

§ 522.1890

21 CFR Ch. I (4–1–14 Edition)

§ 522.1890 Sterile prednisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 10 to 40 milligrams (mg) of prednisone.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Horses.* Administer 100 to 400 mg by intramuscular injection, repeating if necessary.

(ii) *Dogs and cats.* Administer 0.25 to 1.0 mg per pound of body weight by intramuscular injection for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.

(2) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.

(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 16194, Mar. 25, 2014]

§ 522.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each milliliter of solution contains prochlorperazine edisylate equivalent to 4 milligrams (mg) prochlorperazine and isopropamide iodide equivalent to 0.28 mg of isopropamide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) 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

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

(2) *Indications for use.* For use in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

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

[79 FR 16194, Mar. 25, 2014]

§ 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. 054771 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. 000986 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, as amended at 77 FR 31723, May 30, 2012; 79 FR 16194, Mar. 25, 2014]

§ 522.1962 Promazine.

(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. 054771 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 conjunc-

tion with local anesthesia; and as adjunctive therapy for tetanus.

(B) For use as a tranquilizer and preanesthetic.

(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.

(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; 79 FR 16194, Mar. 25, 2014]

§ 522.2002 Propipromazine.

(a) *Specifications.* Each milliliter of solution contains 5 or 10 milligrams (mg) propiromazine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amounts and indications for use.* Administer 0.05 to 0.5 mg per pound of body weight by intravenous or intramuscular injection for tranquilization. Administer 0.25 mg per pound of body weight by intravenous injection as a preanesthetic.

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

[79 FR 16195, Mar. 25, 2014]

§ 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. 000859 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 000044 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(3) No. 054771 for use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section.