

§ 522.1820

21 CFR Ch. I (4-1-03 Edition)

horses: See sponsor Nos. 000010 and 000864 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.

(4) Approval for use of the 200 milligrams per milliliter drug in dogs: See sponsor No. 000864 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 on GPO Access.

§ 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.* Each 1-milliliter ampule of sterile aqueous solution contains 250 milligrams of polysulfated glycosaminoglycan; each 5-milliliter ampule or vial contains 500 milligrams.

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

(c) *Conditions of use—horses.* (1) *Indications for use.* Polysulfated glycosaminoglycan is for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.—

(2) *Amount—(i) Intra-articular use (carpal):* 250 milligrams once a week for 5 weeks. The joint area must be shaved, cleaned, and sterilized as in a surgical procedure prior to injection. If the joint reacts with excessive inflammation, after intra-articular treatment, cease therapy.

(ii) *Intramuscular use (carpal and hock):* 500 milligrams every 4 days for 28 days. Injection site must be thoroughly cleansed prior to injection.

(3) *Limitations.* Not for use in horses intended for food. Safe use in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—dogs—(1) Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(2) *Dosage.* 2 milligrams per pound of body weight by intramuscular injection.