

**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).

§ 520.2345d [Amended]

2. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing "047864, 054273, and 057561" and adding in its place "047864, 054273, 057561, and 059130" and by removing and reserving paragraph (c).

Dated: January 28, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97-2819 Filed 2-4-97; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 520**Oral Dosage Form New Animal Drugs;
Ivermectin Chewables**

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 Merck Research Laboratories, Div. of Merck & Co., Inc. The NADA provides for veterinary prescription use of ivermectin chewables in cats for the prevention of feline heartworm disease for a month after infection and removal and control of certain hookworm infections.

EFFECTIVE DATE: February 5, 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: Merck Research Laboratories, Div. of Merck & Co., Inc., P.O. Box 2000, RY32-209, Rahway, NJ 07065-0914, filed NADA 141-078 that provides for oral use on veterinary prescription of Heartgard™ for Cats (ivermectin chewables) to prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month after infection and for the removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*. The NADA is approved as of December 23,

1996, and the regulations are amended by revising 21 CFR 520.1193 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 December 23, 1996, because the NADA contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety required for approval and conducted or sponsored by the applicant.

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 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 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. Section 520.1193 is amended by revising the section heading and paragraph (a), and by adding new paragraph (d) to read as follows:

**§ 520.1193 Ivermectin tablets and
chewables.**

(a) *Specifications*—(1) *Dogs*. Each tablet or chewable contains 68, 136, or 272 micrograms of ivermectin.

(2) *Cats*. Each chewable contains 55 or 165 micrograms of ivermectin.

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(d) *Conditions of use in cats*—(1) *Amount*. Up to 2.3 kilograms (up to 5 pounds), 55 micrograms; 2.3 to 6.8 kilograms (5 to 15 pounds), 165 micrograms; over 6.8 kilograms (15 pounds), a combination of the appropriate chewables (recommended minimum dose of 24 micrograms of ivermectin per kilogram of body weight (10.9 micrograms per pound).

(2) *Indications for use*. To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

(3) *Limitations*. For use in cats 6 weeks of age and older. Administer once a month. The initial dose must be given within a month after cats first exposure to mosquitoes. The final dose must be given within a month after the cats last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 28, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97-2821 Filed 2-4-97; 8:45 am]

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21 CFR Part 522**Implantation or Injectable Dosage
Form New Animal Drugs; Naltrexone
Hydrochloride Injection**

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 Wildlife Laboratories, Inc. The NADA provides for use of naltrexone hydrochloride sterile injection as an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

EFFECTIVE DATE: February 5, 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: Wildlife Laboratories, Inc., 1401 Duff Dr., suite 600, Fort Collins, CO 80524, filed