AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer by intravenous injection according to label directions. The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use*—(i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic.

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

[75 FR 20269, Apr. 19, 2010, as amended at 75 FR 38700, July 6, 2010; 78 FR 17868, Mar. 25, 2013; 79 FR 16195, Mar. 25, 2014]

§ 522.2012 Prostalene.

(a) *Specifications*. Each milliliter of solution contains 1 milligram of prostalene.

(b) *Sponsor*. No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(2) *Indications for use*. For the control of estrus in mares.

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

[79 FR 16195, Mar. 25, 2014]

§ 522.2063 Pyrilamine.

(a) *Specifications*. Each milliliter of solution contains 20 milligrams (mg) of pyrilamine maleate.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter for uses in paragraph (c) of this section.

(1) No. 000061 for use as in paragraph (c)(1)(i), (2), and (3) of this section.

(2) No. 061623 for use as in paragraph (c)(1)(ii), (2), and (3) of this section.

(c) *Conditions of use*—(1) *Amount*—(i) Horses, 40 to 60 mg per 100 pounds (lbs) body weight; foals, 20 mg/100 lbs body weight. Administer by intramuscular, subcutaneous, or intravenous injection. Dosage may be repeated every 6 to 12 hours whenever necessary.

(ii) Horses, 40 to 60 mg/100 lbs body weight; foals, 20 mg/100 lbs body weight. Administer by slow intravenous injection. Dosage may be repeated every 6 to 12 hours if necessary.

(2) *Indications for use*. It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

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

[79 FR 16195, Mar. 25, 2014]

§ 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*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 47363, Aug. 5, 2004, as amended at 79 FR 16195, Mar. 25, 2014]

§ 522.2100 Selenium and vitamin E.

(a)(1) *Specifications*. Each milliliter of emulsion contains 5.48 milligrams (mg) sodium selenite (equivalent to 2.5 mg selenium) and 50 mg 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 in horses*—(i) *Amount*. Administer 1 milliliter (mL) per (/) 100 pounds (lbs) of body weight by intravenous injection or by deep intramuscular injection in divided

doses in two or more sites in the gluteal or cervical muscles. Administration may be repeated at 5 to 10 day intervals.

(ii) *Indications for use*. For the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. Each milliliter contains 2.19 mg of sodium selenite (equivalent to 1 mg of selenium), 50 mg 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 in dogs*—(i) *Amount*. Administer by subcutaneous or intramuscular injection in divided doses in two or more sites at 1 mL/20 lbs of body weight with a minimum dosage of ¼ mL and a maximum dosage of 5 mL. The dose is repeated at 3-day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 mL per 40 lbs of body weight with a minimum dosage of ¼ mL 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.

(ii) *Indications for use*. As an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

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

(c)(1) *Specifications*. Each milliliter contains 2.19 milligrams of selenite sodium (equivalent to 1 milligram selenium), 50 milligrams vitamin E (68 U.S.P. units).

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

(3) *Conditions of use*—(i) *Dosage*. Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age or older: 1 milliliter per 40 pounds, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds. Sows: 1 milliliter per 40 pounds. Weanling pigs: 1 milliliter per 40 pounds, minimum 1 milliliter.

(ii) *Indications for use*. Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and 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).

(2) *Sponsors*. See Nos. 000061 and 054771 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).

(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; 79 FR 16195, Mar. 25, 2014]

§ 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.

[58 FR 59947, Nov. 12, 1993, as amended at 67 FR 18085, Apr. 15, 2002; 68 FR 62006, Oct. 31, 2003; 74 FR 53164, Oct. 16, 2009]

§ 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. 000859 for conditions of use as in paragraph (d) of this section, and see No. 054771 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