

§ 522.2095

21 CFR Ch. I (4-1-01 Edition)

containing 20 milligrams of pyrrolamine 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.¹

(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.¹

(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.¹

(3) Do not use in horses intended for food purposes.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[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.

¹These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(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).

(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