Food and Drug Administration, HHS

(a) Specifications. Each milliliter of sterile solution contains 1 milligram of prostalene.
(b) Sponsor. No. 000856 in § 510.600(c) of this chapter.
(c) Conditions of use—Horses. (1) It is used in mares for the control of estrus.
   (2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.
   (3) Not for use in horses intended for food.
   (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2063 Pyrilamine maleate injection.
(a) Specifications. The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.
(b) Sponsors. See No. 000061 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see No. 061623 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(ii) of this section.
(c) Conditions of use. (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.
   (2)(i) It is administered intramuscularly, subcutaneously, or intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
   (ii) It is administered intravenously. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours if necessary. Horses, 40 to 60 milligrams per 100 pounds body weight; foals, 20 milligrams per 100 pounds body weight.
   (3) Do not use in horses intended for food purposes.
   (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2076 Romifidine.
(a) Specifications. Each milliliter of solution contains 10 milligrams (mg) romifidine hydrochloride.
(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.
(c) Conditions of use in horses—(1) Amount. 40 to 120 micrograms per kilogram of body weight (mcg/kg BW) intravenously for sedation and analgesia; 100 mcg/kg BW intravenously as a preanesthetic.
   (2) Indications for use. For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses; and for use as a preanesthetic prior to the induction of general anesthesia in adult horses.
   (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.

§ 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).
   (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.

1These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
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 of selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).  

(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 arthopathies 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 and a maximum dosage of 5 milliliters.  

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

(c)(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.  

(d)(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—(1) 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.

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

(3) Limitations. Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. 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.


§ 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. 00009 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