PART 305—[AMENDED]

Accordingly, 16 CFR Part 305 is amended as follows:

1. The authority citation for Part 305 continues to read:

Authority: 42 U.S.C. 6294.

2. Section 305.9(a) is revised to read as follows:

§ 305.9 Representative average unit energy costs.

(a) Table 1, below, contains the representative unit energy costs to be utilized for all requirements of this part.

TABLE 1.—REPRESENTATIVE AVERAGE UNIT COSTS OF ENERGY FOR FIVE RESIDENTIAL ENERGY SOURCES (1997)

Type of energy	In commonly used terms	As required by DOE test procedure	Dollars per million Btu [1]
Electricity	8.31¢/kWh [2 3]	$0.0831/kWh	$24.35
Natural Gas	61.2¢/therm [4] or $6.43/MCF [5 6]	0.00000612/Btu	6.12
No. 2 heating oil	0.99/gallon [7]	0.00000714/Btu	7.14
Propane	0.98/gallon [8]	0.00001073/Btu	10.73
Kerosene	1.16/gallon [9]	0.00000859/Btu	8.59

[1] Btu stands for British thermal unit.
[2] kWh stands for kilowatt hour.
[3] 1 kWh = 3,412 Btu.
[4] 1 therm = 100,000 Btu. Natural gas prices include taxes.
[5] MCF stands for 1,000 cubic feet.
[6] For the purposes of this table, 1 cubic foot of natural gas has an energy equivalence of 1,028 Btu.
[7] For the purposes of this table, 1 gallon of No. 2 heating oil has an energy equivalence of 138,690 Btu.
[8] For the purposes of this table, 1 gallon of liquid propane has an energy equivalence of 91,333 Btu.
[9] For the purposes of this table, 1 gallon of kerosene has an energy equivalence of 135,000 Btu.

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Donald S. Clark,

Secretary.

[FR Doc. 97–2802 Filed 2–4–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tetracycline Hydrochloride Soluble Powder

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 Phoenix Scientific, Inc. The ANADA provides for oral use of tetracycline hydrochloride soluble powder in the drinking water of calves and swine for control and treatment of certain diseases caused by pathogens susceptible to tetracycline, and of chickens and turkeys for control of certain diseases caused by pathogens susceptible to tetracycline.

EFFECTIVE DATE: February 5, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–136, which provides for oral use of tetracycline hydrochloride soluble powder in the drinking water of calves and swine for control and treatment of certain conditions, and of chickens and turkeys for the control of certain conditions, as follows: (1) For calves for control and treatment of bacterial enteritis (scours) caused by *Escherichia coli*, and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae (Hemophilus spp.)*, and *Klebsiella* spp. susceptible to tetracycline; (2) for swine for control and treatment of bacterial enteritis (scours) caused by *E. coli*, and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae (Hemophilus spp.)*, and *Klebsiella* spp. susceptible to tetracycline; (3) for chickens for control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; infectious synovitis caused by *M. synoviae* susceptible to tetracycline; (4) for turkeys for control of infectious synovitis caused by *M. synoviae* and bluecomb (transmissible enteritis or coronaviral enteritis) complicated by bacterial organisms susceptible to tetracycline.

Approval of Phoenix's ANADA 200–136 tetracycline hydrochloride soluble powder is as a generic copy of Fermenta's NADA 65–496 tetracycline hydrochloride soluble powder. ANADA 200–136 is approved as of December 17, 1996, and the regulations are amended in § 520.2345d(a)(1) (21 CFR 520.2345d(a)(1)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, due to enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, the paragraph concerning NAS/NRC status is outdated. Section 520.2345d is amended to remove paragraph (c).

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.

The agency has determined under 21 CFR 25.24 (d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

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).

§ 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