§ 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. 061623 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; 68 FR 59881, Oct. 20, 2003]

§ 522.2076 Romifidine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) romifidine hydrochloride.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 40 to 120 micrograms per kilogram of body weight (mcg/kg BW) intravenously for sedation and analgesia; 100 mcg/kg BW intravenously as a preanesthetic.

(2) *Indications for use.* For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses; and for use as a preanesthetic prior to the induction of general anesthesia in adult horses.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Not for horses intended for human consumption.

[69 FR 47363, Aug. 5, 2004]

§ 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

[1] These 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.