submission form type changes. It is highly recommended that filers download, install, and use the new EDGARLink software and submission templates to ensure that submissions will be processed successfully. Previous versions of the templates may not work properly. Notice of the update has previously been provided on the EDGAR Filing Web site and on the Commission's public Web site. The discrete updates are reflected on the EDGAR Filing Web site and in the updated Filer Manual Volume II.

Along with adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1580, Washington, DC 20549. We will post electronic format copies on the Commission's Web site; the address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml.* You may also obtain copies from Thomson Financial, the paper document contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).[5] It follows that the requirements of the Regulatory Flexibility Act[6] do not apply.

The effective date for the updated Filer Manual and the rule amendments is November 7, 2005. In accordance with the APA,[7] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 9.2 is scheduled to become available on November 7, 2005. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the scheduled system upgrade.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[8] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[9] Section 20 of the Public Utility Holding Company Act of 1935,[10] Section 319 of the Trust Indenture Act of 1939,[11] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[12]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

■ In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: ''General Information,'' Version 1 (September 2005). The requirements for filing on EDGAR are set forth in the EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 2 (November 2005). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: ''N–SAR Supplement,'' Version 1 (September 2005). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1580, Washington, DC 20549 or by calling Thomson Financial at (800) 638–8241. Electronic copies are available on the Commission's Web site. The address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml.* You can also photocopy the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Dated: November 1, 2005.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–22085 Filed 11–4–05; 8:45 am]

BILLING CODE 8010–01–P

[5] 5 U.S.C. 553(b).

[6] 5 U.S.C. 601–612.

[7] 5 U.S.C. 553(d)(3).

[8] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[9] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78o, 78w, and 78*ll.*

[10] 15 U.S.C. 79t.

[11] 15 U.S.C. 77sss.

[12] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tetracycline 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 Cross Vetpharm Group Ltd. The ANADA provides for use of tetracycline hydrochloride soluble powder in the drinking water of calves, swine, chickens, and turkeys for the treatment and control of various bacterial infections.

DATES: This rule is effective November 7, 2005.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9808, e-mail: *john.harshman@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–374 that provides for use of TETRAMED 324 HCA (tetracycline hydrochloride), a soluble powder used in the drinking water of calves, swine, chickens, and turkeys for the treatment and control of various bacterial infections. Cross Vetpharm Group Ltd.'s

TETRAMED 324 HCA is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s TETRASURE 324 (tetracycline hydrochloride), approved under NADA 65–496. The ANADA is approved as of September 13, 2005, and the regulations are amended in § 520.2345d (21 CFR 520.2345d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has noticed that certain withdrawal times for other approved generic products are not reflected in § 520.2345d. At this time, the regulations are amended to reflect the correct withdrawal times in calves and swine. This action is being taken to improve the accuracy of the regulations.

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 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 520.2345d is amended by revising the section heading, paragraphs (a) through (c), the heading and introductory text of paragraph (d), and paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

(a) *Specifications.* Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors.* See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 000069: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) Nos. 000010 and 046573: 102.4 and 324 grams per pound as in paragraph (d) of this section.

(3) No. 053501: 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) No. 046573: 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(5) Nos. 051259, 057561, 059130, and 061623: 324 grams per pound as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use.* It is administered in drinking water as follows:

(1) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for sponsor No. 053501 and within 5 days of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor No. 053501 and within 4 days of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

* * * * *

Dated: October 19, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–21889 Filed 11–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2005P–0366]

Medical Devices; General and Plastic Surgery Devices; Classification of the Low Energy Ultrasound Wound Cleaner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the low energy ultrasound wound cleaner into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the class II device.

DATES: This rule is effective December 7, 2005. The reclassification was effective June 25, 2004.

FOR FURTHER INFORMATION CONTACT: David B. Berkowitz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 152.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified