

(c) *Conditions of use in horses*—(1) *Dosage*. Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use*. For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

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

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996; 79 FR 16192, Mar. 25, 2014]

§ 522.1484 Neomycin.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of neomycin sulfate (equivalent to 35 mg of neomycin base).

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer 5 mg per pound of body weight daily by intramuscular or intravenous injection, divided into portions administered every 6 to 8 hours for 3 to 5 days.

(2) *Indications for use*. For the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(3) *Limitations*. Not for parenteral use in food-producing animals because of prolonged residues in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16192, Mar. 25, 2014]

§ 522.1503 Neostigmine.

(a) *Specifications*. Each milliliter of solution contains 2 milligrams (mg) neostigmine methylsulfate.

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

(c) *Conditions of use*—(1) *Amount*. Administer to cattle and horses at a dosage level of 1 mg per (l) 100 pounds (lbs) of body weight subcutaneously. Administer to sheep at a dosage level of 1 to 1½ mg/100 lbs body weight

subcutaneously. Administer to swine at a dosage level of 2 to 3 mg/100 lbs body weight intramuscularly. These doses may be repeated as indicated.

(2) *Indications for use*. For treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions.

(3) *Limitations*. Not for use in animals producing milk, since this use will result in contamination of the milk. 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 62 FR 61625, Nov. 19, 1997; 79 FR 16192, Mar. 25, 2014]

§ 522.1610 Oleate sodium.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of sodium oleate.

(b) *Sponsor*. See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer by parenteral injection depending on the area of response desired. An injection of 1 milliliter (mL) will produce a response of approximately 15 square centimeters. Do not inject more than 2 mL per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 mL.

(2) *Indications for use*. It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(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.

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985; 79 FR 16192, Mar. 25, 2014]

§ 522.1620 Orgotein for injection.

(a) *Specifications*. Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor*. See No. 024991 in § 510.600(c) of this chapter.

§ 522.1660

21 CFR Ch. I (4-1-14 Edition)

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. Administer by deep intramuscular injection at a dosage level of 5 milligrams (mg) every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(ii) *Indications for use*. It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(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.

(2) *Dogs*—(i) *Amount*. Administer by subcutaneous injection 5 mg daily for 6 days, and thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(ii) *Indications for use*. It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

(iii) *Limitations*. 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 32583, Aug. 4, 1976; 79 FR 16192, Mar. 25, 2014]

§ 522.1660 **Oxytetracycline injectable dosage forms.**

§ 522.1660a **Oxytetracycline solution, 200 milligrams/milliliter.**

(a) *Specifications*. Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) *Sponsors*. See Nos. 000010, 000859, 048164, 054771, 055529, 057561, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.500 of this chapter.

(d) *Special considerations*. When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(e) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including*

prerumenative (veal) calves—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis*.

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(ii) *Limitations*. Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

(2) *Swine*—(i) *Amounts and indications for use*—(A) *Sows*: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.