Branch (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)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning April 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 the 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 520.1350 is added to read as follows:

**§ 520.1350 Meloxicam.**

(a) *Specifications.* Each milliliter of suspension contains 0.5 or 1.5 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally 0.2 mg/kilogram (kg) body weight on the first day of treatment. For all treatment after day 1, administer 0.1 mg/kg body weight once daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

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

Dated: July 8, 2003.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 03–18354 Filed 7–18–03; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### New Animal Drugs; Oxytetracycline 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 a supplemental abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The supplemental ANADA provides for a new pouch size of oxytetracycline hydrochloride soluble powder used to make medicated drinking water for swine.

**DATES:** This rule is effective July 21, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

**SUPPLEMENTARY INFORMATION:** Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200–144 that provides for a new pouch size of TETROXY (oxytetracycline HCl) Soluble Powder used to make medicated drinking water for administration to swine. The supplemental application is approved as of April 21, 2003, and the regulations are amended in 21 CFR 520.1660d 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.

The agency 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.

**§ 520.1660d [Amended]**

■ 2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (a)(9) by removing ''and 19.75 oz'' and by adding in its place '', 19.75 oz, and 3.91 lb''.

Dated: July 8, 2003.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 03–18351 Filed 7–18–03; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 522

### Injectable or Implantable Dosage Form New Animal Drugs; Euthanasia Solution; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. and a supplemental abbreviated new animal drug application (ANADA) filed by Delmarva Laboratories, Inc. The supplemental applications add environmental warning statements to product labeling.

**DATES:** This rule is effective July 21, 2003.

**FOR FURTHER INFORMATION CONTACT:** Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish

Pl., Rockville, MD 20855, 301–827–0159; e-mail: *msharar@cvm.fda.gov.*

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 119–807 for BEUTHANASIA–D–SPECIAL Solution and Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113, filed a supplement to ANADA 200–071 for EUTHASOL Solution. The supplemental applications provide for the addition of environmental warning statements to product labeling. The supplemental applications are approved as of May 2, 2003, and the regulations are amended in § 522.900 (21 CFR 522.900) to reflect the approvals.

In addition, the agency has found that the regulations do not reflect the 1996 change of sponsorship (61 FR 5505, February 13, 1996) of NADA 128–967 for REPOSE Euthanasia Solution from Syntex Animal Health, Division of Syntex Agri-business, Inc., to Fort Dodge Animal Health, Division of Wyeth. At this time, § 522.900 is revised to reflect that change of sponsorship and a current format.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are 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 the 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 522.900 is revised to read as follows:

**§ 522.900 Euthanasia solution.**

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061 and 059079 for use of product described in paragraph (a)(1) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements:

''ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.''

(d) *Conditions of use in dogs*—(1) *Indications for use.* For humane, painless, and rapid euthanasia.

(2) *Amount.* One mL per 10 pounds of body weight.

(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 7, 2003.

**Clifford Johnson,**

*Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.*

[FR Doc. 03–18352 Filed 7–18–03; 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; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**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 Phoenix Scientific, Inc. The ANADA provides for the use of gentamicin sulfate, betamethasone valerate, and clotrimazole ointment for the treatment of canine otitis externa.

**DATES:** This rule is effective July 21, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–287 that provides for use of gentamicin sulfate, United States Pharmacopeia (USP); betamethasone valerate, USP; and clotrimazole, USP; (GBC) Ointment for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin. Phoenix Scientific's GBC Ointment is approved as a generic copy of Schering-Plough Animal Health's OTOMAX Ointment approved under NADA 140–896. The ANADA is approved as of March 28, 2003, and the regulations are amended in § 524.1044g (21 CFR 524.1044g) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 524.1044g is being amended to reflect the supplemental approval of several additional container sizes under NADA 140–896 and ANADA 200–229, which were not codified, and to reflect a current format.

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.

The agency 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 524**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner