§ 522.778 Doxycycline hyclate.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of *N*-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(ii) *Indications for use.* For treatment and control of periodontal disease.

(iii) *Limitations.* Do not use in dogs less than 1-year old. Use of tetracyclines during tooth development has been associated with permanent discoloration of teeth. Do not use in pregnant bitches. Use in breeding dogs has not been evaluated. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 8349, Feb. 19, 1998, as amended at 65 FR 45878, July 26, 2000]

§ 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

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

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.[1]

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.[1]

(3) Not for use in horses intended for food.[1]

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

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

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(*a*) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(*b*) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(*a*) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(*b*) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 64 FR 15684, Apr. 1, 1999]

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor.* See No. 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One mL per 5 pounds of body weight.

(2) *Indications for use.* For euthanasia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005]

§ 522.812 Enrofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.226 of this chapter.

(d) *Special considerations.* 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.

(e) *Conditions of use*—(1) *Dogs.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Single-dose therapy: 7.5 to 12.5 mg/kg of body weight by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (previously *Haemophilus somnus*) in beef and nonlactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Use of enrofloxacin in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) *Swine.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Administer 7.5 mg/kg of body weight once, by subcutaneous injection behind the ear.

(ii) *Indications for use.* For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

[72 FR 10597, Mar. 9, 2007, as amended by 73 FR 17890, Apr. 2, 2008; 73 FR 21819, Apr. 23, 2008]

§ 522.820 Erythromycin.

(a) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(b) *Specifications*—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.

(2) Each mL of solution contains 200 mg erythromycin base.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use*—(1) *Dog.* Administer product described in paragraph (b)(1) of this section as follows: