

weanling pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use. Not for use in newborn pigs. Do not use in pregnant ewes. Calves: Discontinue use 30 days before treated calves are slaughtered for human consumption. Lambs, ewes, sows, or pigs: Discontinue use 14 days before treated lambs, ewes, sows, or pigs are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(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), 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q. s.

(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, 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q. s.

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

(3) *Conditions of use—(i) Dosage.* Newborn 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]

§ 522.2112 Sterile sometribove zinc suspension.

(a) *Specifications.* The drug product consists of a single-dose syringe containing 500 milligrams of sometribove zinc in a sterile, prolonged-release suspension.

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

(c) *Special considerations.* Use may result in reduced pregnancy rates and, in first calf heifers, an increase in days open. Use of the product has also been associated with increases in cystic ovaries and disorders of the uterus during the treatment period. Also, the incidence of retained placenta may be higher following subsequent calving. 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.

(d) *Conditions of use—(1) Amount.* 500 milligrams of sometribove zinc every

14 days beginning during the ninth week after calving and continuing 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. Administer subcutaneously. Safety to replacement bulls born to treated dairy cows has not been established. 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.

[58 FR 59947, Nov. 12, 1993]

§ 522.2120 Spectinomycin 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 Nos. 000033 and 050604 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 poult 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 poult 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 poult 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]

§ 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 weeks. For cats and small breeds of dogs, 25 milligrams. For larger dogs, 50 milligrams.

(3) Administered to horses by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks; 25 milligrams per 100 pounds of body weight.

(4) Not for use in horses intended for food.