Food and Drug Administration, HHS § 522.2100

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Not for horses intended for human consumption.

(69 FR 47363, Aug. 5, 2004)

§ 522.2100 Selenium, vitamin E injection.

(a)(1) Specifications. The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

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

(3) Conditions of use. (i) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(ii) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level of 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(iii) Do not use in horses intended for food.

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

(b)(1) Specifications. The drug contains in each milliliter 2.19 milligrams of sodium selenite (equivalent to 1 milligram selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

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

(3) Conditions of use. (i) The drug is intended for use as an aid in alleviating and controlling inflammation, pain and lameness associated with certain arthropathies in dogs.

(ii) The drug is administered subcutaneously or intramuscularly in divided doses in 2 or more sites at a dosage level of 1 milliliter per 20 pounds of body weight with a minimum dosage of ¼ milliliter and a maximum dosage of 5 milliliters. The dosage is repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 milliliter per 40 pounds of body weight with a minimum dosage of ¼ milliliter which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

(iii) 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).

(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.** 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).


(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.

§ 522.2112 Sometribove zinc suspension.

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

(b) **Sponsor.** See No. 000986 in §510.600(c) of this chapter.

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

(ii) **Indications for use.** To increase production of marketable milk in healthy lactating dairy cows.

(iii) **Limitations.** Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass. There is no milk discard or preslaughter withdrawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

(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) 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 poultys at the rate of 1 to 2 milligrams per poult as an