

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(i) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980. Redesignated and amended at 69 FR 31879, June 8, 2004]

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting § 522.1660a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

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

(d) *Special considerations.* When labeled for use as in paragraph (e)(1)(i)(D) or (e)(1)(i)(E) of this section, 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, nonlactating dairy cattle, and calves including preruminating (veal) calves—(i) Amounts and indications for use—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Histophilus* 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.*

(B) 5 mg/lb BW/day intramuscularly, subcutaneously, or intravenously for treatment of severe foot-rot, and ad-

vanced 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 or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*.

(i) *Limitations.* Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four consecutive days. Do not inject more than 10 mL per site in adult cattle, reducing the volume according to age and body size to 1 to 2 mL in small calves. Exceeding the highest recommended level of drug/lb BW/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 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. Not for use in lactating dairy animals.

(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*.*

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

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(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 73 FR 14926, Mar. 20, 2008]

§ 522.1662 **Oxytetracycline hydrochloride implantation or injectable dosage forms.**

§ 522.1662a **Oxytetracycline hydrochloride injection.**

(a)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.*; *Hemophilis spp.*; *Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per

pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor.* See 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a) *Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Hemophilus spp.*, and *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus spp.* and *Streptococcus spp.* If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale*.

(c) *Limitations.* For 50-milligram-per-milliliter solution, administer intramuscularly or intravenously; for 100-milligram-per-milliliter solution, administer intramuscularly only.