control of flea populations, the control of adult *A. caninum* (hookworm), and the removal and control of adult *T. canis* and *T. leonina* (roundworm), and *T. vulpis* (whipworm) infections. The NADA is approved as of April 10, 1997, and the regulations are amended in part 520 (21 CFR part 520) by adding new § 520.1446 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.

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 a 3-year period of exclusivity beginning April 10, 1997, because the application contains substantial evidence of the effectiveness of the drugs involved, and studies of animal safety, required for 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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.1446 is added to read as follows:

§ 520.1446 Milbemcyin oxime/lufenuron tablets.

(a) *Specifications*. Tablets containing: 2.3 milligrams milbemycin oxime/46 milligrams lufenuron, 5.75 milligrams/115 milligrams, 11.5 milligrams/230 milligrams, and 23 milligrams/460 milligrams.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 0.5 milligrams of milbemycin and 10 milligrams of lufenuron per kilogram of body weight.

(2) *Indications for use*. For use in dogs, 4 weeks of age and older and 2 pounds body weight or greater, for the prevention of heartworm disease caused by *Dirofilaria immitis*, for the prevention and control of flea populations, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis, Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(3) *Limitations*. Administer tablet(s) once a month, preferably on same date each time. All dogs in a household should be treated to achieve maximum efficacy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 6, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–13823 Filed 5–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Inc. The ANADA provides for the use of trenbolone acetate and estradiol implants for increased rate of weight gain and improved feed efficiency in feedlot steers.

EFFECTIVE DATE: May 27, 1997.

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: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, has filed ANADA 200–221, which provides for the use of trenbolone acetate and estradiol implants for increased rate of weight gain and improved feed efficiency in feedlot steers.

The ANADA is approved as a generic copy of Roussel UCLAF's Revalor® S, NADA 140–897. ANADA 200–221 is approved as of March 20, 1997, and the regulations are amended in 21 CFR 522.2477 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.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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 revising paragraph (a) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

(a) *Sponsor*. See No. 012579 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section. See No. 021641 in § 510.600(c) of this chapter for use as in paragraph (c)(1) of this section.

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Dated: May 6, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–13820 Filed 5–23–97; 8:45 am]

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