Food and Drug Administration, HHS

§ 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—(A) Amounts and indications for use—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (i/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 advanced cases of other indicated diseases.

(2) Swine—(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.
(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.

§ 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.; *Hemophilus* 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.