21 CFR Parts 520 and 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 parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for ''Pharmacia, Inc.,'' and ''The Upjohn Co.'' and by alphabetically adding a new entry for ''Pharmacia & Upjohn Co.'' and in the table in paragraph (c)(2) by removing the entry for ''000016'' and by revising the entry for ''000009'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	* *
Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199	000009
* * * * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * * * *
000009	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199
* *	* * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. 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).

4. Section 520.447 is amended by revising the third sentence in paragraph (c)(3) and by adding new paragraph (d) to read as follows:

§ 520.447 Clindamycin hydrochloride liquid.

* * * * *

(c) * * *

(3) * * * Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. * * *

(d) *Conditions of use in cats*—(1) *Amount.* 5.0 to 10.0 milligrams per pound of body weight every 24 hours for a maximum of 14 days (11 to 22 milligrams per kilogram of body weight per day).

(2) *Indications for use.* Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus, S. intermedius, and Streptococcus spp.* Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Clostridium perfringens and Bacteroides fragilis.*

(3) *Limitations.* Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. 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).

§ 522.1145 [Amended]

6. Section 522.1145 *Hyaluronate sodium injection* is amended in paragraph (a)(2) by removing ''000016'' and adding in its place ''000009''.

Dated: November 6, 1996.

Robert C. Livingston,

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

[FR Doc. 96–29696 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin With Pyrantel Pamoate

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 Merck Research Laboratories, Division of Merck & Co., Inc., for chewable tablets containing ivermectin with pyrantel pamoate. The product is used to prevent canine heartworm disease and to treat and control ascarid and hookworm

infections. The supplemental NADA provides for expanding the use for the treatment and control of an additional adult hookworm infection.

EFFECTIVE DATE: November 20, 1996.

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: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA 140–971, which provides for the use of Heartgard™ Plus (ivermectin with pyrantel pamoate) in dogs for the treatment and control of adult hookworm *Ancylostoma braziliense* infections. The product is used to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for 1 month (30 days) after infection, and for the treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina*, and adult hookworms *A. caninum*, *Uncinaria stenocephala*, and *A. braziliense*. The product is limited to use by or on the order of a licensed veterinarian. The supplement is approved as of October 3, 1996, and the regulations are amended in 21 CFR 520.1196(c)(1)(ii) to add treatment and control of adult hookworm *A. braziliense*. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental NADA qualifies for a 3-year marketing exclusivity period beginning October 3, 1996, because it contains reports of new clinical or field investigations essential to the approval and conducted or sponsored by the applicant. The exclusivity period applies only to the added claim for treatment and control of adult hookworm *A. braziliense*.

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 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).

§ 520.1196 [Amended]

2. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (c)(1)(ii) by adding the name ''*, A. braziliense,*'' after ''*Ancylostoma caninum*''.

Dated: October 29, 1996.

Andrew J. Beaulieau,

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

[FR Doc. 96–29631 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 810

[Docket No. 93N–0260]

Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing procedures for implementing the medical device recall authority provided in the Safe Medical Devices Act of 1990 (the SMDA). This statutory authority protects the public health by permitting FDA to remove dangerous devices from the market promptly. This authority complements other provisions of the device law, including tracking and notification.

DATES: The regulation is effective May 19, 1997.

Written comments on the information collection requirements should be submitted by January 21, 1997.

ADDRESSES: Submit written comments on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John H. Samalik, Center for Devices and Radiological Health (HFZ–323), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4703.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 14, 1994 (59 FR 30656), FDA published a proposed rule to establish the procedures it will follow in exercising its medical device recall authority provided in the SMDA. Interested persons were given until September 12, 1994, to comment on the proposed regulation. FDA received a total of nine comments from an infant ventilator manufacturer, a regulatory consulting corporation, an electrical manufacturers association, a medical device manufacturers association, a manufacturer of in vitro diagnostic products, and four other medical device companies.

II. Summary of the Final Rule

Section 8 of the SMDA (Pub. L. 101–629) amends section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) by adding a new subsection (e) entitled ''Recall Authority.'' Section 518(e)(1) of the act provides that, if FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of the device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Section 518(e)(2) of the act states that, after providing an opportunity for an informal hearing, FDA may amend the cease distribution and notification order to require a recall of the device.

Section 502(t) of the act (21 U.S.C. 352(t)) provides that a device is misbranded if there is a failure or refusal to comply with any requirement prescribed under section 518 of the act respecting the device. Section 301(q)(1) of the act (21 U.S.C. 331(q)(1)) makes the failure or refusal to comply with any requirement prescribed under section 518 of the act, or the causing thereof, a prohibited act. A person subject to a cease distribution and notification order or a mandatory recall order issued