pleuropneumoniae, Pastureurella multocida, Salmonella choleraesuis, and *Streptococcus suis* Type 2 at 1.36 to 2.27 mg/pound body weight (3 to 5 mg/kilograms). The NADA is approved as of April 26, 1996, and the regulations are amended by adding new 21 CFR 522.314 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 April 26, 1996, because it contains reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.314 is added to read as follows:

§ 522.314 Ceftiofur hydrochloride sterile suspension.

(a) *Specifications.* Each milliliter contains ceftiofur hydrochloride equivalent to 50 milligrams of ceftiofur.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use.* (1) *Swine*—(i) *Amount.* 3 to 5 milligrams per kilogram (1.36 to 2.27 milligrams per pound) of body weight.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus* (*Haemophilus*) *pleuropneumoniae, Pastureurella multocida, Salmonella choleraesuis,* and *Streptococcus suis* Type 2.

(iii) *Limitations.* For intramuscular use only. Treatment should be repeated at 24–hour intervals for a total of 3 consecutive days. Do not use in animals previously found to be hypersensitive to the drug. Use of dosages in excess of those indicated or route of administration other than that recommended may result in illegal residues in tissues. Safety of ceftiofur has not been determined in breeding swine. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated:May 28, 1996

Stephen F. Sundlof

Director,Center for Veterinary Medicine

[FR Doc. 96–14651 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for an approved new animal drug application (NADA) from Syntex Animal Health, Division of Syntex Agri-business, Inc., to Fort Dodge Laboratories, Division of American Home Products.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Syntex Animal Health, Division of Syntex Agri-business, Inc., 3401 Hillview Ave., Palo Alto, CA 94303, has informed FDA that it has transferred the ownership of, and all rights and interests in, the approved NADA 141–043 (Synovex Plus) to Fort Dodge Laboratories, Division of American Home Products Corp., 800 5th St. NW., Fort Dodge, IA 50501. Accordingly, FDA is amending the regulations in 21 CFR part 522.2478 to reflect the change of sponsor.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.2478 [Amended]

2. Section 522.2478 *Trenbolone acetate and estradiol benzoate* is amended in paragraph (a) by removing ''000033'' and adding in its place ''000856''.

Dated: May 22, 1996.

Robert C. Livingston,

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

[FR Doc. 96–14649 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol

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 Roussel-UCLAF, Division Agro-Veterinaire. The supplemental NADA provides for use of an ear implant containing trenbolone acetate and estradiol in pasture steers for increased rate of weight gain.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Roussel-UCLAF, Division Agro-Veterinaire, 163 Ave. Gambetta, 75020 Paris, France, filed supplemental NADA 140–897, which provides for use of an ear implant containing 2 pellets, each pellet containing 20 milligrams (mg) of trenbolone acetate and 4 mg of estradiol. The implant is used in pasture steers (slaughter, stocker, feeder) for increased rate of weight gain. The supplemental NADA is approved as of March 27, 1996, and the regulations are amended in 21 CFR 522.2477 by adding new paragraph (c)(3) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for a 3-year period of marketing exclusivity beginning on March 27, 1996, because new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2477 is amended by adding new paragraph (c)(3) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(c) * * *

(3) *Pasture steers (slaughter, stocker, and feeder steers).* (i) *Amount.* 40 milligrams of trenbolone acetate and 8 milligrams of estradiol (2 pellets, each pellet containing 20 milligrams of trenbolone acetate and 4 milligrams of estradiol) per animal.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only.

Dated: May 17, 1996.

Robert C. Livingston,

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

[FR Doc. 96–14646 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tripelennamine 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 Phoenix Scientific, Inc. The ANADA provides for use of tripelennamine hydrochloride injection in cattle and horses for conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–162 which provides for intravenous and intramuscular use in cattle and intramuscular use in horses of tripelennamine hydrochloride injection for conditions in which antihistaminic therapy is indicated. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–162 for Phoenix's tripelennamine hydrochloride injection is as a generic copy of Solvay's NADA 006–417 for Re-Covr® Injection (tripelennamine hydrochloride). The ANADA is approved as of March 28, 1996, and the regulations are amended by revising § 522.2615(b) (21 CFR 522.2615(b)) to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, due to enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, § 522.2615(d) is outdated and therefore removed.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.2615 [Amended]

2. Section 522.2615 *Tripelennamine hydrochloride injection* is amended in