§522.1450

(2) Indications for use. Treatment of inflammation and related disorders in dogs, cats, and horses;¹ treatment of allergic and dermatologic disorders in dogs and cats; and as supportive therapy to antibacterial treatment of severe infections in dogs and cats.

(3) *Limitations*. Not for use in horses intended for food. Not for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 51
FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988;
62 FR 35076, June 30, 1997]

§ 522.1450 Moxidectin solution.

(a) *Specifications*. Each milliliter of solution contains 10 milligrams (mg) moxidectin.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.426 of this chapter.

(d) Conditions of use in beef and nonlactating dairy cattle—(1) Amount. 0.2 mg/kilogram body weight (0.2 mg/2.2 pound) as a single subcutaneous injection.

(2) Indications for use. For treatment of gastrointestinal and control roundworms: Ostertagia ostertagi (adults, fourth-stage larvae, and inhibplacei ited larvae), Haemonchus (adults), Trichostrongylus axei (adults and fourth-stage larvae). Trichostrongylus colubriformis (adults and fourth-stage larvae), Cooperia oncophora (adults), Cooperia pectinata (adults), Cooperia punctata (adults and fourth-stage larvae), Cooperia spatulata (adults), Cooperia surnabada (adults and fourth-stage larvae). Nematodirus helvetianus (adults), Oesophagostomum radiatum (adults and fourth-stage larvae). Trichuris spp. (adults): lungworms: Dictyocaulus viviparus (adults and fourth-stage larvae); grubs: bovisand Hypoderma Hypoderma lineatum: mites: Psoroptes ovis (Psoroptes communis var. bovis); lice: Linognathus vituli and Solenopotes *capillatus*: for protection of cattle from reinfection with D. viviparus and O. radiatum for 42 days after treatment, with H. placei for 35 days after treatment, and with O. ostertagi and T. axei for 14 days after treatment.

21 CFR Ch. I (4–1–11 Edition)

(3) *Limitations*. Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

[70 FR 36337, June 23, 2005, as amended at 71 FR 7414, Feb. 13, 2006]

§ 522.1451 Moxidectin for suspension.

(a) Specifications. The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use; dogs—(1) Amount. 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) Indications for use. For prevention of heartworm disease caused by Dirofilaria immitis; for treatment of existing larval and adult hookworm (Ancylostoma caninum) and Uncinaria stenocephala infections.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002]

§522.1452 Nalorphine hydrochloride injection.

(a) *Specifications*. Each milliliter of aqueous solution contains 5 milligrams of nalorphine hydrochloride.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) Indications for use. Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations*. Successive doses of the drug gradually lose their analeptic