### V. Regulatory Flexibility Act Certification

83. The Regulatory Flexibility Act of 1980 (RFA)[67] requires agencies to prepare certain statements, descriptions and analyses of proposed rules that will have a significant economic impact on a substantial number of small entities.[68] However, the RFA does not define ''significant'' or ''substantial.'' Instead, the RFA leaves it up to an agency to determine the effect of its regulations on small entities.

84. Most filing companies regulated by the Commission do not fall within the RFA's definition of small entity.[69] Further, as noted above, the Supplemental Policy Statement does not propose any changes to the Commission's current regulations under section 203; therefore there is no change in how the Commission's regulations under section 203 affect small entities. Therefore, the Commission certifies that the Supplemental Policy Statement will not have a significant economic impact on a substantial number of small entities. As a result, no regulatory flexibility analysis is required.

### VI. Document Availability

85. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington DC 20426.

86. From the Commission's Home Page on the Internet, this information is available in the Commission's document management system, eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number (excluding the last three digits of the docket number), in the docket number field.

87. User assistance is available for eLibrary and the Commission's website during normal business hours. For assistance, please contact FERC Online Support at (202) 502–6652 (toll-free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

### VII. Effective Date and Congressional Notification

88. This Supplemental Policy Statement is effective July 20, 2007. The Commission has determined that, consistent with the discussion above with regard to information collection and the RFA, this policy statement also is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission will submit this Supplemental Policy Statement to both houses of Congress and to the General Accounting Office.

### List of Subjects in 18 CFR Part 33

Electric utilities, Reporting and recordkeeping requirements, Securities.

By the Commission.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. E7–14956 Filed 8–1–07; 8:45 am]

**BILLING CODE 6717–01–P**

[67] 5 U.S.C. 601–12.

[68] The RFA definition of ''small entity'' refers to the definition provided in the Small Business Act, which defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. 15 U.S.C. 632. The Small Business Size Standards component of the North American Industry Classification System defines a small electric utility as one that, including its affiliates, is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and whose total electric output for the preceding fiscal year did not exceed 4 million MWh. 13 CFR 121.201.

[69] 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632. Section 3 of the Small Business Act defines a ''small-business concern'' as a business which is independently owned and operated and which is not dominant in its field of operation.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 522

## Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride 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 an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for use of an oxytetracycline hydrochloride injectable solution in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for the treatment of various bacterial diseases.

**DATES:** This rule is effective August 2, 2007.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200–452 that provides for use of OXYTET 10 (oxytetracycline hydrochloride) Injection in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for the treatment of various bacterial diseases. Norbrook Laboratories, Ltd.'s OXYTET 10 Injection is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s, MEDAMYCIN Injectable approved under NADA 108–963. The ANADA is approved as of June 27, 2007, and the regulations are amended in 21 CFR 522.1662a 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.

FDA 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 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:** 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