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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1662a is amended by revising paragraph (h)(2) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(h) * * *

(2) *Sponsors.* See 054273 in § 510.600(c) of this chapter for use of 50 and 100 milligrams/milliliter solution, and see No. 057319 in § 510.600(c) for use of 100 milligrams/milliliter solution.

* * * * *

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23250 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Cyclosporine Ophthalmic Ointment

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 Schering-Plough Animal Health Corp. The NADA provides for use of cyclosporine ophthalmic ointment for treatment of chronic keratoconjunctivitis sicca in dogs.

EFFECTIVE DATE: October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., P.O. Box 529, Galloping Hill Rd., Kenilworth, NJ 07033, filed NADA 141–052, which provides for use of Optimmune® (0.2 percent cyclosporine, USP) Ophthalmic Ointment for treatment of chronic keratoconjunctivitis sicca in dogs. The drug product is available on a prescription basis. The NADA is approved as of August 2, 1995, and the regulations are amended in part 524 (21 CFR part 524) by adding new § 524.575 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 2, 1995, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 524.575 is added to read as follows:

§ 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a 1/4-inch strip of ointment to the affected eye(s) every 12 hours.

(2) *Indications for use.* For treatment of chronic keratoconjunctivitis sicca in dogs.

(3) *Limitations.* Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23247 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 505

[Department of the Army Reg. 340-21]

Department of the Army Privacy Program

AGENCY: Department of the Army, DoD.

ACTION: Final Rule.