

(*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.

(d) *Special considerations.* Store in a cool place. Protect from light. Do not use if precipitate appears.

(e) *Conditions of use.* (1) It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

(2) It is administered intramuscularly at a recommended dose from 15 to 20 milligrams ketamine base per pound of body weight, depending on the effect desired.

(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 42 FR 3838, Jan. 21, 1977; 53 FR 27851, July 25, 1988]

#### § 522.1225 Ketoprofen solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 100 milligrams of ketoprofen.

(b) *Sponsor.* See 000856 in 21 CFR 510.600(c) of this chapter.

(c) *Conditions of use in horses—*(1) *Amount.* 1.0 milligram per pound of body weight once daily for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(3) *Limitations.* For intravenous use only. Do not use in breeding animals. Effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 40653, Oct. 4, 1990]

#### § 522.1228 [Reserved]

#### § 522.1244 Levamisole phosphate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor.* See No. 000061 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 043781 for use of 13.65 and 18.2 percent injection.

(c) *Conditions of use—*(1) *Amount.* 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use.* (i) The 13.65 percent injection is used as an anthel-

mintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) and lungworms (*Dictyocaulus*).

(3) *Limitations.* Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not administer to cattle within 7 days of slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997]

#### § 522.1258 Lidocaine injection with epinephrine.

(a) *Specifications.* Each milliliter of the drug contains 20 milligrams (2 percent) of lidocaine hydrochloride, 0.01 milligram of epinephrine, with sodium chloride, and with methylparaben as a preservative, in water for injection.

(b) *Sponsor.* See No. 000402 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* The drug is administered by injection as a 2 percent solution or diluted with bacteriostatic water for injection to a

<sup>1</sup>These conditions are National Academy of Science/National Research Council reviewed and deemed effective for this drug. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.