should be done periodically for 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.

[48 FR 34469, July 29, 1983, as amended at 49 FR 26714, June 29, 1984; 53 FR 11063, Apr. 5, 1988; 61 FR 5506, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 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 reevaluate 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.* Tylosin is the antibiotic substance produced by growth of *Streptromyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the tartrate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled ''Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,'' which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

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

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

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

(e) *Conditions of use.* It is used in drinking water of animals as follows:

(1) *Chickens*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Aid in the treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 1 to 5 days as sole source of drinking water; treated chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter .

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 0.25 gram per gallon.

(ii) *Indications for use.* For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) *Limitations.* As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated: mix fresh solution daily; medication must be withheld from animals 48 hours prior to slaughter.

[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]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.