Dated: September 15, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23598 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ketamine 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 an abbreviated new animal drug application (ANADA) filed by Fermenta Animal Health Co. The ANADA provides for intramuscular use of ketamine hydrochloride injection in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., P.O. Box 338, 15th and Oak Sts., Elwood, KS 66024, filed ANADA 200–029, which provides for intramuscular use of ketamine hydrochloride injection (equivalent to 100 milligrams/milliliter (mg/mL) ketamine) in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint. The drug is limited to use by or on the order of a licensed veterinarian.

Fermenta Animal Health's ANADA 200–029 for ketamine hydrochloride injection (equivalent to 100 mg/mL ketamine) is approved as a generic copy of Fort Dodge Laboratories' NADA 045–290 for Vetalar® /Ketaset® (ketamine hydrochloride injection equivalent to 100 mg/mL ketamine). The ANADA is approved as of August 16, 1995, and the regulations are amended in 21 CFR 522.1222a(c) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.1222a is amended by removing and reserving paragraphs (a) and (d).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20855, from 9 a.m. to 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 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 522.1222a is amended by removing and reserving paragraphs (a) and (d), and by revising paragraph (c) to read as follows:

§ 522.1222a Ketamine hydrochloride injection.

(a) [Reserved]

* * * * *

(c) *Sponsors.* See Nos. 000856, 045984, 054273, and 057319 in § 510.600(c) of this chapter.

(d) [Reserved]

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Dated: September 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23600 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Melarsomine Dihydrochloride for 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 Rhone Merieux, Inc. The NADA provides for intramuscular use of injectable melarsomine dihydrochloride for the treatment of heartworm disease in dogs.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed NADA 141–042 to provide for intramuscular use of the injectable drug product Immiticide Sterile Powder which consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride to be reconstituted with the provided 2 milliliters of sterile water. The drug is indicated for the treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs. The drug product is available by prescription. The NADA is approved as of July 21, 1995, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1362 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 21, 1995, because no active ingredient