

hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

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

[40 FR 17838, Apr. 23, 1975, as amended at 67 FR 67521, Nov. 6, 2002]

#### § 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.<sup>1</sup>

<sup>1</sup>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.

(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.<sup>1</sup>

(3) Not for use in horses intended for food.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[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

## § 522.812

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.

(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]

### § 522.812 Enrofloxacin solution.

(a) *Specifications.* Each milliliter of sterile solution contains either 22.7 milligrams of enrofloxacin when intended for use in dogs or 100 milligrams of enrofloxacin when intended for use in cattle.

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

(c) *Related tolerance.* See § 556.228 of this chapter.

(d) *Conditions of use—(1) Dogs—(i) Amount.* 2.5 milligrams per kilogram (1.13 milligrams per pound) of body weight as an initial dose only.

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

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

(2) *Cattle—(i) Amount.* Single-dose therapy: 7.5 to 12.5 milligrams enrofloxacin per kilogram of body weight (3.4 to 5.7 milliliters per 100 pounds). Multiple-day therapy: 2.5 to 5.0 milligrams per kilogram of body weight (1.1 to 2.3 milliliters per 100 pounds) administered once daily for 3 to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations.* For subcutaneous use in cattle only. Do not inject more

## 21 CFR Ch. I (4–1–03 Edition)

than 20 milliliters at each site. Do not slaughter within 28 days of 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. The effect of enrofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined. 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.

[55 FR 26683, June 29, 1990, as amended at 62 FR 38907, July 21, 1997; 63 FR 49003, Sept. 14, 1998]

### § 522.820 Erythromycin injection.

(a) *Sponsor.* See 061623 in § 510.600(c) of this chapter.

(b) *NAS/NRC status.* The conditions of use have been reviewed by NAS/NRC and found effective.

(c) *Dogs and cats—(1) Specifications.* Each milliliter of polyethylene glycol vehicle contains 100 milligrams of erythromycin base with 2 percent butyl aminobenzoate.

(2) *Conditions of use—(i) Amount.* 3 to 5 milligrams per pound of body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use—(A) Dogs.* For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(B) *Cats.* For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations.* Administer by deep intramuscular injection into the heavy muscles of the neck and limbs. Do not administer intravenously or intraperitoneally. Avoid subcutaneous use. Do not administer from moist or