Food and Drug Administration, HHS

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

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

(d) 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

§ 522.1222a Ketamine.

(a) Specifications. Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) Sponsors. See Nos. 000010, 059130, 061690, 026537, and 063286 in §510.600(c) of this chapter.

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

(d) Conditions of use. (1) Cats—(1) Amount. 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(2) Subhuman primates—(1) Amount. 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

§ 522.1222 Ketamine hydrochloride injectable dosage forms.

§ 522.1222a Ketamine.

(a) Specifications. Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) Sponsors. See Nos. 000010, 059130, 061690, 026537, and 063286 in §510.600(c) of this chapter.

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

(d) Conditions of use. (1) Cats—(1) Amount. 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(2) Subhuman primates—(1) Amount. 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

§ 522.1224 Kanamycin sulfate injection.

(a) Specifications. Each milliliter of kanamycin sulfate injection veterinary 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.

§ 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.

(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 retreatment 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.

§ 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 Nos. 000009 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) Nos. 058005 and 059130 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 046573 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(3) of this section.

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

(c) Special considerations. When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to