

**§ 522.1920**

**21 CFR Ch. I (4-1-11 Edition)**

corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 13446, Feb. 29, 1980, as amended at 50 FR 6160, Feb. 14, 1985; 52 FR 7832, Mar. 13, 1987]

**§ 522.1920 Prochlorperazine, isopropamide for injection.**

(a) *Specifications.* Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(2) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in Milliliters
Up to 4 .....	0.25
5 to 14 .....	0.5-1
15 to 30 .....	2-3
30 to 45 .....	3-4
45 to 60 .....	4-5
Over 60 .....	6

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

**§ 522.1940 Progesterone and estradiol benzoate.**

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000856 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), (c)(2)(iii), and (c)(3) of this section.

(2) No. 021641 for use as in paragraphs (c)(1) and (c)(2) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(c) *Conditions of use in cattle.* It is used for implantation as follows:

(1) *Suckling beef calves—(i) Amount—*(A) 100 milligrams (mg) progesterone and 10 mg estradiol benzoate (one implant consisting of 4 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of 5 pellets, each of 4 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds (lb) of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers—(i) Amount—*(A) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 9 pellets, each of 8 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For animals weighing 400 lb or more; for subcutaneous ear implantation, one dose per animal. Safety and effectiveness have not been

established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount*. Reimplant 200 mg progesterone and 20 mg estradiol benzoate on approximately day 70 following an initial implant of 100 mg progesterone and 10 mg estradiol benzoate or 200 mg progesterone and 20 mg estradiol benzoate.

(ii) *Indications for use*. For additional improvement in rate of weight gain.

(iii) *Limitations*. For subcutaneous ear implantation. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 70055, Dec. 2, 2004]

#### § 522.1962 Promazine hydrochloride.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000856 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

(2) No. 061623 for use as in paragraphs (c)(1)(i)(B), (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*—(A) 0.2 to 0.5 milligrams per pounds (mg/lb) body weight intramuscularly or intravenously every 4 to 6 hours.

(B) 0.2 to 0.5 mg/lb body weight intravenously as required.

(ii) *Indications for use*—(A) For use as a tranquilizer, preanesthetic, or for minor operative procedures in conjunction with local anesthesia; and as adjunctive therapy for tetanus.

(B) For use as a tranquilizer and preanesthetic.

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

(2) *Dogs and cats*—(i) *Amount*. 1 to 2 mg/lb body weight intramuscularly or intravenously every 4 to 6 hours.

(ii) *Indications for use*. For use as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic prior to worming; or to prevent motion sickness in dogs.

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

[46 FR 18962, Mar. 27, 1981, as amended at 68 FR 59881, Oct. 20, 2003; 70 FR 50183, Aug. 26, 2005]

#### § 522.2002 Propiopromazine hydrochloride injection.

(a) *Chemical name*. 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications*. Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5507, Feb. 13, 1996]

#### § 522.2005 Propofol.

(a) *Specifications*. Each milliliter of emulsion contains 10 milligrams (mg) propofol.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 059130 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 000074 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.