Food and Drug Administration, HHS

§ 522.1720 Pituitary thyroid hormone for injection.

(a) Specifications. The drug is a lyophilized pituitary extract. Each 1-milliliter vial contains an amount equivalent to 2.5 milligrams of standard pituitary thyroid hormone and is reconstituted for use by addition of 0.2 milliliters of 9 percent aqueous sodium chloride solution.

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

(c) Conditions of use. (1) The drug is used for the treatment of hypothyroidism and secondary hypothyroidism in dogs and horses.

(2) Preferably given by intramuscular injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 1.25 to 2.5 mg; swine, 0.25 to 0.5 mg; sheep, 0.125 to 0.25 mg; and dogs, 0.05 to 0.1 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.

§ 522.1725 Pituitary adrenocorticotropin hormone for injection.

(a) Specifications. The drug is a lyophilized pituitary extract. Each 1-milliliter vial contains an amount equivalent to 2 milligrams of standard pituitary adrenocorticotropin hormone and is reconstituted for use by addition of 0.4 milliliters of 9 percent aqueous sodium chloride solution.

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

(c) Conditions of use. (1) The drug is used for the treatment of hypoadrenocorticism in dogs and horses.

(2) Preferably given by intramuscular injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 1 to 2 mg; swine, 0.2 to 0.5 mg; sheep, 0.1 to 0.2 mg; and dogs, 0.05 to 0.1 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.

§ 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) It is used for 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.

§ 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).

§ 522.1855 Tuberculin for bovine, goat, and human use.

(a) Specifications. The drug is a lyophilized tuberculin extract. Each 1-milliliter vial contains an amount equivalent to 0.1 milligrams of standard tuberculin for bovine, goat, and human use and is reconstituted for use by addition of 0.1 milliliters of 9 percent aqueous sodium chloride solution.

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

(c) Conditions of use. (1) It is used for the treatment of tuberculosis and for the diagnosis and treatment of tuberculosis in bovine, goat, and human use.

(2) Preferably given by subcutaneous injection, it may be administered intramuscularly; dosage is as follows: Cattle, 0.5 to 1 mg; goats, 25 to 50 μg; and humans, 5 to 10 μg. 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.

§ 522.1880 Leukocyte interferon.

(a) Specifications. The drug is a lyophilized leukocyte interferon extract. Each 1-milliliter vial contains an amount equivalent to 10 milligrams of standard leukocyte interferon and is reconstituted for use by addition of 0.1 milliliters of 9 percent aqueous sodium chloride solution.

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

(c) Conditions of use. (1) It is used 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).