

(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*<sup>1</sup>—(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.

0.5 percent solution for local anesthesia of large and small animals, as follows:

(i) Cats: Administer approximately 2 milliliters of 2 percent solution with epinephrine by caudal injection.

(ii) Cattle: Administer 5 milliliters of 2 percent solution with epinephrine by epidural injection (standing animal). Administer 10 to 20 milliliters of 2 percent solution with epinephrine by cornual nerve block injection. For teat operations and infiltration, inject 0.5 percent solution with epinephrine to effect.

(iii) Dogs: Administer 2 to 10 milliliters of 2 percent solution with epinephrine by caudal injection. Do not give intravascularly. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(iv) Horses: Administer 5 to 10 milliliters of 2 percent solution with epinephrine by volar nerve block. Administer 10 to 15 milliliters of 2 percent solution with epinephrine by epidural injection. For standing animal, apply slowly and observe individual sensitivity. For infiltration, administer 0.5 percent solution with epinephrine to effect.

(2) *Limitations.* (i) The drug is contraindicated in the presence of sepsis in the region of proposed injection, shock and heart block, neurologic disease, spinal deformities, septicemia, and hypertension.

(ii) Do not give intravascularly.

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

[43 FR 46300, Oct. 6, 1978; 43 FR 59059, Dec. 19, 1978, as amended at 52 FR 25212, July 6, 1987]

#### § 522.1260 Lincomycin injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains lincomycin hydrochloride equivalent to 25, 50, 100, or 300 milligrams of lincomycin.

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

(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 the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) *Conditions of use.* It is used for animals as follows:

(1) *Dogs and cats—(i) Amount.* 5 to 10 milligrams per pound of body weight per day.

(ii) *Indications for use.* Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations.* Administer intramuscularly 10 milligrams per pound of body weight once a day or 5 milligrams per pound of body weight twice daily or intravenously 5 to 10 milligrams per pound of body weight one or two times daily by slow injection. May be diluted with 5 percent glucose in water or normal saline and given as an infusion; as lincomycin hydrochloride monohydrate; for use by or on the order of a licensed veterinarian.

(2) *Swine—(i) Amount.* 5 milligrams per pound of body weight per day.

(ii) *Indications for use.* Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) *Limitations.* Administer intramuscularly as a single daily dose for 3 to 7 days; as lincomycin hydrochloride monohydrate; do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985]

#### § 522.1290 Luprostitol sterile solution.

(a) *Specifications.* Each milliliter of sterile solution contains 7.5 milligrams of luprostitol.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: *Warning:* Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostitol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use—(1) Amount.* 7.5 milligrams per mare.