dermatitis in dogs.

DATES: This rule is effective September 19, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–218 that provides for the veterinary prescription use of ATOPICA (cyclosporine) Capsules for the control of atopic dermatitis in dogs weighing at least 4 pounds body weight. The NADA is approved as of August 15, 2003, and part 520 (21 CFR part 520) is amended by adding new § 520.522 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning August 15, 2003.

The agency has determined under 21 CFR 25.33(d)(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. Section 520.522 is added to read as follows:

§ 520.522 Cyclosporine.

(a) *Specifications.* Each capsule contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 5 mg per kilogram of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(2) *Indications for use.* For the control of atopic dermatitis in dogs weighing at least 4 pounds body weight.

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

Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–23944 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 hybrid new animal drug application (NADA) filed by Norbrook Laboratories, Ltd. The NADA provides for the prescription and over-the-counter use of a 300 milligram per milliliter (mg/mL) oxytetracycline injectable solution for the treatment of various bacterial diseases of cattle and swine, and for the control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD).

DATES: This rule is effective September 19, 2003.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry, BT35 6JP, Northern Ireland, filed NADA 141–143, a hybrid application that provides for veterinary prescription use of TETRADURE 300 (oxytetracycline) Injection and over-the-counter use of Oxytetracycline Injection 300 mg/mL for the treatment of various bacterial diseases of cattle and swine. Norbrook Laboratories' TETRADURE 300 Injection and Oxytetracycline Injection 300 mg/mL are approved as generic copies of Pfizer's LIQUAMYCIN LA–200, approved under NADA 113–232. TETRADURE 300 Injection is also indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*. The application is approved as of July 25, 2003, and the regulations in part 522 (21 CFR part 522) are amended to reflect the approval by revising § 522.1660 and by adding § 522.1660b. The basis of approval is discussed in the freedom of information summary.

NADA 141–143 is a hybrid application as defined in the Center for Veterinary Medicine's Seventh Generic Animal Drug Policy Letter, dated March