

§522.2112

21 CFR Ch. I (4-1-03 Edition)

(d)(1) *Specifications.* Each milliliter contains 10.95 milligrams selenite sodium (equivalent to 5 milligrams selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsor.* See Nos. 000061 and 000856 in §510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Breeding beef cows: 1 milliliter per 200 pounds of body weight during the middle third of gestation, and 30 days before calving. Weanling calves: 1 milliliter per 200 pounds of body weight.

(ii) *Indications for use.* Weanling calves and breeding beef cows: For the prevention and treatment of selenium-tocopherol deficiency syndrome.

(iii) *Limitations.* For subcutaneous or intramuscular use. Discontinue use 30 days before treated cattle are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter contains 0.55 milligram selenite sodium (equivalent to 0.25 milligram selenium), 50 milligrams (68 U.S.P. units) vitamin E.

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

(3) *Conditions of use—(i) Dosage.* New-born lambs: 1 milliliter. Lambs 2 weeks of age or older: 4 milliliters. Baby pigs: 1 milliliter (or treat the sow during the last week of pregnancy).

(ii) *Indications for use.* Lambs: for prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Baby pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use only. Discontinue use 14 days before treated animals are slaughtered for human consumption. 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 52 FR 7832, Mar. 13, 1987; 57 FR 21209, May 19, 1992; 58 FR 57556, Oct. 26, 1993; 60 FR 57833, Nov. 22, 1995; 64 FR 27916, May 24, 1999]

§522.2112 Somtribove zinc suspension.

(a) *Specifications.* Each single-dose syringe contains 500 milligrams (mg) somtribove zinc in a prolonged-release suspension.

(b) *Sponsor.* See No. 059945 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Inject 500 mg every 14 days beginning during the 9th or 10th week (57 to 70 days) after calving and continue until the end of lactation.

(2) *Indications for use.* For use in healthy lactating dairy cows to increase the production of marketable milk.

(3) *Limitations.* For use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Administer subcutaneously. To minimize injection site blemishes on carcass at time of slaughter, avoid injections within 2 weeks of expected slaughter. No milk discard or preslaughter withdrawal period is required. Use may result in reduced pregnancy rates and, in first calf heifers, an increase in days open. The incidence of retained placenta may be higher. Treated cows are at an increased risk for clinical mastitis and subclinical mastitis. In some herds, use has been associated with increases in somatic cell counts in milk. Care should be taken to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Use may result in an increase in digestive disorders such as indigestion, bloat, and diarrhea. There may be an increase in the number of cows experiencing periods of “off-feed” (reduced feed intake) during treatment. Cows treated with this product may have increased numbers of enlarged hocks and lesions of the knee (carpal region), and second lactation or older cows may have more disorders of the foot region. Use has been associated with reductions in hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

[58 FR 59947, Nov. 12, 1993, as amended at 67 FR 18085, Apr. 15, 2002]

§522.2120 Spectinomycin dihydrochloride injection.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces flavopersicus*

(var. Abbott) or the same antibiotic substance produced by any other means. Each milliliter of the drug contains the following amount of spectinomycin activity from spectinomycin dihydrochloride pentahydrate:

(1) 5 milligrams when used as provided in paragraph (d)(1) of this section.

(2) [Reserved]

(3) 100 milligrams when used as provided in paragraphs (d) (2), (3), and (4) of this section.

(b) *Sponsor*. In § 510.600 of this chapter, see No. 059130 for conditions of use as in paragraph (d) of this section, and see No. 000009 for conditions of use as in paragraph (d)(2) and (d)(4) of this section.

(c) *Special considerations*. The quantity of spectinomycin referred to in this section refers to the equivalent weight of base activity for the drug.

(d) *Conditions of use*. It is administered as spectinomycin dihydrochloride pentahydrate as follows:

(1) Subcutaneously in the treatment of 1-to-3-day-old turkey poults at the rate of 1 to 2 milligrams per poult as an aid in the prevention of mortality associated with Arizona group infection.

(2) Subcutaneously in the treatment of 1-to-3-day old:

(i) Turkey poults at the rate of 5 milligrams per poult as an aid in the control of chronic respiratory disease (CRD) associated with *E. coli*.

(ii) Baby chicks at the rate of 2.5 to 5 milligrams per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae*, *S. typhimurium*, *S. infantis*, and *E. coli*.

(3) Intramuscularly in the treatment of dogs:

(i) At a dosage level of 2.5 milligrams to 5.0 milligrams per pound of body weight twice daily. Treatment may be continued for 4 days. For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

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

(4) Administer single injection of 0.1 milliliter (10 milligrams) subcutaneously in nape of neck of 1- to

3-day-old turkey poults as an aid in control of airsacculitis associated with *M. meleagridis* sensitive to spectinomycin.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 9273, Mar. 7, 1978; 46 FR 18964, Mar. 27, 1981; 47 FR 14149, Apr. 2, 1982; 61 FR 5507, Feb. 13, 1996; 61 FR 31028, June 19, 1996; 65 FR 45877, July 26, 2000; 66 FR 22118, May 3, 2001]

§ 522.2121 Spectinomycin sulfate solution.

(a) *Specifications*. Each milliliter of sterile aqueous solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams of spectinomycin.

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

(c) *Related tolerances*. See § 556.600 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Dose*. 10 to 15 milligrams per kilogram of body weight, at 24-hour intervals for 3 to 5 consecutive days.

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

(iii) *Limitations*. For subcutaneous injection in the neck. Do not inject more than 50 milliliters at each site. Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 24107, May 1, 1998]

§ 522.2150 Stanozolol sterile suspension.

(a) *Specifications*. Each milliliter of sterile suspension contains 50 milligrams of stanozolol.

(b) *Sponsor*. No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) Used as an anabolic steroid treatment in dogs, cats, and horses.

(2) Administered to dogs and cats by deep intramuscular injection in the thigh at weekly intervals, for several