

Food and Drug Administration, HHS

§ 522.1850

in dogs and horses: See sponsor Nos. 000061, 000856, 059130, and 061623 in § 510.600(c) of this chapter.

(2) Approval for use of the 200 milligrams per milliliter drug for use in horses: See sponsor Nos. 000010 and 058005 in § 510.600(c) of this chapter.

(3) Approval for use of the 100 milligrams per milliliter drug in dogs and horses: See sponsor No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use for dogs.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 10 milligrams per pound of body weight daily in 3 divided doses, not to exceed 800 milligrams daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

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

(d) *Conditions of use for horses.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 1 to 2 grams per 1,000 pounds of body weight daily in 3 divided doses, not to exceed 4 grams daily. Limit intravenous administration to not more than 5 successive days.

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

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

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1720, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.1820 Pituitary luteinizing hormone for injection.

(a) *Specifications.* The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

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

(c) *Conditions of use.* (1) The drug is an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(2) Preferably given by intravenous injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 25 mg; swine, 5 mg; sheep, 2.5 mg, and dogs, 1.0 mg. Treatment may be repeated in 1 to 4 weeks, or as indicated.

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

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications.* (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.

(2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials contains 100 mg polysulfated glycosaminoglycan.

(b) *Sponsor.* See No. 010797 in § 510.600(c) of this chapter.

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

(d) *Conditions of use—(1) Horses—(i) Indications for use.* For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount—(A) Intra-articular use (carpal):* 250 mg once a week for 5 weeks.

(B) *Intramuscular use (carpal and hock):* 500 mg every 4 days for 28 days.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Dogs—(i) Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount.* 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

[72 FR 56896, Oct. 5, 2007, as amended at 74 FR 67816, Dec. 21, 2009]