withdrawal time for treated dairy cattle of breeding age is the same as that established for beef cattle in the original NADA 128–620.

Supplemental NADA's 128–620 and 132–872 are approved as of March 28, 1996, and §§ 520.905a and 520.905c are amended to reflect the approvals. Supplemental NADA 137–600 is approved as of (*insert date of publication in the* Federal Register), and § 558.258 is amended to reflect the approval. The basis for the approvals is discussed in the freedom of information summaries.

Approval of NADA 137–600 is for use of fenbendazole Type A medicated article to make Type C medicated feed. Fenbendazole is a Category II drug which, as provided in 21 CFR 558.4, requires an appproved Form FDA 1900 for making a Type C medicated feed. Therefore, use of fenbendazole Type A medicated articles to Type C medicated feeds as in NADA 137–600 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)), summaries of safety and effectiveness data and information submitted to support approval of these applications 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)), these approvals for food-producing animals do not qualify for exclusivity because the supplemental applications do not contain new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals 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 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 520, 556, and 558 are 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.905a [Amended]

2. Section 520.905a *Fenbendazole suspension* is amended in paragraph (d)(2) by revising the paragraph heading to read ''*Beef and dairy cattle*'' and in paragraph (d)(2)(i)(B) by removing the third sentence.

§ 520.905c [Amended]

3. Section 520.905c *Fenbendazole paste* is amended in paragraph (d)(2) by revising the paragraph heading to read ''*Beef and dairy cattle*'' and in paragraph (d)(2)(iii) by removing the third sentence.

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

4. 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).

5. Section 556.275 is amended by adding new paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(c) *Cattle milk*. A safe concentration of 1.67 parts per million is established for total fenbendazole residues. A tolerance of 0.6 part per million is established based on the fenbendazole sulfoxide metabolite (marker residue).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

6. 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).

7. Section 558.258 is amended by revising the introductory text of paragraph (c)(2), by removing the last sentence of paragraph (c)(2)(iii), by revising the introductory text of paragraph (c)(3) , and by removing the fourth sentence of paragraph (c)(3)(iii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(c) * * *

(2) It is used in the feed of beef and dairy cattle as follows:

* * * * *

(3) It is used in free-choice beef and dairy cattle feed as follows:

* * * * *

Dated: May 28, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14645 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride Sterile Suspension

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 The Upjohn Co. The NADA provides for use of ceftiofur hydrochloride sterile suspension for intramuscular injection in swine for treatment and control of certain forms of swine bacterial respiratory disease.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, is sponsor of NADA 140–890, which provides for use of Excenel® Sterile Suspension (ceftiofur hydrochloride equivalent to 50 milligrams (mg) per milliliter ceftiofur). The NADA provides for intramuscular injection in swine 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 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