calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 20159, Apr. 3, 1981, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 28630, May 27, 1997]

§ 522.522 Danofloxacin.

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

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

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

(d) *Conditions of use in cattle*—(1) *Amount*. 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*.

(3) *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]

§ 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. 043246 for use of product described in paragraph (a)(1) as in paragraph (c)(1) of this section.

(2) No. 051330 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 mL 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 mL 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]

§ 522.535 Desoxycorticosterone pivalate.

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

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 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.

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

(iii) *Limitations*. For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]