

## § 522.144

(2) *Indications for use.* For the treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Streptococcus* spp. (including *S. equi*), *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(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.

[72 FR 45158, Aug. 13, 2007, as amended at 79 FR 16184, Mar. 25, 2014; 86 FR 57997, Oct. 20, 2021]

## § 522.144 Arsenamide.

(a) *Specifications.* Each milliliter of solution contains 10.0 milligrams arsenamide sodium.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 0.1 milliliter (mL) per pound of body weight (1.0 mL for every 10 pounds) by intravenous injection twice a day for 2 days.

(2) *Indications for use.* For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis*.

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

[79 FR 16184, Mar. 25, 2014, as amended at 84 FR 39183, Aug. 9, 2019]

## § 522.147 Atipamezole.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams atipamezole hydrochloride.

(b) *Sponsor.* See Nos. 015914 and 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Inject intramuscularly the same volume as that of dexmedetomidine or medetomidine used.

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

## 21 CFR Ch. I (4–1–22 Edition)

(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; 84 FR 8973, Mar. 13, 2019]

## § 522.150 Azaperone.

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

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.68 of this chapter.

(d) *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, as amended at 77 FR 46613, Aug. 6, 2012; 81 FR 48702, July 26, 2016; 84 FR 32992, July 11, 2019]

## § 522.161 Betamethasone.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Betamethasone acetate equivalent to 10.8 milligrams (mg) betamethasone and betamethasone disodium phosphate equivalent to 3 mg of betamethasone.

(2) Betamethasone dipropionate equivalent to 5 mg betamethasone and betamethasone sodium phosphate equivalent to 2 mg of betamethasone.

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

(1) No. 000061 for product described in paragraph (a)(1) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) No. 000061 for product described in paragraph (a)(2) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer by intramuscular injection 0.25 to 0.5 milliliter (mL) 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 four injections.

(ii) *Indications for use.* As an aid in the control of pruritus associated with dermatoses.

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

(2) *Horses*—(i) *Amount.* Administer 2.5 to 5 mL by intra-articular injection.

(ii) *Indications for use.* (A) For the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpal and fetlock joints.

(B) As an aid in the control of inflammation associated with various arthropathies.

(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.

[79 FR 16184, Mar. 25, 2014]

**§ 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 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.

(4) *Restrictions.* 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 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

**§ 522.167 Betamethasone sodium phosphate and betamethasone acetate.**

(a) *Specifications.* Each milliliter (mL) of suspension contains 6 milligrams (mg) betamethasone (3.15 mg betamethasone sodium phosphate and 2.85 mg betamethasone acetate).

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1.5 mL (9 mg total betamethasone) per joint by intra-articular injection. May be administered concurrently in up to two joints per horse.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in horses.

(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.

[80 FR 18776, Apr. 8, 2015]

**§ 522.204 Boldenone.**

(a) *Specifications.* Each milliliter of solution contains 25 or 50 milligrams (mg) boldenone undecylenate.

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

(c) *Conditions of use in horses*—(1) *Amount.* 0.5 mg per pound body weight by intramuscular injection. Treatment may be repeated at 3-week intervals.