

§ 522.150

21 CFR Ch. I (4–1–10 Edition)

(2) *Indications for use.* For reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride or medetomidine hydrochloride.

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

[61 FR 48830, Sept. 17, 1996, as amended at 64 FR 71640, Dec. 22, 1999; 72 FR 264, Jan. 4, 2007]

§ 522.150 **Azaperone.**

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) azaperone.

(b) *Sponsor.* See No. 012578 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 mg per kilogram (1 mg per pound) by deep intramuscular injection.

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

[74 FR 65689, Dec. 11, 2009]

§ 522.161 **Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.**

(a) *Chemical names.* Betamethasone acetate: 9- $\alpha$ -Fluoro-16- $\beta$ -methylprednisolone - 21 - acetate (C<sub>24</sub>H<sub>31</sub>FO<sub>6</sub>). Betamethasone disodium phosphate: 9- $\alpha$ -Fluoro-16- $\beta$ -methylprednisolone-21-disodium phosphate (C<sub>22</sub>H<sub>28</sub>FNa<sub>2</sub>O<sub>8</sub>P).

(b) *Specifications.* The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phosphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection q.s.

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

(d) *Conditions of use.* It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpal and fetlock joints. Administer from 2.5 to 5 cubic centimeters per dose. Dose may be repeated when necessary depending upon the duration of relief obtained. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

[40 FR13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.163 **Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.**

(a) *Specifications.* Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

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

(c) *Conditions of use—(1) Dogs.* (i) It is used as an aid in the control of pruritus associated with dermatoses.

(ii) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of 4 injections.

(2) *Horses.* (i) It is used as an aid in the control of inflammation associated with various arthropathies.

(ii) It is administered aseptically by intraarticular injection at a dosage of 2.5 to 5 milliliters per joint, depending on the severity of the condition and the joint size. Dosage may be repeated upon recurrence of clinical signs. Injection into the joint cavity should be preceded by withdrawal of synovial fluid.

(iii) Not for use in horses intended for food.

(3) *Clinical and experimental data.* It has been demonstrated that