

(c) *Conditions of use—(1) Dogs.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 66582, Dec. 18, 1996, as amended at 62 FR 61625, Nov. 19, 1997]

§ 522.2012 Prostalene solution.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of prostalene.

(b) *Sponsor.* No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—Horses.* (1) It is used in mares for the control of estrus.

(2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(3) Not for use in horses intended for food.

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

[41 FR 26854, June 30, 1976, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.2063 Pyrilamine maleate injection.

(a) *Specifications.* The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

(b) *Sponsors.* See No. 000061 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see No. 000864 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(ii) of this section.

(c) *Conditions of use.* (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(2)(i) It is administered intramuscularly, subcutaneously, or intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours whenever necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.

(ii) It is administered intravenously. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.

(3) Do not use in horses intended for food purposes.

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

[40 FR 13858, Mar. 27, 1975; 41 FR 9150, Mar. 3, 1976, as amended at 42 FR 13549, Mar. 11, 1977; 42 FR 61256, Dec. 2, 1977; 51 FR 41477, Nov. 17, 1986; 52 FR 7832, Mar. 13, 1987; 54 FR 1164, Jan. 12, 1989]

§ 522.2095 Sarafloxacin solution for injection.

(a) *Specifications.* Each milliliter contains sarafloxacin hydrochloride equivalent to 50 milligrams of sarafloxacin in a 20 percent propylene glycol solution.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.594 of this chapter.

(d) *Conditions of use.* 18-day embryonated broiler eggs and day-old broiler chickens:

(1) *Amount—(i)* 18-day embryonated broiler eggs: 0.05 milligram sarafloxacin in 0.1 milliliter dose in single in ovo injection.

(ii) Day-old broiler chickens: 0.1 milligrams sarafloxacin per 0.2 milliliter dose in single subcutaneous injection in the neck.

(2) *Indications for use.* For control of early chick mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations.* Dilute 1 milliliter with 99 milliliters of sterile water or physiologic saline for use. Use entire contents of diluted solution within 24 hours. No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with dosages in excess of that recommended may result in illegal drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. Do not use in eggs intended for human consumption. The effects of sarafloxacin on the reproductive function of treated fowl have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 57833, Nov. 22, 1995, as amended at 62 FR 10220, Mar. 6, 1997]

§ 522.2100 Selenium, vitamin E injection.

(a)(1) *Specifications.* The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 250 milligrams polyoxyethylated vegetable oil, and 2.0 percent benzyl alcohol, and water for injection.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(ii) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level of 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(iii) Do not use in horses intended for food.

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

(b)(1) *Specifications.* The drug contains in each milliliter 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 100 milligrams of polyoxyethylated vegetable oil, 1:10,000 thimerosal, and water for injection.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use as an aid in alleviating and controlling inflammation, pain and lameness associated with certain arthropathies in dogs.

(ii) The drug is administered subcutaneously or intramuscularly in divided doses in 2 or more sites at a dosage level of 1 milliliter per 20 pounds of body weight with a minimum dosage of ¼ milliliter and a maximum dosage of 5 milliliters. The dosage is repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 milliliter per 40 pounds of body weight with a minimum dosage of ¼ milliliter which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

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

(c)(1) *Specifications.* Each milliliter contains 2.19 milligrams of selenite sodium (equivalent to 1 milligram selenium), 50 milligrams vitamin E (68 U.S.P. units), 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q. s.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age or older: 1 milliliter per 40 pounds, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds. Sows: 1 milliliter per 40 pounds. Weanling pigs: 1 milliliter per 40 pounds, minimum 1 milliliter.

(ii) *Indications for use.* Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and