

twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use.* For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

(iii) *Limitations.* For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor.* See 063112 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use.* The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations.* Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997]

§ 522.1004 Fomepizole.

(a) *Specifications.* Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) *Sponsor.* See 062161 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

(2) *Indications for use.* As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are

suspected of having ingested ethylene glycol.

(3) *Limitations.* Administer intravenously. For use by or on the order of a licensed veterinarian.

[61 FR 68147, Dec. 27, 1996]

§ 522.1010 Furosemide injection.

(a) *Specifications.* Each milliliter of sterile solution contains 50 milligrams of furosemide as the diethanolamine salt.

(b) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter for use in dogs and cats as in paragraph (c)(1) of this section, horses as in paragraph (c)(2)(i) of this section, and cattle as in paragraph (c)(3) of this section. See Nos. 000010 and 000864 in § 510.600(c) for use in horses as in paragraph (c)(2)(ii) of this section. See No. 000010 in § 510.600(c) of this chapter for use in dogs as in paragraph (c)(1) of this section.

(c) *Conditions of use—(1) Dogs and cats.* (i) It is used for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(ii) The drug is administered intramuscularly or intravenously at a dosage of 12.5 to 25 milligrams per 10 pounds of body weight; once or twice daily after a 6- to 8-hour interval. The lower dosage is suggested for cats. The dosage should be adjusted to the individual animal's response. In refractory or severe edematous cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. The established effective dose should be administered once or twice daily on an intermittent daily schedule. Diuretic therapy should be discontinued after reduction of edema, or when necessary, maintained after determining a programmed dosage schedule to prevent recurrence.

(2) *Horses.* (i) It is used for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(a) Administer intramuscularly or intravenously at 250 to 500 milligrams per animal once or twice daily at 6- to