

viviparus); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment.

(iii) *Limitations*. For subcutaneous use only. Not for intramuscular use. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Reindeer*—(i) *Amount*. 10 milligrams per 50 kilograms (110 pounds) body weight.

(ii) *Indications for use*. It is used in reindeer for treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations*. For subcutaneous use only. Not for intramuscular use. Do not treat reindeer within 56 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount*. 300 micrograms per kilogram (2.2 pounds).

(ii) *Indications for use*. It is used in swine for treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostromylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *Strongyloides ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

(iii) *Limitations*. For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assist-

ance in the diagnosis, treatment, and control of parasitism.

(5) *Ranch-raised foxes*—(i) *Amount*. 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) *Indications for use*. For treatment and control of ear mites (*Otodectes cynotis*).

(iii) *Limitations*. For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) *American bison*—(i) *Amount*. 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use*. It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations*. For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 5344, Feb. 13, 1984, as amended at 50 FR 30268, July 25, 1985; 51 FR 25686, July 16, 1986; 51 FR 27021, July 29, 1986; 51 FR 29463, Aug. 18, 1986; 53 FR 11064, Apr. 5, 1988; 56 FR 14020, Apr. 5, 1991; 60 FR 45041, Aug. 30, 1995; 62 FR 14634, Mar. 27, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 7702, Feb. 17, 1998]

§ 522.1193 Ivermectin and clorsulon injection.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams (1 percent) of ivermectin and 100 milligrams (10 percent) of clorsulon.

(b) *Sponsor*. See 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.163 and 556.344 of this chapter.

(d) *Conditions of use*—(1) *Amount*. 1 milliliter (10 milligrams of ivermectin and 100 milligrams of clorsulon) per 50 kilograms (110 pounds).

(2) *Indications for use*. It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only)

(*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. Ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997]

§ 522.1204 Kanamycin sulfate injection.

(a) *Specifications.* Kanamycin sulfate injection veterinary conforms to the standards of identity, strength, quality, and purity prescribed by § 444.230(a) of this chapter, except that each milliliter contains either 50 or 200 milligrams of kanamycin.

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

(c) *Conditions of use.* (1) It is used in the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

(2) It is administered subcutaneously or intramuscularly at 5 milligrams per pound of body weight per day in equally divided doses at 12-hour intervals.

(3) Its label shall bear an appropriate expiration date.

(4) Restricted to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 522.1222 Ketamine hydrochloride injectable dosage forms.

§ 522.1222a Ketamine hydrochloride injection.

(a) [Reserved]

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity and 1:10,000 benzethonium chloride.

(c) *Sponsors.* See Nos. 000010, 000856, 045984, and 059130 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) *Conditions of use.* (1) In cats:

(i) It is used for restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(ii) It is administered intramuscularly at a recommended dose that ranges from 5 to 15 milligrams per pound of body weight depending on the effect desired.

(2) In subhuman primates:

(i) It is used for restraint.

(ii) It is administered intramuscularly at a recommended dose that ranges from 3 to 15 milligrams per kilogram of body weight depending upon the species, general condition, and age of the subject.

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

[40 FR 59342, Dec. 23, 1975, as amended at 53 FR 27851, July 25, 1988; 59 FR 41976, Aug. 16, 1994; 59 FR 49291, Sept. 27, 1994; 60 FR 49339, Sept. 25, 1995; 62 FR 22888, Apr. 28, 1997; 62 FR 35076, June 30, 1997]

§ 522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* Ketamine hydrochloride, (±), -2-(*o*-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride, with promazine hydrochloride, 10-[3-(dimethylamino) propyl] phenothiazine monohydrochloride, and aminopentamide hydrogen sulfate.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity, 7.5 milligrams of promazine hydrochloride, and 0.0625 milligram of aminopentamide hydrogen sulfate, with 1:10,000 benzethonium chloride.

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