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 522.84 is added to read as follows:

§ 522.84 Beta-aminopropionitrile fumarate.

(a) *Specifications.* Each vial contains 7.0 milligrams of beta-aminopropionitrile fumarate sterile lyophilized powder which is reconstituted for injection with 10 milliliters of sterile physiologic saline, USP.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 7 milligrams (10 milliliters) intralesionally every other day for 5 treatments beginning about 30 days after initial injury.

(ii) *Indications for use.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing.

(iii) *Limitations.* Single dose container for intralesional injection. Do not use in horses with dermal irritation or open skin lesions in the injection area. Do not administer intraarticularly, into the tendon sheath, or in the presence of concurrent limb fractures. Do not use in breeding animals since the effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: July 29, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–22228 Filed 8–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Deslorelin Acetate

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 Peptech Animal Health Pty, Ltd. The NADA provides for veterinary prescription use of deslorelin acetate implants in horses and ponies for inducing ovulation in estrous mares with an ovarian follicle greater than 30 millimeters (mm) in diameter.

EFFECTIVE DATE: August 19, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia, filed NADA 141–044 that provides for veterinary prescription use of 2.1 milligrams deslorelin acetate (Ovuplant™) implant to induce ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 mm in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment. NADA 144–044 is approved as of June 18, 1998, and the regulations are amended by adding § 522.533 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Peptech Animal Health Pty, Ltd., has not been previously listed in the animal drug regulations as the sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) are amended by adding a new listing to reflect the sponsor.

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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning June 18, 1998, because no active ingredient (including any salt or ester of the active ingredient) has been approved in any other application.

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.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Peptech Animal Health Pty, Ltd.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''064288'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

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: