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

paragraph (b) by removing ''No. 053501'' and adding in its place ''Nos. 053501 and 059130'' and by removing paragraph (d).

Dated: May 28, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14644 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Semduramicin With Bacitracin Methylene Disalicylate and Roxarsone

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 Pfizer, Inc. The NADA provides for using approved single ingredient Type A medicated articles to make combination drug Type C medicated broiler chicken feeds containing semduramicin with bacitracin methylene disalicylate and roxarsone. The Type C medicated feed is used for prevention of coccidiosis and for improved feed efficiency.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1607.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–058, which provides for combining approved Type A medicated articles containing Aviax® (semduramicin sodium) with BMD® (bacitracin methylene disalicylate) and 3–Nitro® (roxarsone) to make combination drug Type C medicated broiler chicken feeds containing 22.7 grams (g) of semduramicin, 10 to 50 g of bacitracin methylene disalicylate, and 45.4 g of roxarsone per ton. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*/*E. miti*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone, and for improved feed efficiency in broiler chickens. The NADA is approved as of June 11, 1996, and the regulations are amended by adding new 21 CFR 558.555(b)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Roxarsone is a Category II drug which, as provided in 21 CFR 558.4, requires an approved medicated feed application (Form FDA 1900) for making a Type C medicated feed. Therefore, making a Type C medicated feed containing semduramicin, bacitracin methylene disalicylate, and roxarsone requires an approved Form FDA 1900.

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, rm. 1–23, 12420 Parklawn Dr., 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 marketing exclusivity beginning June 11, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(ii) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.555 is amended by adding new paragraph (b)(2) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) * * *

(2) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams and roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*/*E. mitis*, *E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone, and for improved feed efficiency.

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis.

Dated: May 28, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14650 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

DEPARTMENT OF TRANSPORTATION

Coast Guard

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AI04

Montgomery GI Bill—Selected Reserve: Miscellaneous

AGENCIES: Department of Defense, Department of Transportation (Coast Guard), and Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends regulations concerning the Montgomery GI Bill—Selected Reserve program. It removes provisions that are obsolete, duplicative, or otherwise unnecessary. It also makes changes for purposes of clarification.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer, Assistant Director for Policy and Program Administration, Education Service, Veterans Benefits Administration, Department of Veterans Affairs, 202–273–7187.

SUPPLEMENTARY INFORMATION: The regulations governing the Montgomery GI Bill—Selected Reserve program are found in 38 CFR, Part 21, Subpart L (see