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(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998, as amended at 79 FR 16185, Mar. 25, 2014; 84 FR 32992, July 11, 2019]

**§ 522.480 Corticotropin.**

(a) *Specifications.* Each milliliter of aqueous solution contains 40 or 80 U.S.P. (I.U.) units of repository corticotropin.

(b) *Sponsor.* See sponsors in § 510.600(c) of this chapter.

(1) No. 061133 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 043264 for use as in paragraph (c)(2) and (3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular injection.

(ii) *Indications for use.* As a diagnostic aid to test for adrenal dysfunction.

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

(2) *Dogs and cats*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular or subcutaneous injection, to be repeated as indicated.

(ii) *Indications for use.* For stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH).

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

(3) *Cattle*—(i) *Amount.* Administer 200 to 600 units by intramuscular or subcutaneous injection as an initial dose, followed by a dose daily or every other day of 200 to 300 units.

(ii) *Indications for use.* As a therapeutic agent for primary bovine ketosis; and for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

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

[79 FR 16185, Mar. 25, 2014, as amended at 84 FR 8973, Mar. 13, 2019; 85 FR 45308, July 28, 2020]

**§ 522.522 Danofloxacin.**

(a) *Specifications.* Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

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

(c) *Related tolerances.* See § 556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount and indications for use.* Administer by subcutaneous injection either:

(i) 6 mg per kilogram (/kg) of body weight, repeated in 48 hours, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* and *Pasteurella multocida*; or

(ii) 8 mg/kg of body weight as a single dose for the treatment of BRD associated with *M. haemolytica* and *P. multocida* and for the control of BRD in beef cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*.

(2) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 53136, Sept. 8, 2014]

**§ 522.533 Deslorelin.**

(a) *Specifications.* (1) Each implant contains 2.1 milligrams (mg) deslorelin acetate.

(2) Each milliliter (mL) of suspension contains 1.8 mg deslorelin acetate.

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

(1) No. 051311 for use of product described in paragraph (a)(1) as in paragraph (c)(1) of this section.

(2) No. 043264 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount*. One implant per mare subcutaneously in the neck.

(ii) *Indications for use*. For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters (mm) in diameter.

(iii) *Limitations*. Do not use in horses or ponies intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer 1.8 mg (1 mL) by intramuscular injection in the neck.

(ii) *Indications for use*. For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mm in diameter.

(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.

[75 FR 81456, Dec. 28, 2010, as amended at 79 FR 18158, Apr. 1, 2014; 87 FR 17945, Mar. 29, 2022; 87 FR 58962, Sept. 29, 2022]

#### § 522.535 Desoxycorticosterone.

(a) *Specifications*. Each milliliter of suspension contains 25 milligrams (mg) of desoxycorticosterone pivalate.

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

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(ii), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use*—(1) *Amount*. (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) *Indications for use*—(i) For use as replacement therapy for

mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's Disease).

(ii) For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

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

[81 FR 22524, Apr. 18, 2016]

#### § 522.536 Detomidine.

(a) *Specification*. Each milliliter of solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor*. See Nos. 015914, 052483, and 059399 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required. For sedation, administer by intravenous (IV) or intramuscular (IM) injection; for analgesia, administer by IV injection; for both sedation and analgesia, administer by IV injection.

(2) *Indication for use*. As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(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 16186, Mar. 25, 2014, as amended at 86 FR 13184, Mar. 8, 2021; 88 FR 27699, May 3, 2023]

#### § 522.540 Dexamethasone solution.

(a)(1) *Specifications*. Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 016592, and 061133 for use as in paragraph (a)(3) of this section.

(ii) No. 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount*. The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows: