Authority: 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 No. 000010 in § 510.600(c) of this chapter for use of 50 and 100 milligrams per milliliter solution; and Nos. 055529 and 059130 in § 510.600(c) for use of 100 milligrams per milliliter solution.

* * * * *

Dated: July 17, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–14950 Filed 8–1–07; 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; Emodepside and Praziquantel

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 Bayer HealthCare LLC. The NADA provides for veterinary prescription use of an emodepside and praziquantel topical solution on cats for the treatment and control of infections by several internal parasites.

DATES: This rule is effective August 2, 2007.

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: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141–275 that provides for veterinary prescription use of PROFENDER (emodepside and praziquantel) Topical Solution for the treatment and control of infections by several internal parasites of cats. The NADA is approved as of June 29, 2007, and the regulations are amended in 21 CFR part 524 by adding § 524.775 to reflect the approval.

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 on the date of the approval.

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 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: 21 U.S.C. 360b.

■ 2. Add § 524.775 to read as follows:

§ 524.775 Emodepside and praziquantel.

(a) *Specifications.* Each milliliter of solution contains 21.4 milligrams (mg) emodepside and 85.7 mg praziquantel.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* The recommended minimum dose is 1.36 mg/pound (lb) (3 mg/kilogram (kg)) emodepside and 5.45 mg/lb (12 mg/kg) praziquantel applied as a single topical dose.

(2) *Indications for use.* For the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).

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

Dated: July 17, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–14945 Filed 8–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 26, and 602

[TD 9348]

RIN 1545–BC50

Qualified Severance of a Trust for Generation-Skipping Transfer (GST) Tax Purposes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations providing guidance regarding the qualified severance of a trust for generation-skipping transfer (GST) tax purposes under section 2642(a)(3) of the Internal Revenue Code (Code), which was added to the Code by the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA). The regulations will affect trusts that are subject to the GST tax.

DATES: *Effective Date:* The regulations are effective August 2, 2007.

Applicability Date: For dates of applicability, see § 26.2642–6(k)(1) and § 26.2642–6(k)(2).

FOR FURTHER INFORMATION CONTACT: Mayer R. Samuels, (202) 622–3090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1902.

The collection of information in these final regulations is in § 26.2642–6(e). This information is requested by the IRS to identify whether a trust is exempt from the GST tax. This information is