Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(g) The actions required by this AD shall be done in accordance with the following PW SBs:

Document No.	Pages	Date
PW4G–100–72–69.	1–10	Aug. 6, 1996.
Total pages: 10.		
PW4G–100–72–81.	1–8	Dec. 18, 1996.
NDIP–883	1–27	Dec. 11, 1996.
NDIP–893	1–9	Dec. 11, 1996.
Total pages: 44.		
PW4G–100–72–92.	1–24	Apr. 24, 1997.
Total pages: 24.		

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–6600, fax (860) 565–4503. Copies may be inspected at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on June 11, 1997.

Issued in Burlington, Massachusetts, on May 15, 1997.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 97–13464 Filed 5–22–97; 9:57 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority by adding a new authority from the Assistant Secretary for Health to the Commissioner of Food and Drugs (the Commissioner) for all the authorities delegated to the Assistant Secretary for Health under the Safe Medical Devices Act of 1990 (the SMDA), as amended. The delegation excludes the authority to submit reports to Congress.

EFFECTIVE DATE: May 27, 1997.

FOR FURTHER INFORMATION CONTACT: Loretta W. Davis, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4809.

SUPPLEMENTARY INFORMATION: On February 10, 1994, the Secretary of Health and Human Services delegated to the Assistant Secretary for Health all of the authorities vested in the Secretary under the SMDA (Pub. L. 101–629), as amended, including any section not amending the Food, Drug, and Cosmetic Act. On February 23, 1994, the Assistant Secretary for Health delegated to the Commissioner all the authorities delegated to the Assistant Secretary for Health under the SMDA, as amended.

FDA is amending 21 CFR 5.10 by adding a new paragraph (a)(38) to reflect the new authority.

Further redelegation of the authority delegated may only be authorized with the Commissioner's approval. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.10 is amended by adding new paragraph (a)(38) to read as follows:

§ 5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.

(a) * * *

(38) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), as amended. The delegation excludes the authority to submit reports to Congress.

* * * * *

Dated: May 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13826 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 520

Oral Dosage Form New Animal Drugs; Milbemycin Oxime/Lufenuron Tablets

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 Novartis Animal Health US, Inc. The NADA provides for use of milbemycin oxime/lufenuron tablets for prevention of heartworm disease caused by *Dirofilaria immitis*, control of adult *Ancylostoma caninum*, the removal and control of adult *Toxocara canis*, *Toxascaris leonina*, and *Trichuris vulpis* infections, and the prevention and control of flea populations in dogs.

EFFECTIVE DATE: May 27, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300, filed NADA 141–084, which provides for oral administration of SENTINEL™ (milbemycin oxime/lufenuron) tablets containing 2.3 milligrams (mg) milbemycin oxime/46 mg lufenuron, 5.75 mg/115 mg, 11.5 mg/230 mg, or 23 mg/460 mg per tablet. SENTINEL™ tablets are administered once a month to dogs, 4 weeks of age and older and 2 pounds body weight or greater, for the prevention of heartworm disease caused by *D. immitis*, for the prevention and

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.

* * * * *

Dated: May 6, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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

BILLING CODE 4160–01–F