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).

§ 522.1290 [Amended]

2. Section 522.1290 *Luprostiol sterile solution* is amended in paragraph (b) by removing ''000069'' and adding in its place ''057926''.

Dated: December 5, 1996.

Robert C. Livingston,

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

[FR Doc. 96–32072 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Propofol 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 a new animal drug application (NADA) filed by Mallinckrodt Veterinary, Inc. The NADA provides for intravenous use of propofol injection in dogs as an anesthetic.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Mallinckrodt Veterinary, Inc., 421 East Hawley St., Mundelein, IL 60060, filed NADA 141–070, which provides for intravenous use in dogs of Rapinovet™ Anesthetic Injection (each milliliter contains 10 milligrams of propofol). The drug is used as a single injection to provide general anesthesia for procedures lasting up to 5 minutes, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of November 7, 1996, and the regulations are amended in 21 CFR part 522 by adding new § 522.2005 to reflect the approval. The basis of approval is provided 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, 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)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for a 5-year period of marketing exclusivity beginning November 7, 1996, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

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 § 522.2005 is added to read as follows:

§ 522.2005 Propofol injection.

(a) *Specifications.* The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: December 6, 1996.

Stephen F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 96–32069 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Ceftiofur Sterile Powder for 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 a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for intramuscular use in sheep of a reconstituted solution of ceftiofur sterile powder for treatment of sheep respiratory disease (pneumonia).

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 140–338, which provides for use of Naxcel® Sterile Powder (ceftiofur sodium) in sheep as a 50 milligrams per milliliter reconstituted injectable solution. The product is currently approved for use in cattle, swine, day-old chicks, horses, and dogs. The supplemental NADA is approved as of October 25, 1996, and the regulations are amended in 21 CFR 522.313 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulations are amended in 21 CFR 556.113 to state that a tolerance for ceftiofur residues in edible tissues of sheep is not required.

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, 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 does not qualify for marketing exclusivity because it does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety or human food safety (other than bioequivalence or residue studies) required for 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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 522 and 556 are 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 522.313 is amended by adding new paragraph (d)(7) to read as follows:

§ 522.313 Ceftiofur sterile powder for injection.

* * * * *

(d) * * *

(7) *Sheep*—(i) *Amount.* 0.5 to 1.0 milligram per pound (1.1 to 2.2 milligrams per kilogram) of body weight.

(ii) *Indications for use.* For treatment of sheep respiratory disease (pneumonia) associated with *Pasteurella haemolytica* and/or *P. multocida.*

(iii) *Limitations.* For intramuscular use only. Treatment should be repeated at 24 hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

§ 556.113 [Amended]

4. Section 556.113 *Ceftiofur* is amended by removing ''and poultry'' and by adding in its place ''poultry, and sheep''.

Dated: December 6, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32071 Filed 12–17–96; 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

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. The Type C medicated feed is used for prevention of coccidiosis and for improved feed efficiency.

EFFECTIVE DATE: December 18, 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 141–065, which provides for combining approved Type A medicated articles containing Aviax™ (semduramicin sodium) with BMD® (bacitracin methylene disalicylate) to make combination drug Type C medicated broiler chicken feed containing 22.7 grams (g) of semduramicin and 10 to 50 g of bacitracin methylene disalicylate. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/E. mitis, E. necatrix,* and *E. tenella,* and for improved feed efficiency in broiler chickens. The NADA is approved as of October 18, 1996, and the regulations are amended by revising 21 CFR 558.76(d)(3)(xiv) and by adding 21 CFR 558.555(b)(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 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.