

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, 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.

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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