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.

* * * * *

(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]

BILLING CODE 4160–01–F

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

NADA 141–074 that provides for the use of Trexonil™ Sterile Injection (50 milligrams of naltrexone hydrochloride per milliliter) as an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*). The NADA is approved as of December 23, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1465 to reflect the approval. The drug product is available on a prescription basis. The basis of approval is discussed in the freedom of information summary.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning December 23, 1996, because no active ingredient of the drug (including any ester or salt of the active ingredient) has been previously approved in any other application filed under section 512(b)(1) of the act.

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 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. New § 522.1465 is added to read as follows:

§ 522.1465 Naltrexone hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose*—(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Available data are inadequate to recommend use in pregnant animals. Avoid using during breeding season. Do not use in domestic food-producing animals. Do not use in free-ranging animals for 45 days before or during hunting season. 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. 97–2869 Filed 2–4–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

30 CFR Part 250

RIN 1010–AB99

Training of Lessee and Contractor Employees Engaged in Oil and Gas and Sulphur Operations in the Outer Continental Shelf (OCS)

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: Their rule amends MMS regulations governing the training of lessee and contractor employees engaged in oil and gas and sulphur operations in the OCS. MMS is making this amendment to simplify the training options and to provide the flexibility to use alternative training methods.

EFFECTIVE DATE: March 7, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Levine, Information and Training Branch, at (703) 787–1033.

SUPPLEMENTARY INFORMATION: On November 2, 1995, MMS published the proposed rule in the Federal Register (60 FR 55683). During the 90-day comment period that ended on January 31, 1996, MMS held a workshop. The workshop held on December 6, 1995, in New Orleans, Louisiana, received excellent participation from industry and training schools. We are highlighting the comments we received for the proposed rule in the ''Response to Comments'' section.

Response to Comments

MMS received 28 comments on the proposed rule. We appreciate the suggestions and comments that we received. We also appreciate the positive comments on our new ''plain English'' style of writing regulations.

We reviewed all of the comments, and in some instances, we revised the final language based on these comments. MMS grouped the major comments and organized them by regulation paragraph number or subject as highlighted in the comment table.

COMMENT TABLE

Requirement/subject	Comment	MMS response
250.210	''Alternative Training'' definition is restrictive	Disagree—MMS is not limiting the methods, we're only giving examples by using the term ''such as.''
250.210, 250.217, 250.222	Typographical errors appear in the Federal Register	Agree—We noted and corrected the errors.
250.214 (a) and (b)	MMS should add a 60-day grace period to the training limits.	Disagree—MMS wants to eliminate the cost and confusion caused by using the training ''windows'' of the past.
250.214(c)	The ''combination courses'' have too many hours	Disagree—Although the hours have slightly increased, we moved small tubing training to well workover.