

§ 522.970

(iii) *Limitations.* See paragraph (c)(1)(iii) of this section.

[44 FR 16011, Mar. 16, 1978, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.970 Flunixin meglumine solution.

(a) *Specifications.* The drug contains 50 milligrams of flunixin per milliliter of aqueous solution.

(b) *Sponsors.* See 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See 000856 and 059130 for use as in paragraph (d)(1) of this section only.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Conditions of use—(1) Horses—(i) Amount.* 0.5 milligram of flunixin per pound of body weight (1 milliliter per 100 pounds) per day.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* For musculoskeletal disorders, administer intravenously or intramuscularly for up to 5 days. For colic, administer a single dose intravenously—treatment may be repeated when signs of colic recur. Caution: The effect of this drug on pregnancy has 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.

(2) *Beef cattle and nonlactating dairy cattle—(i) Amount.* 1.1 to 2.2 milligrams per kilogram of body weight (0.5 to 1 milligram per pound, 1 to 2 milliliters per 100 pounds), once a day as a single dose or divided into 2 doses administered at 12-hour intervals for up to 3 days.

(ii) *Indications for use.* For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Do not use in bulls intended for breeding as reproductive effects in this class of cattle have not been studied. Federal law re-

21 CFR Ch. I (4–1–01 Edition)

stricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998]

§ 522.995 Fluprostenol sodium injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains fluprostenol sodium equivalent to 50 micrograms of fluprostenol.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 0.55 microgram fluprostenol per kilogram of body weight.

(2) *Indications for use.* The drug is used in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(3) *Limitations.* Administer by intramuscular injection only. *Warning:* Not for use in horses intended for food. For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian. 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. Fluprostenol 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.

[44 FR 52191, Sept. 7, 1979, as amended at 47 FR 22092, May 21, 1982]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications.* Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor.* See 059521 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* 12.5 units of follicle stimulating hormone

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