

Food and Drug Administration, HHS

§ 522.1145

and no later than 10 weeks after the second dose.

[76 FR 27889, May 13, 2011, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16189, Mar. 25, 2014]

§ 522.1085 Guaifenesin powder for injection.

(a) *Specifications.* The product is a sterile powder containing guaifenesin. A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution.

(b) *Sponsors.* See Nos. 037990 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 1 milliliter of prepared solution per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a muscle relaxant.

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

[79 FR 16189, Mar. 25, 2014]

§ 522.1086 Guaifenesin solution.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of guaifenesin and 50 mg of dextrose.

(b) *Sponsors.* See Nos. 000859 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 1 milliliter per pound of body weight by rapid intravenous infusion.

(2) *Indications for use.* For use as a skeletal muscle relaxant.

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

[79 FR 16189, Mar. 25, 2014]

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Amount.* One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

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

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000; 79 FR 16189, Mar. 25, 2014]

§ 522.1145 Hyaluronate.

(a)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 054771 in § 510.600(c).

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock): 20 mg; larger joint (hock): 40 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

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

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount.* Small and medium-size joints (carpal, fetlock): 10 mg; larger joint (hock): 20 mg. Treatment may be repeated at weekly intervals for a total of four treatments.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

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