| Firm name and address | Drug labeler code |
|---|---|
| * * * | * * * * |
| Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia | 064288 |
| * * * | * * * * |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * | * * * * |
| 064288 | Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia |
| * * * | * * * * |

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

**Authority:** 21 U.S.C. 360b.

4. Section 522.533 is added to read as follows:

### § 522.533 Deslorelin acetate.

(a) *Specifications.* Each implant contains 2.1 milligrams deslorelin acetate.

(b) *Sponsor.* See 064288 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount.* One implant per mare.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimiters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations.* Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: August 3, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98–22224 Filed 8–18–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form 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 new animal drug application (NADA) filed by Pfizer Inc. The supplemental NADA provides for added package sizes of oxytetracycline hydrochloride (OTC HCl) soluble powder to be used in the drinking water of poultry for control of specific diseases, in the drinking water of cattle, swine, and sheep for control and treatment of specific diseases, and for control of specific diseases of bees.

**EFFECTIVE DATE:** August 19, 1998.

**FOR FURTHER INFORMATION CONTACT:** William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

**SUPPLEMENTARY INFORMATION:** Pfizer Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 8–622 that provides for use of 2.25 pound jars and 4.5 pound pails of Terramycin–343® (oxytetracycline hydrochloride) soluble powder for making drinking water for poultry for control of specific OTC-susceptible diseases, drinking water for cattle, swine, and sheep for control and treatment of specific OTC-susceptible diseases, and for control of specific OTC–susceptible diseases of bees. The supplemental NADA is approved as of June 19, 1998, and 21 CFR 520.1660d(a)(3) is amended to reflect the approval.

Approval of this supplemental NADA does not require additional safety or effectiveness data. A freedom of information summary as provided under 21 CFR part 20 and 514.11(e)(2)(ii) is not required.

The agency has determined under 21 CFR 25.33(a)(4) 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.

### 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 520.1660d is amended by revising paragraph (a)(3) to read as follows:

**§ 520.1660d Oxytetracycline hydrochloride soluble powder.**

(a) * * *

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

* * * * *

Dated: July 29, 1998.

**Margaret Ann Miller,**

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

[FR Doc. 98–22266 Filed 8–18–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs; Iron Hydrogenated Dextran 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 Phoenix Scientific, Inc. The ANADA provides for intramuscular use of iron hydrogenated dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

**EFFECTIVE DATE:** August 19, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–254 that provides for intramuscular use of iron hydrogenated dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

Approval of Phoenix Scientific, Inc.'s ANADA 200–254 for iron hydrogenated dextran injection is as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 106–772 iron dextran complex injection. The ANADA is approved as of July 14, 1998, and the regulations are amended in § 522.1183(e)(1) (21 CFR 522.1183(e)(1)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.1183(b) provides for the National Academy of Sciences/National Research Council (NAS/NRC) status of the product. With enactment of the Generic Animal Drug and Patent Term Restoration Act of 1996, that paragraph is outdated. Therefore, paragraph (b) is removed and reserved.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of the application may be seen in the Dockets Management 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.

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.

**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.

**§ 522.1183 [Amended]**

2. Section 522.1183 *Iron hydrogenated dextran injection* is amended by removing and reserving paragraph (b), and in paragraph (e)(1) by removing ''Nos. 000010, 017287, and 050604,'' and adding in its place ''Nos. 000010, 017287, 050604, and 059130''.

Dated: July 29, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98–22229 Filed 8–18–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 524

### Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical Solution

**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 Phoenix Scientific, Inc. The ANADA provides for use of ivermectin topical (pour-on) solution on cattle for the treatment and control of worms, grubs, lice, mites, and flies.

**EFFECTIVE DATE:** August 19, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–219 that provides for the topical use of Phoenectin™ Pour-On (5 milligrams of ivermectin per milliliter) for cattle for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites.

Phoenix Scientific, Inc.'s ANADA 200–219 ivermectin topical (pour-on) solution for cattle is approved as a generic copy of Merial, Ltd.'s NADA 140–841 Ivomec® (ivermectin) Pour–On for Cattle. The ANADA is approved as of July 6, 1998, and 21 CFR 524.1193(b) and (d)(2) are amended 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 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, 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.

**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