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: *Hypoderma bovis* and *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.

(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 20 months of age and older. A withdrawal period has not been established for pre-ruminating 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; 76 FR 48714, Aug. 9, 2011]

§ 522.1451 Moxidectin microspheres for injection.

(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. 054771 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; 79 FR 16191, Mar. 25, 2014]

§ 522.1452 Nalorphine.

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

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

(c) *Conditions of use in dogs*—(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.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997; 79 FR 16191, Mar. 25, 2014]

§ 522.1465 Naltrexone.

(a) *Specifications.* Each milliliter of 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.* 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.

[62 FR 5320, Feb. 5, 1997, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Dosage*. Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use*. For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

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

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996; 79 FR 16192, Mar. 25, 2014]

§ 522.1484 Neomycin.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of neomycin sulfate (equivalent to 35 mg of neomycin base).

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer 5 mg per pound of body weight daily by intramuscular or intravenous injection, divided into portions administered every 6 to 8 hours for 3 to 5 days.

(2) *Indications for use*. For the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(3) *Limitations*. Not for parenteral use in food-producing animals because of prolonged residues in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16192, Mar. 25, 2014]

§ 522.1503 Neostigmine.

(a) *Specifications*. Each milliliter of solution contains 2 milligrams (mg) neostigmine methylsulfate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer to cattle and horses at a dosage level of 1 mg per (/) 100 pounds (lbs) of body weight subcutaneously. Administer to sheep at a dosage level of 1 to 1½ mg/100 lbs body weight subcutaneously. Administer to swine at a dosage level of 2 to 3 mg/100 lbs body weight intramuscularly. These doses may be repeated as indicated.

(2) *Indications for use*. For treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions.

(3) *Limitations*. Not for use in animals producing milk, since this use will result in contamination of the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 61625, Nov. 19, 1997; 79 FR 16192, Mar. 25, 2014]

§ 522.1610 Oleate sodium.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of sodium oleate.

(b) *Sponsor*. See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer by parenteral injection depending on the area of response desired. An injection of 1 milliliter (mL) will produce a response of approximately 15 square centimeters. Do not inject more than 2 mL per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 mL.

(2) *Indications for use*. It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

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

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985; 79 FR 16192, Mar. 25, 2014]

§ 522.1620 Orgotein for injection.

(a) *Specifications*. Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor*. See No. 024991 in § 510.600(c) of this chapter.