(iii) *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.

[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; 76 FR 53051, Aug. 25, 2011]

### § 522.1450 Moxidectin solution.

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

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

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

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in beef and nonlactating dairy cattle—* (1) *Amount.* Administer 0.2 mg/kg of body weight (0.2 mg/2.2 pound) as a single, subcutaneous injection.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (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: *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 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 effect and eventually induce respiratory depression equal to that of opiates. Therefore, do not exceed therapeutic dosage. Do not mix drug with

meperidine solutions because the buffer will cause precipitation. 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]

### § 522.1462 Naloxone hydrochloride injection.

(a) *Specifications.* Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) *Sponsor.* See No. 060951 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 47 FR 20757, May 14, 1982; 54 FR 32632, Aug. 9, 1989; 63 FR 7701, Feb. 17, 1998]

### § 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.

[62 FR 5320, Feb. 5, 1997]

### § 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 000856 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]

### § 522.1484 Neomycin sulfate sterile solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of neomycin sulfate (equivalent to 35 milligrams of neomycin base).[1]

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 milligrams per pound of body weight daily divided into portions administered every 6 to 8 hours for 3 to 5 days.[1]

(2) *Indications for use.* Administer to dogs and cats for the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.[1]

[1] These claims are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.