(5) During long term treatment, periodic platelet counts and white and red blood cell counts are recommended.

(6) The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity.

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

[41 FR 3853, Jan. 27, 1976, as amended at 44 FR 32214, June 5, 1979; 46 FR 23231, Apr. 24, 1981; 47 FR 36814, Aug. 24, 1982; 50 FR 9800, Mar. 12, 1985; 50 FR 11852, Mar. 26, 1985; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2611 Trimethoprim and sulfadiazine paste.

(a) *Specifications.* Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000856 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

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

[71 FR 30802, May 31, 2006]

§ 520.2612 Trimethoprim and sulfadiazine oral suspension.

(a) *Specifications.* Each milliliter of oral suspension contains 60 milligrams of drug (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine).

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

(c) *Conditions of use. Dogs*—(1) *Dosage.* 1 milliliter (10 milligrams of trimethoprim and 50 milligrams of sulfadiazine) per 5 pounds of body weight.

(2) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

(3) *Limitations.* For oral use only. Administer the recommended dose once daily or one-half the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. If no improvement is seen in 3 days, discontinue therapy and re-evaluate diagnosis. Do not treat for more than 14 consecutive days. During long-term treatment, a complete blood count is recommended. The drug should not be used in patients showing marked liver parenchymal damage or blood dyscrasia, nor in those with a history of sulfonamide sensitivity. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 19168, May 7, 1985, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2613 Trimethoprim and sulfadiazine powder.

(a) *Specifications.* Each gram of powder contains 67 milligrams of trimethoprim and 333 milligrams of sulfadiazine.

(b) *Sponsor.* See No. 000009 and 058711 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses*—(1) *Dosage.* 3.75 grams of powder per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use.* For control of bacterial infections of horses during

treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

(3) *Limitations.* Administer orally in a small amount of feed, as a single daily dose, for 5 to 7 days. Continue therapy for 2 to 3 days after clinical signs have subsided. If no improvement is seen in 3 to 5 days, reevaluate diagnosis. A complete blood count should be done periodically with prolonged use. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 36135, July 6, 1993, as amended by 64 FR 68289, Dec. 7, 1999]

§ 520.2640 Tylosin.

(a) *Specifications.* Each container contains tylosin tartrate equivalent to 100 grams tylosin base.

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

(1) No. 000986 for use as in paragraph (d) of this section.

(2) No. 016592 for use as in paragraphs (d)(1), (d)(2), (d)(3)(i), (d)(3)(ii)(B), (d)(3)(iii), and (d)(4) of this section.

(c) *Related tolerances.* See § 556.740 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* 2 grams per gallon for 1 to 5 days as the sole source of drinking water. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(ii) *Indications for use.* As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) associated with *M. gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) associated with *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations.* Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

(ii) *Indications for use.* For maintaining weight gains and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Prepare a fresh solution every 3 days. Do not use in layers producing eggs for human consumption. Do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

(ii) *Indications for use*—(A) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(B) For the treatment and control of swine dysentery associated with *B. hyodysenteriae.*

(iii) *Limitations.* Prepare a fresh solution daily. Do not administer within 48 hours of slaughter. Follow with tylosin phosphate medicated feed as in § 558.625(f)(1)(vi)(*c*) of this chapter.

(4) *Honey bees*—(i) *Amount.* Mix 200 milligrams tylosin in 20 grams confectioners'/powdered sugar. Use immediately. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997; 68 FR 24879, May 9, 2003; 70 FR 69439, Nov. 16, 2005; 73 FR 76946, Dec. 18, 2008; 75 FR 76259, Dec. 8, 2010]