

§ 522.2112

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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 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 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 Nos. 000033 and 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.