§ 516.2980 Verdinexor.

(a) *Specifications.* Each tablet contains 2.5, 10, or 50 milligrams (mg) verdinexor.

(b) *Sponsor.* See No. 086121 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer verdinexor tablets orally at an initial dose of 1.25 mg per kilogram (mg/kg) of body weight twice per week with at least 72 hours between doses. If tolerated after 2 weeks, increase the dose to 1.5 mg/kg twice per week with at least 72 hours between doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

[86 FR 57996, Oct. 20, 2021]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13838, Mar. 27, 1975, unless otherwise noted.

§ 520.23 Acepromazine.

(a) *Specifications.* Each tablet contains 10 or 25 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See Nos. 000010 and 086117 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.25 to 1.0 mg per pound (/lb) body weight orally.

(ii) *Indications for use.* As an aid in tranquilization and as a preanesthetic agent.

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

(2) *Cats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight orally.

(ii) *Indications for use.* As a tranquilizer.

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

[75 FR 10165, Mar. 5, 2010, as amended at 88 FR 84699, Dec. 6, 2023]

§ 520.28 Acetazolamide.

(a) *Specifications.* A powder containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a dosage of 5 to 15 milligrams per pound of body weight daily.

(2) *Indications for use.* As an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.

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

[79 FR 28816, May 20, 2014]

§ 520.35 Afoxolaner, moxidectin, and pyrantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 9.375 milligrams (mg) afoxolaner, 45 micrograms (mcg) moxidectin, and 18.75 mg pyrantel (as pamoate salt);

(2) 18.75 mg afoxolaner, 90 mcg moxidectin, and 37.5 mg pyrantel (as pamoate salt);

(3) 37.5 mg afoxolaner, 180 mcg moxidectin, and 75 mg pyrantel (as pamoate salt);

(4) 75 mg afoxolaner, 360 mcg moxidectin, and 150 mg pyrantel (as pamoate salt); or

(5) 150 mg afoxolaner, 720 mcg moxidectin, and 300 mg pyrantel (as pamoate salt).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally once a month at the minimum dose of 1.14 mg/lb (2.5 mg/kg) afoxolaner, 5.45 mcg/lb (12 mcg/kg) moxidectin, and 2.27 mg/lb (5.0 mg/kg) pyrantel. For heartworm disease prevention, give once monthly for at least 6 months after last exposure to mosquitoes.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult hookworm (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*) and roundworm (*Toxocara canis* and *Toxascaris leonina*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), and *Haemaphysalis longicornis* (longhorned tick) infestations for 1 month in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater.

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

[88 FR 84699, Dec. 6, 2023, as amended at 90 FR 6799, Jan. 21, 2025]

§ 520.38 Albendazole oral dosage forms.

§ 520.38a Albendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 45.5 milligrams (mg) (4.55 percent) or 113.6 mg (11.36 percent) albendazole.

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

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Cattle.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/pound (lb) body weight (10 mg/kilogram (kg)) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni* and *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus* and *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls.

(2) *Sheep.* Administer 4.45 or 11.36 percent suspension:

(i) *Amount.* 3.4 mg/lb body weight (7.5 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For removal and control of adult liver flukes (*Fasciola hepatica* and *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcinta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams.

(3) *Goats.* Administer 11.36 percent suspension:

(i) *Amount.* 4.54 mg/lb body weight (10 mg/kg) as a single oral dose using dosing gun or dosing syringe.

(ii) *Indications for use.* For the treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats.

(iii) *Limitations.* Do not slaughter within 7 days of last treatment. Do not administer to does during the first 30 days of pregnancy or for 30 days after removal of bucks.

[73 FR 11027, Feb. 29, 2008. Redesignated at 78 FR 66264, Nov. 5, 2013, as amended at 79 FR 28816, May 20, 2014]

§ 520.38b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

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

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments

of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*)); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotmum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations.* Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995. Redesignated at 78 FR 66264, Nov. 5, 2013, as amended at 79 FR 28816, May 20, 2014]

§ 520.43 Afoxolaner.

(a) *Specifications.* Each chewable tablet contains 11.3, 28.3, 68, or 136 milligrams (mg) afoxolaner.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally once a month at a minimum dosage of 1.14 mg/pound (2.5 mg/kilogram).

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month; and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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

[78 FR 66264, Nov. 5, 2013, as amended at 79 FR 37619, July 2, 2014; 84 FR 8972, Mar. 13, 2019; 84 FR 39182, Aug. 9, 2019; 88 FR 55563, Aug. 16, 2023]

§ 520.48 Altrenogest.

(a) *Specifications.* Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

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

(1) Nos. 000061 and 051072 for use as in paragraph (d) of this section.

(2) No. 061133 for use as in paragraph (d)(1) of this section.

(3) No. 013744 for use as in paragraph (d)(2) of this section.

(c) *Tolerances.* See § 556.36 of this chapter.

(d) Conditions of use—(1) *Horses*—(i) *Amount.* 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use.* For suppression of estrus in mares.

(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.

(2) *Swine*—(i) *Amount.* Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days by top-dressing on a portion of each gilt's daily feed.

(ii) *Indications for use.* For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

(iii) *Limitations.* Do not use in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis). Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

[66 FR 47960, Sept. 17, 2001, as amended at 68 FR 62006, Oct. 31, 2003; 72 FR 9455, Feb. 21, 2008; 74 FR 61516, Nov. 25, 2009; 77 FR 32012, May 31, 2012; 80 FR 34278, June 16, 2015; 82 FR 21690, May 10, 2017; 83 FR 13635, Mar. 30, 2018; 84 FR 8972, Mar. 13, 2019; 88 FR 27698, May 3, 2023]

§ 520.62 Aminopentamide.

(a) *Specifications.* Each tablet contains 0.2 milligram (mg) aminopentamide hydrogen sulphate.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg; for animals weighing 11 to 20 lbs: 0.2 mg; for animals weighing 21 to 50 lbs: 0.3 mg; for animals weighing 51 to 100 lbs: 0.4 mg; for animal weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(2) *Indications for use.* For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

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

[79 FR 28816, May 20, 2014]

§ 520.82 Aminopropazine oral dosage forms.

§ 520.82a Aminopropazine.

(a) *Specifications.* Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally at a dosage of 1 to 2 milligrams per pound of body weight, repeated every 12 hours as indicated.

(2) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

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

[79 FR 28816, May 20, 2014]

§ 520.82b Aminopropazine and neomycin.

(a) *Specifications.* Each tablet contains aminopropazine fumarate equivalent to 25 percent aminopropazine base and neomycin sulfate equivalent to 50 milligrams (mg) of neomycin base.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a dosage of 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated.

(2) *Indications for use.* For control of bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.

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

[79 FR 28816, May 20, 2014]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams (mg) amoxicillin.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

(ii) *Indications for use.* Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

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

(2) *Cats*—(i) *Amount.* Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

(ii) *Indications for use.* Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract due to *E. coli;* and skin and soft tissue (abscesses, lacerations,

and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

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

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 79 FR 28816, May 20, 2014]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin.

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

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount*. Administer orally 5 mg per pound (/lb) of body weight, twice a day for 5 to 7 days.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis;* genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis;* bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis;* and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

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

(ii) *Cats*—(A) *Amount*. Administer orally 5 to 10 mg/lb of body weight, once daily for 5 to 7 days.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis;* genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

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

(2) [Reserved]

(c) *Sponsors*. See Nos. 000856 and 051311 in § 510.600(c) of this chapter.

(1) *Conditions of use*. *Dogs*—(i) *Amount*. Administer orally 5 mg/lb of body weight, twice a day for 5 to 7 days.

(ii) *Indications for use*. Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

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

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003; 79 FR 28816, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.88c Amoxicillin trihydrate oral suspension.

(a) *Specifications*. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams (mg) amoxicillin.

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

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount*. Administer 40 mg orally twice a day using a dosing pump. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days.

(2) *Indications for use*. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations*. Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 79 FR 28817, May 20, 2014; 85 FR 18118, Apr. 1, 2020]

§ 520.88d Amoxicillin trihydrate soluble powder.

(a) *Specifications.* Each gram of powder contains amoxicillin trihydrate equivalent to 115.4 milligrams (mg) amoxicillin.

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

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use in preruminating calves including veal calves*—(1) *Amount.* Administer 400 mg per 100 pounds of body weight twice daily by drench or in milk. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 5525, Feb. 6, 1997; 79 FR 28817, May 20, 2014]

§ 520.88e Amoxicillin trihydrate boluses.

(a) *Specifications.* Each bolus contains amoxicillin trihydrate equivalent to 400 milligrams (mg) amoxicillin.

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

(c) *Related tolerances.* See § 556.38 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 400 mg per 100 pounds of body weight twice daily. Treatment should be continued for 48 hours after all symptoms have subsided but not to exceed 5 days.

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* Do not slaughter animals during treatment or for 20 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 62 FR 5526, Feb. 6, 1997; 79 FR 28817, May 20, 2014]

§ 520.88f Amoxicillin trihydrate tablets.

(a) *Specifications.* Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 200, or 400 milligrams (mg) amoxicillin.

(b) *Sponsors.* See Nos. 051311 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 5 mg per pound of body weight twice daily for 5 to 7 days or 48 hours after all symptoms have subsided.

(2) *Indications for use.* For treatment of bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., *Staphylococcus* spp., and *Escherichia coli;* and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Enterococcus faecalis*, *E. coli*, *Proteus mirabilis*, and *Staphylococcus* spp.

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

[79 FR 28817, May 20, 2014, as amended at 83 FR 64740, Dec. 18, 2018]

§ 520.88g Amoxicillin and clavulanate potassium tablets.

(a) *Specifications.* Each tablet or chewable tablet contains amoxicillin and clavulanate potassium equivalent to 50 milligrams (mg) amoxicillin and 12.5 mg clavulanic acid, 100 mg amoxicillin and 25 mg clavulanic acid, 200 mg amoxicillin and 50 mg clavulanic acid, or 300 mg amoxicillin and 75 mg clavulanic acid.

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

(1) No. 054771 for use of tablets and chewable tablets as in paragraph (c) of this section.

(2) Nos. 017033 and 069043 for use of tablets as in paragraph (c) of this section.

(3) No. 013744 for use of chewable tablets as in paragraph (c) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Deep pyoderma may require treatment for 21 days; do not treat for more than 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*. Periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

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

(2) *Cats*—(i) *Amount.* 62.5 milligrams (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily for 5 to 7 days or for 48 hours after all signs have subsided. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

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

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998; 79 FR 28817, May 20, 2014; 80 FR 34278, June 16, 2015; 82 FR 11508, Feb. 24, 2017; 82 FR 43484, Sept. 18, 2017; 82 FR 58556, Dec. 13, 2017; 87 FR 58960, Sept. 29, 2022; 89 FR 42357, May 15, 2024]

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When constituted, each milliliter (mL) of suspension contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin and clavulanate potassium equivalent to 12.5 mg clavulanic acid.

(b) *Sponsors.* See Nos. 017033, 054771, and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 mg/lb (1 mL/10 lb of body weight) twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

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

(2) *Cats*—(i) *Amount.* 62.5 mg (1 mL) twice daily. Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5 to 7 days or 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli*, *Pasteurella multocida*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

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

[87 FR 17944, Mar. 29, 2022]

§ 520.90 Ampicillin oral dosage forms.

§ 520.90a Ampicillin tablets.

(a) *Specifications.* Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use.* Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli, Proteus mirabilis,* and *Pasteurella* spp., urinary tract infections (cystitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E., coli, P. mirabilis,* and *Enterococcus* spp.; gastrointestinal infections due to *Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., and *E. coli.* ; infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus* spp., and *Streptococcus* spp.

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

[57 FR 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 79 FR 28818, May 20, 2014. Redesignated at 85 FR 18118, Apr. 1, 2020]

§ 520.90b Ampicillin capsules.

(a) *Specifications.* Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight, three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use.* Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

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

(2) *Cats*—(i) *Amount.* 10 to 30 milligrams per pound of body weight or three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use.* Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

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

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 79 FR 28818, May 20, 2014. Redesignated at 85 FR 18118, Apr. 1, 2020]

§ 520.90c Ampicillin boluses.

(a) *Specifications.* Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

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

(c) *Related tolerances.* See § 556.40 of this chapter.

(d) *Conditions of use in nonruminating calves*—(1) *Amount.* 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(2) *Indications for use.* Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli.*

(3) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995; 79 FR 28818, May 20, 2014. Redesignated and amended at 85 FR 18118, Apr. 1, 2020]

§ 520.100 Amprolium.

(a) *Specifications.* (1) Each milliliter of solution contains 96 milligrams (mg) amprolium (9.6 percent solution).

(2) Each gram of powder contains 200 mg amprolium (20 percent).

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

(1) Nos. 016592 and 061133 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 051072 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use*—(1) *Growing chickens, turkeys, and laying hens.* It is used in drinking water as follows:

(i) *Amount.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks.

(ii) *Indications for use.* For the treatment of coccidiosis.

(iii) *Limitations.* Use as the sole source of amprolium.

(2) *Calves.* Administer concentrate solution or soluble powder as a drench or in drinking water as follows:

(i) *Indications for use and amounts*—(A) As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

(ii) *Limitations.* Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Use as the sole source of amprolium.

[71 FR 56346, Sept. 27, 2006, as amended at 72 FR 60551, Oct. 25, 2007; 73 FR 45611, Aug. 6, 2008; 73 FR 70276, Nov. 20, 2008; 74 FR 10484, Mar. 11, 2009; 76 FR 38554, July 1, 2011; 76 FR 40808, July 12, 2011; 78 FR 23, Jan. 2, 2013; 78 FR 17596, Mar. 22, 2013; 78 FR 57058, Sept. 17, 2013; 81 FR 22523, Apr. 18, 2016; 81 FR 59133, Aug. 29, 2016; 84 FR 8972, Mar. 13, 2019; 86 FR 13184, Mar. 8, 2021; 89 FR 85426, Oct. 28, 2024]

§ 520.110 Apramycin sulfate soluble powder.

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day for 7 days.

(2) *Indications for use.* For the control of porcine colibacillosis (weanling pig scours) caused by strains of *Escherichia coli* sensitive to apramycin.

(3) *Limitations.* Do not slaughter treated swine for 28 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988; 79 FR 28818, May 20, 2014; 81 FR 48702, July 26, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Bacitracin methylenedisalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

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

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Broiler and replacement chickens*—(i) *Amount.* 100 mg per gal in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylenedisalicylate.

(B) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water.

(ii) *Amount.* 200 to 400 mg per gal in drinking water. Administer continuously 5 to 7 days or as long as clinical signs persist, then reduce to prevention levels (100 mg/gal).

(A) *Indications for use.* Treatment of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylenedisalicylate.

(B) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water.

(2) *Growing turkeys*—(i) *Amount.* 400 milligrams (mg) per gallon (gal) in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.

(iii) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Brachyspira hyodysenteriae.* Administer continuously for 7 days or until signs of dysentery disappear.

(iii) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water. Treatment not to exceed 14 days. Not to be given to swine that weigh more than 250 pounds.

(4) *Growing quail*—(i) *Amount.* 400 mg per gal in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

[57 FR 37322, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 63 FR 38474, July 17, 1998; 64 FR 13068, Mar. 17, 1999; 76 FR 53050, Aug. 25, 2011; 79 FR 28818, May 20, 2014; 80 FR 34278, June 16, 2015; 88 FR 14897, Mar. 10, 2023]

§ 520.154b Bacitracin methylenedisalicylate and streptomycin sulfate powder.

(a) *Specifications.* Each gram of powder contains 200 units bacitracin methylenedisalicylate and streptomycin sulfate equivalent to 20 milligrams of streptomycin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., and for the symptomatic treatment of associated diarrhea.

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

[71 FR 17702, Apr. 7, 2006, as amended at 79 FR 28818, May 20, 2014; 81 FR 17607, Mar. 30, 2016]

§ 520.154c Bacitracin zinc soluble powder.

(a) *Specifications.* Each pound contains the equivalent of not less than 5 grams of bacitracin.

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

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Broiler chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations.* Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount.* 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams

per gallon in drinking water for 10 days.

(ii) *Indications for use.* Control of ulcerative enteritis caused by *Clostridium* spp. Susceptible to bacitracin zinc.

(iii) *Limitations.* Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28818, May 20, 2014]

§ 520.170 Bexagliflozin.

(a) *Specifications.* Each tablet contains 15 milligrams bexagliflozin.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer one tablet by mouth to cats 6.6 lb (3.0 kg) or greater once daily, at approximately the same time each day, with or without food, and regardless of blood glucose level.

(2) *Indications for use.* To improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.

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

[88 FR 16547, Mar. 20, 2023]

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name. N,N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications.* The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

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

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum, Taenia pisiformis,* and *Echinococcus granulosus,* and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis.*

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 13018, Mar. 8, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.246 Butorphanol tablets.

(a) *Specifications.* Each tablet contains butorphanol tartrate equivalent to 1, 5, or 10 milligrams (mg) butorphanol base.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.25 mg butorphanol base per pound of body weight. Repeat at intervals of 6 to 12 hours as required. Treatment should not normally be required for longer than 7 days.

(2) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheobronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

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

[79 FR 28818, May 20, 2014]

§ 520.260 *n*-Butyl chloride.

(a) *Specifications.* Each capsule contains 221, 442, 884, or 1,768 milligrams (mg); or 4.42 grams of *n*-butyl chloride.

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

(1) No. 023851 for capsules containing 221, 442, 884, or 1,768 mg, or 4.42 grams (g); and

(2) No. 054771 for capsules containing 221 mg.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer capsules orally based on body weight as follows:

(i) Capsules containing 221 mg: Under 5 pounds, 1 capsule per 1¼ pounds of body weight.

(ii) Capsules containing 442 mg: Under 5 pounds, 1 capsule per 2½ pounds of body weight.

(iii) Capsules containing 884 mg:

(A) Under 5 pounds, 1 capsule;

(B) 5 to 10 pounds, 2 capsules;

(C) 10 to 20 pounds, 3 capsules;
(D) 20 to 40 pounds, 4 capsules;
(E) Over 40 pounds, 5 capsules.
(iv) Capsules containing 1,768 mg: Dogs weighing 5 to 10 pounds, 1 capsule.
(v) Capsules containing 4.42 g: Dogs weighing 40 pounds or over, 1 capsule.
(2) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs.
(3) *Limitations.* Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks. A veterinarian should be consulted before using in severely debilitated dogs.

[86 FR 10819, Feb. 23, 2021]

§ 520.292 Capromorelin.

(a) *Specifications.* Each milliliter of solution contains:
(1) 30 milligrams (mg) capromorelin; or
(2) 20 mg capromorelin.
(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.
(c) *Conditions of use*—(1) *Dogs.* Use product described in paragraph (a)(1) of this section as follows:
(i) *Amount.* Administer 3 mg/kg once daily by mouth.
(ii) *Indications for use.* For appetite stimulation in dogs.
(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.
(2) *Cats.* Use product described in paragraph (a)(2) of this section as follows:
(i) *Amount.* Administer 2 mg/kg once daily by mouth.
(ii) *Indications for use.* For management of weight loss in cats with chronic kidney disease.
(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[81 FR 59133, Aug. 29, 2016, as amended at 85 FR 4207, Jan. 24, 2020; 86 FR 17063, Apr. 1, 2021]

§ 520.301 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5st caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.
(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.
(c) *Conditions of use in dogs*—(1) *Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.
(2) *Indications for use.* For relief of cough.

[43 FR 55385, Nov. 28, 1978, as amended at 79 FR 28819, May 20, 2014. Redesignated at 80 FR 13229, Mar. 13, 2015]

§ 520.302 Carnidazole tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of carnidazole.
(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.
(c) *Conditions of use*—(1) *Amount.* Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).
(2) *Indications for use.* For treating trichomoniasis (canker) in ornamental and homing pigeons.
(3) *Limitations.* Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989. Redesignated at 80 FR 13229, Mar. 13, 2015]

§ 520.304 Carprofen.

(a) *Specifications.* (1) Each caplet contains 25, 75, or 100 milligrams (mg) carprofen.
(2) Each chewable tablet contains 25, 75, or 100 mg carprofen.
(3) Each chewable tablet contains 25, 37.5, 50, 75, or 100 mg carprofen.
(4) Each flavored tablet contains 25, 75, or 100 mg carprofen.
(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.
(1) Nos. 017033, 054771, 055529, and 062250 for use of products described in paragraphs (a)(1) and (a)(2) of this section as in paragraph (c) of this section.
(2) Nos. 058198, 086101 and 086117 for use of product described in paragraph

(a)(2) as in paragraph (c) of this section.

(3) No. 069043 for use of product described in paragraph (a)(3) of this section as in paragraph (c) of this section.

(4) No. 086101 for use of product described in paragraphs (a)(1), (a)(2), and (a)(4) of this section as in paragraph (c) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Indications for use*. For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

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

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999; 66 FR 63165, Dec. 5, 2001; 67 FR 6866, Feb. 14, 2002; 67 FR 65038, Oct. 23, 2002; 67 FR 65697, Oct. 28, 2002; 70 FR 30626, May 27, 2005; 71 FR 51995, Sept. 1, 2006; 72 FR 68478, Dec. 5, 2007; 74 FR 21768, May 11, 2009; 78 FR 52853, Aug. 27, 2013; 78 FR 66264, Nov. 5, 2013; 79 FR 28819, May 20, 2014. Redesignated and amended at 80 FR 13229, Mar. 13, 2015; 80 FR 34278, June 16, 2015; 80 FR 61296, Oct. 13, 2015; 82 FR 43484, Sept. 18, 2017; 84 FR 12493, Apr. 2, 2019; 85 FR 4207, Jan. 24, 2020; 86 FR 13184, Mar. 8, 2021; 86 FR 14817, Mar. 19, 2021; 86 FR 61684, Nov. 8, 2021; 88 FR 27698, May 3, 2023; 89 FR 42357, May 15, 2024; 89 FR 95103, Dec. 2, 2024]

§ 520.314 Cefadroxil.

(a) *Specifications*. (1) Each tablet contains 50, 100, or 200 milligrams (mg) or 1 gram of cefadroxil.

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

(b) *Sponsor*. See No. 042791 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs*. Administer 10 mg per pound (/lb) body weight twice daily orally.

(ii) *Cats*. Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use*—(i) *Dogs*. For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus*.

(ii) *Cats*. For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *S. aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

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

[75 FR 10165, Mar. 5, 2010, as amended at 87 FR 76421, Dec. 14, 2022]

§ 520.370 Cefpodoxime tablets.

(a) *Specifications*. (1) Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(2) Each chewable tablet contains cefpodoxime proxetil equivalent to 100 or 200 mg cefpodoxime.

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

(1) No. 017033 for use of product in paragraph (a)(1) of this section as in paragraph (c) of this section.

(2) No. 054771 for use of products in paragraph (a) of this section as in paragraph (c) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use*. For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus pseudintermedius*, *S. aureus*, *Streptococcus canis* (group G, beta-hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

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

[69 FR 52815, Aug. 30, 2004, as amended at 78 FR 5714, Jan. 28, 2013; 79 FR 28819, May 20, 2014; 80 FR 13229, Mar. 13, 2015; 82 FR 12169, Mar. 1, 2017; 88 FR 16547, Mar. 20, 2023]

§ 520.376 Cephalexin.

(a) *Specifications.* Each chewable tablet contains 75, 150, 300, or 600 milligrams (mg) cephalexin.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 22 mg per kilogram of body weight twice daily for 28 days.

(ii) *Indications for use.* For the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius.*

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

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a) *Specifications.* Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.

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

(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:

(i) No. 069043 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;

(ii) No. 054771 for 100-, 250-, and 500-mg tablets;

(2) For use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section:

(i) No. 061133 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;

(ii) [Reserved]

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 25 mg per pound of body weight by mouth every 6 hours.

(2) *Indications for use*—(i) For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[77 FR 4896, Feb. 1, 2012, as amended at 78 FR 21059, Apr. 9, 2013; 79 FR 28819, May 20, 2014; 83 FR 48944, Sept. 28, 2018; 84 FR 8972, Mar. 13, 2019]

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.

(b) *Sponsors.* See Nos. 050057 and 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Special considerations.* Federal law prohibits the extralabel use of this product in food-producing animals.

(d) *Conditions of use in dogs*—(1) *Amount.* 25 mg per pound of body weight every 6 hours.

(2) *Indications for use.* For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

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

[70 FR 75398, Dec. 20, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 75 FR 55676, Sept. 14, 2010; 79 FR 28819, May 20, 2014]

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) *Specifications.* Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

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

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight every 6 hours. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals that are raised for food production. Must not be used in meat-, egg-, or milk-producing animals. The length of

time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 79 FR 28819, May 20, 2014]

§ 520.434 Chlorphenesin carbamate tablets.

(a) *Specifications.* Each tablet contains 400 milligrams of chlorphenesin carbamate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 50 milligrams per pound of body weight on first day; 25 milligrams per pound of body weight each following day. Divide total daily dose into 2 or 3 equal doses—administer at 12- or 8-hour intervals.

(2) *Indications for use.* For use as an adjunct to therapy of acute inflammatory and traumatic conditions of skeletal muscles. The drug provides relief of the signs of discomfort associated with myositis, muscle sprains, traumatic injuries, stifle injuries—especially when administered before or after surgery—and invertebral disc syndrome (can be used concurrently with adrenal corticosteroids).

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

[44 FR 16009, Mar. 16, 1979, as amended at 79 FR 28819, May 20, 2014]

§ 520.441 Chlortetracycline powder.

(a) *Specifications.* Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 069254 for use as in paragraph (d) of this section.

(2) No. 066104 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

(3) Nos. 069043 and 076475 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) and (iii) of this section.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use.* (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(*1*) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(*2*) *Limitations.* Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(*1*) Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount.* 200 to 400 milligrams per gallon.

(*1*) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 400 to 800 milligrams per gallon.

(*1*) *Indications for use.* Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(C) *Amount.* One thousand milligrams per gallon.

(*1*) *Indications for use.* Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(*2*) *Limitations.* See paragraph (d)(4)(i)(A)(*2*) of this section.

(ii) *Growing turkeys*—(A) *Amount.* 400 milligrams per gallon.

(*1*) *Indications for use.* Control of infectious synovitis caused by *M. synoviae.*

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 25 milligrams per pound of body weight daily.

(*1*) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(*2*) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Swine*—(A) *Amount.* 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. And bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily as the sole source of chlortetracycline. Do not use for more than 5 days. For Nos. 066104, 069043, 069254, and 076475: Do not slaughter animals for food within 5 days of treatment. For No. 069254: Do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 milligrams per pound daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. And bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Haemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) Use in a drench or drinking water as follows:

(i) *Chickens*—(A) *Amount.* 200 to 400 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(*2*) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not use in laying chickens; do not administer to chickens within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 400 to 800 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of chronic respiratory disease (CRD) and air-sac infections caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(i)(A)(*2*) of this section.

(C) *Amount.* One thousand mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of mortality due to fowl cholera caused by Pasteurella multocida susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(i)(A)(*2*) of this section.

(ii) *Growing Turkeys*—(A) *Amount.* 400 mg/gal, for 7 to 14 days.

(*1*) *Indications for use.* Control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.

(*2*) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not administer to growing turkeys within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) *Amount.* 25 mg/lb body weight daily, for 7 to 14 days.

(*1*) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(*2*) *Limitations.* As in paragraph (d)(5)(ii)(A)(*2*) of this section.

(iii) *Swine*—(A) *Amount.* 10 mg/lb body weight daily, for 3 to 5 days.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae*, and *Klebsiella* spp. Susceptible to chlortetracycline.

(C) *Limitations.* Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to swine within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 mg/lb body weight daily in divided doses, for 3 to 5 days.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Histophilus* spp., and *Klebsiella* spp. Susceptible to chlortetracycline.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to cattle within 24 hours of slaughter; do not use in lactating dairy cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37324, Aug. 18, 1992]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.441, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 520.443 Chlortetracycline tablets and boluses.

(a) *Specifications.* Each tablet contains 25 milligrams (mg) chlortetracycline hydrochloride; each bolus contains 250 or 500 mg chlortetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 069043 for use of a 250-mg bolus as in paragraph (d)(1) of this section.

(2) No. 016592 for use of a 25-mg tablet as in paragraph (d)(2) of this section.

(3) No. 016592 for use of a 500-mg bolus as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use in calves*—(1) *Amount*. One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klesbsiella* spp., and *Haemophilus* spp.

(ii) *Limitations*. Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding. Do not use for more than 5 days. Do not administer within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount*. One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. And bacterial pneumonia associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Amount*. One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use*. Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations*. Do not use for more than 5 days. Do not administer within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002. Redesignated and amended at 76 FR 49649, Aug. 11, 2011; 78 FR 21059, Apr. 9, 2013; 81 FR 17607, Mar. 30, 2016; 88 FR 16547, Mar. 20, 2023; 88 FR 27698, May 3, 2023; 88 FR 55563, Aug. 16, 2023]

§ 520.445 Chlortetracycline and sulfamethazine powder.

(a) *Specifications*. Each pound of soluble powder contains chlortetracycline bisulfate equivalent to 102.4 grams (g) of chlortetracycline hydrochloride and sulfamethazine bisulfate equivalent to 102.4 g of sulfamethazine.

(b) *Sponsor*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use in swine*. Administer in drinking water as follows:

(1) *Amount*. 250 milligrams (mg) of chlortetracycline and 250 mg of sulfamethazine per gallon.

(2) *Indications for use*. For the prevention and treatment of bacterial enteritis; as an aid in the reduction of the incidence of cervical abscesses; and as an aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations*. Use as the sole source of chlortetracycline and sulfonamide. Not to be used for more than 28 consecutive days. Withdraw 15 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 49649, Aug. 11, 2011, as amended at 81 FR 17607, Mar. 30, 2016; 81 FR 94989, Dec. 27, 2016]

§ 520.446 Clindamycin capsules and tablets.

(a) *Specifications*. (1) Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.

(2) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(3) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

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

(1) Nos. 054771 and 069043 for use of capsules described in paragraph (a)(1) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.

(3) No. 043806 for use of tablets described in paragraph (a)(3) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(2) *Indications for use*. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

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

[67 FR 54954, Aug. 27, 2002, as amended at 68 FR 55824, Sept. 29, 2003; 69 FR 32273, June 9, 2004; 71 FR 39204, July 12, 2006; 73 FR 4077, Jan. 24, 2008; 78 FR 17596, Mar. 22, 2013; 79 FR 28819, May 20, 2014; 80 FR 76386, Dec. 9, 2015; 81 FR 17607, Mar. 30, 2016]

§ 520.447 Clindamycin solution.

(a) *Specifications*. Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors*. See Nos. 051311, 054771, 058829, 061133, and 069043 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*; dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*; and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(2) Cats—(i) *Amount*. 5.0 to 15.0 mg/lb body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *Staphylococcus aureus*, *S. intermedius*, *Streptococcus spp.*; deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*; and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus spp.*, *C. perfringens*, and *B. fragilis*.

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004; 71 FR 39543, July 13, 2006; 72 FR 19796, Apr. 20, 2007; 78 FR 17596, Mar. 22, 2013; 78 FR 30197, May 22, 2013; 79 FR 28819, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 84 FR 8972, Mar. 13, 2019]

§ 520.452 Clenbuterol syrup.

(a) *Specifications*. Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use*. Indicated for the management of horses affected

with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations.* Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine.

(a) Specifications. Each tablet contains 5, 20, 40, or 80 milligrams (mg) clomipramine hydrochloride.

(b) *Sponsors.* See Nos. 051311 and 086039 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use.* For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

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

[64 FR 1762, Jan. 12, 1999, as amended at 72 FR 262, Jan. 4, 2007; 86 FR 57996, Oct. 20, 2021]

§ 520.462 Clorsulon drench.

(a) *Specifications.* The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.163 of this chapter.

(d) *Conditions of use. Cattle*—(1) *Amount.* One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use.* For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997; 84 FR 32992, July 11, 2019; 84 FR 39183, Aug. 9, 2019]

§ 520.522 Cyclosporine.

(a) *Specifications.* (1) Each cyclosporine capsule, USP (MODIFIED) contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(2) Each milliliter of cyclosporine oral solution, USP (MODIFIED) contains 100 mg cyclosporine.

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

(1) No. 058198 for use of products described in paragraph (a) as in paragraph (d) of this section.

(2) No. 017033 for use of product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(3) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1) of this section.

(4) No. 013744 for use of product described in paragraph (a)(2) as in paragraph (d) of this section.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs.* Use capsules described in paragraph (a)(1) of this section as follow:

(i) *Amount.* Administer 5 mg per kilogram (mg/kg) of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(ii) *Indications for use.* For the control of atopic dermatitis in dogs weighing at least 4 pounds.

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

(2) *Cats.* Use the solution described in paragraph (a)(2) of this section as follow:

(i) *Amount.* Administer 7 mg/kg of body weight orally as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or twice weekly to maintain the desired therapeutic effect.

(ii) *Indications for use.* For the control of feline allergic dermatitis as manifested by excoriations (including facial and neck), miliary dermatitis, eosinophilic plaques, and self-induced alopecia in cats at least 6 months of age and at least 3 lbs (1.4 kg) in body weight.

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

[68 FR 54804, Sept. 19, 2003, as amended at 76 FR 78815, Dec. 20, 2011; 84 FR 12493, Apr. 2, 2019; 86 FR 17063, Apr. 1, 2021; 88 FR 16547, Mar. 20, 2023; 88 FR 27698, May 3, 2023; 89 FR 95103, Dec. 2, 2024]

§ 520.530 Cythioate oral liquid.

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 054771 and 058198 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

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

[49 FR 5614, Feb. 14, 1984, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28819, May 20, 2014; 86 FR 14818, Mar. 19, 2021; 87 FR 58961, Sept. 29, 2022]

§ 520.531 Cythioate tablets.

(a) *Specifications.* Each tablet contains 30 or 90 milligrams (mg) cythioate.

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

(1) No. 058198 for use of 30- and 90-mg tablets.

(2) No. 054771 for use of the 30-mg tablet.

(c) *Conditions of use*—(1) *Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

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

[49 FR 5615, Feb. 14, 1984, as amended at 59 FR 26942, May 25, 1994; 67 FR 78355, Dec. 24, 2002; 79 FR 28819, May 20, 2014; 86 FR 14818, Mar. 19, 2021]

§ 520.534 Decoquinate.

(a) *Specifications.* Each gram of powder contains 8 milligrams (0.8 percent) decoquinate.

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

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount.* Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use.* For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii.*

(3) *Limitations.* Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

[64 FR 10103, Mar. 2, 1999, as amended at 64 FR 30386, June 8, 1999; 79 FR 28819, May 20, 2014]

§ 520.538 Deracoxib.

(a) *Specifications.* Each tablet contains 12, 25, 50, 75, or 100 milligrams (mg) deracoxib.

(b) *Sponsors.* See Nos. 013744, 058198, and 086101 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as needed, as a single daily dose based on body weight:

(i) 1 to 2 mg/kilogram (kg) (0.45 to 0.91 mg/pound (lb)), for use as in paragraph (d)(2)(i) of this section.

(ii) 1 to 2 mg/kg (0.45 to 0.91 mg/lb) for 3 days, for use as in paragraph (d)(2)(ii) of this section.

(iii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(iii) of this section.

(2) *Indications for use.* (i) For the control of pain and inflammation associated with osteoarthritis.

(ii) For the control of postoperative pain and inflammation associated with dental surgery.

(iii) For the control of postoperative pain and inflammation associated with orthopedic surgery.

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

[67 FR 68760, Nov. 13, 2002, as amended at 68 FR 18882, Apr. 17, 2003; 72 FR 37437, July 10, 2007; 73 FR 33692, June 13, 2008; 77 FR 3928, Jan. 26, 2012; 84 FR 39183, Aug. 9, 2019; 86 FR 61684, Nov. 8, 2021]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications.* Each packet contains 10 milligrams (mg) of dexamethasone.

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

(c) *Conditions of use in cattle and horses*—(1) *Amount.* Administer 5 to 10 mg per animal the first day then 5 mg per day as required by drench or by sprinkling on a small amount of feed.

(2) *Indications for use.* As supportive therapy following parenteral steroid administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

[79 FR 28819, May 20, 2014]

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

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

(3) *Conditions of use in cattle and horses*—(i) *Amount.* Administer orally 5 to 10 milligrams on the first day, then 5 milligrams per day as required.

(ii) *Indications for use.* As supportive therapy following parenteral steroid administration for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(b)(1) *Specifications.* Each tablet contains 0.25 milligram of dexamethasone.

(2) *Sponsors.* See Nos. 000061 and 061133 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs and cats*—(i) *Amount.* Dogs: Administer orally 0.25 to 1.25 milligrams per day for up to 7 days. Cats: Administer orally 0.125 to 0.5 milligrams per day for up to 7 days.

(ii) *Indications for use.* As an anti-inflammatory agent.

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

[40 FR 26273, June 23, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 50 FR 49372, Dec. 2, 1985; 52 FR 7832, Mar. 13, 1987; 55 FR 8461, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 70 FR 16934, Apr. 4, 2005; 79 FR 28819, May 20, 2014; 84 FR 8972, Mar. 13, 2019]

§ 520.540c Dexamethasone chewable tablets.

(a) *Specifications.* Each half-scored tablet contains 0.25 milligram of dexamethasone.

(b) *Sponsor.* See No. 051031 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by free-choice feeding or crumbled over food 0.25 to 1.25 milligrams daily in single or two divided doses until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced by 0.125 milligram per day until maintenance level is achieved.

(2) *Indications for use.* As supportive therapy in nonspecific dermatosis and inflammatory conditions.

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

[44 FR 7130, Feb. 6, 1979, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28820, May 20, 2014; 82 FR 11508, Feb. 24, 2017]

§ 520.563 Diatrizoate.

(a) *Specifications.* Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. Administered rectally 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(2) *Indications for use.* For radiography of the gastrointestinal tract.

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

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985; 79 FR 28820, May 20, 2014]

§ 520.580 Dichlorophene and toluene.

(a) *Specifications.* Each capsule contains 50 milligrams (mg) of dichlorophene and 60 mg of toluene, or multiples thereof.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) Nos. 017135 and 023851 for use only as a single dose.

(2) Nos. 000061, 054771, and 069043 for use in a single dose or divided-dosage regimen.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use*—(1) *Amount.* Administer as follows:

(i) Single dose: Administer 100 mg of dicholorophene and 120 mg of toluene per pound of body weight.

(ii) Divided dose: Administer 100 mg of dichlorophene and 120 mg of toluene per 5 pounds of body weight (20 and 24 mg per pound) daily for 6 days.

(2) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and as an aid in removing tapeworms (*Taenia pisiformis*, *Dipylidium caninum*, and *Echinococcus granulosus*) from dogs and cats.

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward. Repeat treatment in 2 to 4 weeks in animals subject to reinfection.

[45 FR 10332, Feb. 15, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.580, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 520.581 Dichlorophene tablets.

(a) *Specifications.* Each tablet contains 1 gram of dichlorophene.

(b) *Sponsor.* See 023851 in § 510.600(c) of this chapter.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use. Dogs*—(1) *Amount.* Single dose of 1 tablet (1 gram of dichlorophene) for each 10 pounds of body weight.

(2) *Indications for use.* It is used as an aid in the removal of tapeworms (*Taenia pisiformis* and *Dipylidium caninum*).

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward.

[45 FR 10333, Feb. 15, 1980]

§ 520.596 Dichlorvos powder.

(a) *Specifications*—(1) Each 2-ounce packet contains 2.27 grams (4 percent) dichlorvos.

(2) Each milligram of powder contains 2.27 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section and the product described

in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See §556.180 of this chapter.

(d) *Conditions of use*—(1) *Swine (adult gilts, sows, and boars)*—(i) *Amount.* Add powder to the indicated amount of feed and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.08 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.08 ounce of dichlorvos
20–30	4	0.33	12
31–40	5	0.56	9
41–60	6	1.00	6
61–80	5	1.00	5
81–100	4	1.00	4
	16	4.00	4

(ii) *Indications for use.* For the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* spp.), large round-worm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(iii) *Limitations.* Do not use this product on animals either simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(2) *Horses*—(i) *Amount.* Administer in the grain portion of the ration at a dosage of 14.2 to 18.5 mg per pound of body weight as a single dose. Administered at one-half of the single recommended dosage and repeated 8 to 12 hours later in the treatment of very aged, emaciated, or debilitated subjects or those reluctant to consume medicated feed. In suspected cases of severe ascarid infection sufficient to cause concern over mechanical blockage of the intestinal tract, the split dosage should be used.

(ii) *Indications for use.* For the removal and control of bots (*Gastrophilus intestinalis*, *G. nasalis*), large strongyles (*Strongylus vulgaris*, *S. equinus*, *S. edentatus*), small strongyles (of the genera *Cyathostomum*, *Cylicocercus*, *Cylicocyclus*, *Cylicodontophorus*, *Triodontophorus*, *Poteriostomum*, *Gyalocephalus*), pinworms (*Oxyuris equi*), and large roundworm (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(iii) *Limitations.* Do not use in horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia, or colic. Do not administer in conjunction with or within 1 week of administration of muscle relaxant drugs, phenothiazine derived tranquilizers or central nervous system depressant drugs. Horses should not be subjected to insecticide treatment for 5 days prior to or after treating with the drug. Do not administer to horses afflicted with chronic alveolar emphysema (heaves) or related respiratory conditions. The product is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. Do not use in animals other than horses, ponies, and mules. Do not use in horses, ponies, and mules intended for food purposes. Do not allow fowl access to feed containing this preparation or to fecal excrement from treated animals.

[83 FR 48944, Sept. 28, 2018]

§ 520.598 Dichlorvos tablets.

(a) *Specifications.* Each tablet contains 2, 5, 10, or 20 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs, puppies, cats, and kittens*—(1) *Amount.* Administer orally at 5 mg dichlorvos per pound of body weight.

(2) *Indications for use*—(i) *Dogs and puppies:* Removal and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(ii) *Cats and kittens:* Removal and control of intestinal roundworms (*Toxocara cati* and *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme* and *Uncinaria stenocephala*).

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

[83 FR 48945, Sept. 28, 2018]

§ 520.600 Dichlorvos capsules and pellets.

(a) *Specifications.* Each capsule contains 2.27 milligrams (mg) (4 percent) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 mg of dichlorvos per pound of body weight.

(2) *Indications for use.* For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

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

[83 FR 48945, Sept. 28, 2018]

§ 520.602 Dichlorvos gel.

(a) *Specifications.* Each milligram (mg) of gel contains 2.27 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 mg per kilogram of body weight for the removal of bots and ascarids. Repeat administration every 21 to 28 days for the control of bots and ascarids. For the control of bots only, the repeat dosage is 10 milligrams per kilogram of body weight every 21 to 28 days during bot fly season.

(2) *Indications for use.* For the removal and control of first, second, and third instar bots (*Gastrophilus intestinalis* and *G. nasalis*), sexually mature and sexually immature (4th stage) ascarids (*Parascaris equorum*) in horses and foals.

(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.

[83 FR 48945, Sept. 28, 2018]

§ 520.606 Diclazuril.

(a) *Specifications.* Each 100 grams (g) of pellets contain 1.56 g diclazuril.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milligram (mg) per kilogram (0.45 mg per pound) of body weight in the daily grain ration for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(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.

[72 FR 20943, Apr. 27, 2007]

§ 520.608 Dicloxacillin.

(a) *Specifications.* Each capsule contains dicloxacillin sodium monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally 5 to 10 milligrams per pound of body weight, three times daily. In severe cases, up to 25 milligrams per pound of body weight three times daily.

(2) *Indications for use.* For the treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to dicloxacillin.

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

[57 FR 37325, Aug. 18, 1992, as amended at 79 FR 28820, May 20, 2014]

§ 520.620 Diethylcarbamazine oral dosage forms.

§ 520.622 Diethylcarbamazine citrate oral dosage forms.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) *Sponsors.* (1) [Reserved]

(2) See 054771 in § 510.600(c) of this chapter for use of 100, 200, and 300 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs.

(3) See 061133 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(4) [Reserved]

(5) See No. 000061 in § 510.600(c) of this chapter for use of 60, 120, or 180 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(6) See No. 069043 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use*—(1) *Dosage/indications for use.* (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

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

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 76 FR 17777, Mar. 31, 2011; 77 FR 4896, Feb. 1, 2012; 78 FR 21059, Apr. 7, 2013; 79 FR 28820, May 20, 2014; 83 FR 48945, Sept. 28, 2018; 84 FR 8972, Mar. 13, 2019]

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

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

(3) *Conditions of use.* (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina.* It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

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

(b) [Reserved]

(c)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor*. See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is used in dogs between 4 weeks and 8 months of age for the removal of ascarids (*Toxacara canis*) and in animals over 4 weeks of age for the prevention of heartworm disease (*Dirofilaria immitis*).

(ii) The drug is administered (*a*) for removal of ascarids at a dosage of 50 milligrams per pound of body weight divided into two equal doses and administered 8 to 12 hours apart (morning and night), orally or mixed with either dry or wet food, and (*b*) for prevention of heartworm disease at a dosage of 3 milligrams per pound of body weight daily, orally or in food, in heartworm endemic areas, from the beginning of mosquito activity, during the mosquito season, and for 2 months following the end thereof.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis*. Use of the drug is contraindicated in dogs with active *D. immitis* infections.

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 28265, July 9, 1976; 44 FR 3967, Jan. 19, 1979; 47 FR 14150, Apr. 2, 1982; 47 FR 35186, Aug. 13, 1982; 49 FR 33997, Aug. 28, 1984; 50 FR 41489, Oct. 11, 1985; 53 FR 47027, Oct. 18, 1988; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 77 FR 4897, Feb. 1, 2012; 78 FR 21059, Apr. 9, 2013; 79 FR 28820, May 20, 2014; 83 FR 48945, Sept. 28, 2018]

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Specifications*. Each chewable tablet contains 30, 45, 60, 120, 150, or 180 milligrams of diethylcarbamazine citrate.

(b) *Sponsors*. See drug listing nos. in § 510.600(c) of this chapter for identification of sponsors as follows:

(1) [Reserved]

(2) For 054771, use of 60, 120, or 180 milligram tablets as in paragraph (c)(2)(ii) of this section.

(3) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(iii) of this section.

(4) For 061133, use of 60-, 120-, or 180-milligram tablets as in paragraph (c)(2)(i) of this section.

(5) For 000061, use of 60-milligram tablets as in paragraph (c)(2)(i) of this section.

(6) For 069043, use of 30, 60, 120, or 180 milligram tablets as in paragraph (c)(2)(i) of this section.

(c) *Conditions of use*—(1) *Amount*. 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(2) *Indications for use*. (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats.

(ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.

(iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

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

[43 FR 6941, Feb. 17, 1978]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.622c, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 520.623 Diethylcarbamazine and oxibendazole chewable tablets.

(a) *Specifications*. Each tablet contains either 60, 120, or 180 milligrams of diethylcarbamazine citrate with 45, 91, or 136 milligrams of oxibendazole, respectively.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally to dogs at a dosage level of 6.6 milligrams of diethylcarbamazine citrate per kilogram of body weight (3 milligrams per pound of body weight) and 5.0 milligrams of oxibendazole per kilogram of body weight (2.27 milligrams per pound of body weight).

(2) *Indications for use*. For prevention of infection with *Dirofilaria immitis* (heartworm disease) and *Ancylostoma caninum* (hookworm infection) and for

removal and control of *Trichuris vulpis* (whipworm infection) and mature and immature stages of intestinal *Toxocara canis* (ascarid infection).

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

[50 FR 28768, July 16, 1985, as amended at 53 FR 45759, Nov. 14, 1988; 54 FR 3776, Jan. 26, 1989; 54 FR 6804, Feb. 14, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28820, May 20, 2014]

§ 520.666 Dirlotapide.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

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

(c) *Conditions of use in dogs*—(1) *Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

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

[72 FR 263, Jan. 4, 2007, as amended at 79 FR 28820, May 20, 2014]

§ 520.763 Dithiazanine oral dosage forms.

§ 520.763a Dithiazanine tablets.

(a) *Specifications.* Each tablet contains 10, 50, 100, or 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* Administer orally immediately after feeding as follows:

(i) For large roundworms (*Toxocara canis*, *Toxascaris leonina*): 10 mg per pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For Strongyloides (*Strongyloides canis*, *Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitus*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

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

[79 FR 28820, May 20, 2014, as amended at 83 FR 48945, Sept. 28, 2018]

§ 520.763b Dithiazanine powder.

(a) *Specifications.* Each tablespoon of powder contains 200 milligrams (mg) dithiazanine iodide.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* Administer orally by mixing in food as follows:

(i) For large roundworms (*Toxocara canis*, *Toxascaris leonina*): 10 mg per pound (/lb) of body weight for 3 to 5 days;

(ii) For hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*) and whipworms (*Trichuris vulpis*): 10 mg/lb of body weight for 7 days;

(iii) For Strongyloides (*Strongyloides canis*, *Strongyloides stercoralis*): 10 mg/lb of body weight for 10 to 12 days;

(iv) For heartworm microfilariae (*Dirofilaria immitus*): 3 to 5 mg/lb of body weight for 7 to 10 days. Treatment for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

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

[79 FR 28820, May 20, 2014, as amended at 83 FR 48945, Sept. 28, 2018]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of suspension contains 69 milligrams (mg) dithiazanine iodide and 83 mg piperazine base (as piperazine citrate).

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 1 ounce (30 milliliters) per 100

pounds of body weight for the first 500 pounds; ¾ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10¼ ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum;* small strongyles; large strongyles, *Strongylus vulgaris;* and pinworms, *Oxyuris equi.*

(3) *Limitations.* Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 78 FR 21059, Apr. 9, 2013; 79 FR 28820, May 20, 2014; 83 FR 48945, Sept. 28, 2018]

§ 520.766 Domperidone.

(a) *Specifications.* Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) *Indications for use.* For prevention of fescue toxicosis in periparturient 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.

[75 FR 67031, Nov. 1, 2010]

§ 520.784 Doxylamine.

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

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

(c) *Conditions of use*—(1) *Amount.* Horses: Administer orally 1 to 2 milligrams (mg) per pound (/lb) of body weight per day divided into 3 or 4 equal doses. Dogs and cats: Administer orally 2 to 3 mg/lb of body weight per day divided into 3 or 4 equal doses.

(2) *Indications for use.* For use when antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(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.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 79 FR 28821, May 20, 2014]

§ 520.812 Enrofloxacin.

(a) *Specifications.* (1) Each tablet contains:

(i) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(ii) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(2) Each chewable tablet contains 22.7, 68.0, or 136.0 mg enrofloxacin.

(3) Each soft chewable tablet contains 22.7, 68.0, or 136.0 mg enrofloxacin.

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

(1) No. 058198 for use of products described in paragraph (a) of this section.

(2) Nos. 017033 and 086117 for use of product described in paragraph (a)(1)(i) of this section.

(3) Nos. 055529 and 086101 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally as a single, daily dose or divided into two equal doses at 12-hour intervals.

(i) *Dogs.* 5 to 20 mg per kilogram (/kg) (2.27 to 9.07 mg per pound (/lb)) of body weight.

(ii) *Cats.* 5 mg/kg (2.27 mg/lb) of body weight.

(2) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

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

licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[78 FR 30197, May 22, 2013, as amended at 78 FR 52853, Aug. 27, 2013; 84 FR 8972, Mar. 13, 2019; 84 FR 53310, Oct. 7, 2019; 86 FR 13184, Mar. 8, 2021; 87 FR 58961, Sept. 29, 2022; 88 FR 27698, May 3, 2023]

§ 520.816 Epsiprantel.

(a) *Specifications.* Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis.*

(2) *Cats*—(i) *Amount.* 1.25 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of feline cestodes *D. caninum* and *T. taeniaeformis.*

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

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28821, May 20, 2014; 83 FR 64740, Dec. 18, 2018]

§ 520.823 Erythromycin.

(a) *Specifications.* Each gram of powder contains erythromycin phosphate equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

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

(1) *Broiler and replacement chickens*—(i) *Amount.* Administer 0.500 gram per gallon for 5 days.

(ii) *Indications for use.* As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Replacement chickens and chicken breeders*—(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

(ii) *Indications for use.* As an aid in the control of infectious coryza due to *Haemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Growing turkeys*—(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

(ii) *Indications for use.* As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations.* Do not use in turkeys producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 79 FR 28821, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 94989, Dec. 27, 2016; 84 FR 8972, Mar. 13, 2019]

§ 520.852 Estriol.

(a) *Specifications.* Each tablet contains 1 milligram (mg) estriol.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer at an initial dose of 2 mg per dog per day. The dosage may be titrated to as low as 0.5 mg per dog every second day, depending on response.

(2) *Indications for use.* For the control of estrogen-responsive urinary incontinence in ovariohysterectomized female dogs.

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

[76 FR 78150, Dec. 16, 2011]

§ 520.863 Ethylisobutrazine.

(a) *Specifications.* Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally 2 to 5 milligrams per pound of body weight once daily.

(2) *Indications for use.* As a tranquilizer.

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

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 79 FR 28821, May 20, 2014]

§ 520.903 Febantel oral dosage forms.

§ 520.903a Febantel paste.

(a) *Specifications.* Each gram of paste contains 455 milligrams (45.5 percent) febantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer paste orally at 6 milligrams per kilogram (2.73 milligrams per pound) of body weight on the base of the tongue or well mixed into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use.* For removal of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); ascarids (*Parascaris equorum*—sexually mature and immature); pinworms (*Oxyuris equi*—adult and 4th stage larva); and various small strongyles in horses, foals, and ponies.

(3) *Limitations.* Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[79 FR 28821, May 20, 2014, as amended at 86 FR 14818, Mar. 19, 2021]

§ 520.903b Febantel suspension.

(a) *Specifications.* Each ounce of suspension contains 2.75 grams (9.3 percent ounce) febantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight). Administer by stomach tube or drench, or by mixing well into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.

(2) *Indications for use.* For removal of ascarids (*Parascaris equorum*—adult and sexually immature), pinworms (*Oxyuris equi*—adult and 4th stage larvae), large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*), and various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.

(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.

(d) *Special considerations.* Febantel suspension may be used in combination with trichlorfon oral liquid in accordance with the provisions of § 520.2520c, this section, and the following conditions:

(1) Combine 1 part febantel suspension with 5 parts trichlorfon liquid.

(2) Allow animal to consume a portion of daily grain ration; administer mixture by stomach tube at rate of 18 milliliters per 100 pounds of body weight.

[45 FR 8587, Feb. 8, 1980, as amended at 79 FR 28821, May 20, 2014; 86 FR 14818, Mar. 19, 2021]

§ 520.903c Febantel and praziquantel paste.

(a) *Specifications.* Each gram of paste contains 34 milligrams of febantel and 3.4 milligrams of praziquantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) Dogs and cats (over 6 months of age): 10 milligrams of febantel and 1 milligram of praziquantel per kilogram of body weight (1 gram of paste per 7.5 pounds body weight) administered by mouth or in the food once daily for 3 days.

(ii) Puppies and kittens (less than 6 months of age): 15 milligrams of febantel and 1.5 milligrams of praziquantel per kilogram of body weight (1 gram of paste per 5 pounds body weight) administered by mouth on a full stomach once daily for 3 days.

(2) *Indications for use.* (i) Dogs and puppies: For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(ii) Cats and kittens: For removal of hookworms (*Ancylostoma tubaeforme*), ascarids (*Toxocara cati*) and tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*).

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

[50 FR 19167, May 7, 1985, as amended at 53 FR 48533, Dec. 1, 1988; 56 FR 50813, Oct. 9, 1991; 79 FR 28821, May 20, 2014. Redesignated at 85 FR 18119, Apr. 1, 2020; 86 FR 14818, Mar. 19, 2021]

§ 520.903d Febantel tablets.

(a) *Specifications.* Each scored tablet contains 27.2 milligrams of febantel for use in dogs, puppies, cats, and kittens or 163.3 milligrams of febantel for use in dogs, puppies, and cats.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats.* Ten milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(ii) *Puppies and kittens fewer than 6 months of age.* Fifteen milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(2) *Indications for use.* (i) For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*) and whipworms (*Trichuris vulpis*) in dogs and puppies.

(ii) For removal of hookworms (*Ancylostoma tubaeforme*) and ascarids (*Toxocara cati*) in cats and kittens.

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

[56 FR 50655, Oct. 8, 1991, as amended at 79 FR 28821, May 20, 2014. Redesignated at 85 FR 18119, Apr. 1, 2020, as amended at 86 FR 14818, Mar. 19, 2021]

§ 520.905 Fenbendazole oral dosage forms.

§ 520.905a Fenbendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) fenbendazole for use as in paragraphs (e)(1), (2), (3), and (4) of this section; or 200 mg fenbendazole for use as in paragraphs (e)(5) and (6) of this section.

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

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* (1) See § 500.25 of this chapter.

(2) Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (e) of this section and for treating infections of stomach bot as provided in § 520.2520, have been shown to be compatible and not to interfere with one another.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally 5 mg per kilogram (/kg) (2.3 mg per pound (/lb)) for the control of large strongyles, small strongyles, and pinworms; 10 mg/kg for the control of ascarids.

(ii) *Indications for use.* For the treatment and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* species), small strongyles (*Cyathostomum* species, *Cylicocyclus* species, *Cylicostephanus* species, *Cylicodontophorus* species), pinworms (*Oxyuris equi*) and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Beef and dairy cattle*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*); adult and fourth-stage larvae barberpole worms (*Haemonchus contortus* and *H. placei*); adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small

intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations.* Milk taken from cows during treatment and for 48 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

(3) *Beef cattle*—(i) *Amount.* Administer orally 4.6 mg/lb of body weight (10 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (fourth-stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi,* and tapeworms, *Moniezia benedeni.*

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta.*

(iii) *Limitations.* Goats must not be slaughtered for human consumption within 6 days following last treatment with this drug product. Because a milk discard time has not been established, do not use in lactating goats.

(5) *Chickens*—(i) *Amount.* Administer orally via drinking water at a daily dose of 1 mg/kg body weight (0.454 mg/lb) for 5 consecutive days.

(ii) *Indications for use.* For the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens, and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens and laying hens.

(6) *Swine, except for nursing piglets*—(i) *Amount.* Administer orally via the drinking water at a daily dose of 2.2 mg/kg of body weight (1.0 mg/lb) for 3 consecutive days.

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult *Metastrongylus apri,* Adult *Metastrongylus pudendotectus;* Gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (*Ascaris suum*), Adult nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*), Adult small stomach worms (*Hyostrongylus rubidus*), Adult and larvae (L2, L3, L4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and Kidney worms: Adult and larvae *Stephanurus dentatus.*

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days from the last treatment.

[42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998; 66 FR 47960, Sept. 17, 2001; 68 FR 26205, May 15, 2003; 74 FR 17770, Apr. 17, 2009; 74 FR 61516, Nov. 25, 2009; 76 FR 17336, Mar. 29, 2011; 80 FR 76386, Dec. 9, 2015; 81 FR 22523, Apr. 18, 2016; 86 FR 14818, Mar. 19, 2021; 86 FR 61684, Nov. 8, 2021; 87 FR 58961, Sept. 29, 2022]

§ 520.905b Fenbendazole granules.

(a) *Specifications.* Each gram of granules contains 222 milligrams (mg) fenbendazole.

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

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.

(ii) *Indications for use.* For the control of infections of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Sprinkle the appropriate amount of drug on a small

amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food.

(2) *Dogs*—(i) *Amount.* 50 mg/kg daily for 3 consecutive days.

(ii) *Indications for use.* For the treatment and control of ascarids (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed.

(3) *Zoo and wildlife animals*—(i) *Amount.* 10 mg/kg per day for 3 days.

(ii) *Indications for use.* For control of internal parasites of *Felidae* and *Ursidae* as follows:

(A) Lion (*Panthera leo*) and Tiger (*Panthera tigris*): Ascarid (*Toxocara cati, Toxascaris leonina*), Hookworm (*Ancylostoma* spp.).

(B) Cheetah (*Acinonyx jubatus*): Ascarid (*Toxocara cati, Toxascaris leonina*).

(C) Puma (*Felis concolor*), Panther (*Panthera* spp.), Leopard (*Panthera pardus*), Jaguar (*Panthera onca*): Ascarid (*Toxocara cati, Toxascaris leonina*), Hookworm (*Ancylostoma* spp.), Tapeworm (*Taenia hydatigena, T. krabbei, T. taeniaeformis*).

(D) Black Bear (*Ursus americanus*): Ascarid (*Baylisascaris transfuga, Toxascaris leonina*), Hookworm (*Ancylostoma caninum*), Tapeworm (*Taenia hydatigena, T. krabbei*).

(E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga, Toxascaris leonina*).

(iii) *Limitations.* Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994; 66 FR 47960, Sept. 17, 2001; 67 FR 47450, July 19, 2002; 71 FR 19429, Apr. 14, 2006; 74 FR 61516, Nov. 25, 2009]

§ 520.905c Fenbendazole paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).

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

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Indications for use and amounts.* (A) For the treatment and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*). For large strongyles, small strongyles, and pinworms, the recommended dose is 5 mg/kg (2.3 mg/lb).

(B) For treatment and control of ascarids (*Parascaris equorum*). For ascarids, the recommended dose is 10 mg/kg (4.6 mg/lb).

(C) For treatment and control of hypobiotic (encysted early third-stage), late third-stage, and fourth-stage cyathostome larvae, as well as fourth-stage *Strongylus vulgaris* larvae, the recommended dose is 10 mg/kg (4.6 mg/lb) daily for 5 consecutive days.

(D) For the control of arteritis caused by fourth-stage larvae of *Strongylus vulgaris* in horses.

(E) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Beef and dairy cattle*—(i) *Amount.* Administer orally 2.3 mg/lb (5 mg/kg) body weight.

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small

intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations.* Milk taken during treatment and for 96 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

[72 FR 24185, May 2, 2007, as amended at 74 FR 61516, Nov. 25, 2009; 76 FR 17337, Mar. 29, 2011; 86 FR 57996, Oct. 20, 2021; 87 FR 10968, Feb. 28, 2022]

§ 520.905d Fenbendazole powder.

(a) *Specifications.* Each 2-ounce packet contains 2.27 grams (4 percent) fenbendazole.

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

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use.* It is administered to swine as follows:

(1) *Amount.* 3 milligrams fenbendazole per kilogram body weight per day (1.36 milligrams per pound per day).

(2) *Indications for use.* For removal and control of large roundworms (*Ascaris suum*); lungworms (*Metastrongylus apri*); nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*); whipworms (*Trichuris suis*); and kidneyworms (*Stephanurus dentatus*—mature and immature).

(3) *Limitations.* Thoroughly mix the contents of the packet(s) with swine ration and administer according to label directions. Feed as sole ration for 3 consecutive days. Can be fed to pregnant sows. No prior withdrawal of feed or water is necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 18090, Apr. 27, 1984, as amended at 49 FR 20485, May 15, 1984; 66 FR 47960, Sept. 17, 2001; 70 FR 32489, June 3, 2005; 74 FR 61516, Nov. 25, 2009; 83 FR 48945, Oct. 9, 2018]

§ 520.928 Firocoxib tablets.

(a) *Specifications.* (1) Each chewable tablet contains 57 or 227 milligrams (mg) firocoxib.

(2) Each tablet contains 57 mg firocoxib.

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

(1) Nos. 000010, 013744, 055246, 055529, and 086101 for use of products described in paragraph (a)(1) as in paragraph (c)(1) of this section; and

(2) Nos. 000010 and 055246 for use of the product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 mg/kg (2.27 mg/lb) body weight. Administer once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. Administer approximately 2 hours before soft tissue or orthopedic surgery.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis; and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

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

(2) *Horses*—(i) *Amount.* Administer one 57-mg tablet to horses weighing 800 to 1,300 lb once daily for up to 14 days.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(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.

[69 FR 51171, Aug. 18, 2004, as amended at 73 FR 2808, Jan. 16, 2008; 73 FR 64885, Oct. 31, 2008; 81 FR 67151, Sept. 30, 2016; 87 FR 58961, Sept. 29, 2022; 88 FR 14897, Mar. 10, 2023; 88 FR 55563, Aug. 16, 2023; 88 FR 84700, Dec. 6, 2023; 89 FR 42357, May 15, 2024]

§ 520.929 Firocoxib solution.

(a) *Specifications.* Each milliliter of solution contains 9 milligram (mg) firocoxib.

(b) *Sponsors.* See No. 051072 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 0.1 mg per kilogram (0.045 mg per pound) of body weight once daily for up to 14 days.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(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.

[89 FR 42357, May 15, 2024]

§ 520.930 Firocoxib paste.

(a) *Specifications*. Each milligram (mg) of paste contains 0.82 mg firocoxib.

(b) *Sponsors*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.1 mg per kilogram (0.045 mg per pound) body weight daily for up to 14 days.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(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.

[71 FR 5788, Feb. 3, 2006, as amended at 84 FR 39183, Aug. 9, 2019]

§ 520.955 Florfenicol.

(a) *Specifications*. Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

(b) *Sponsors*. See Nos. 000061, 054925, and 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.283 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount*. Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis*.

(3) *Limitations*. Do not slaughter within 16 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 78357, Dec. 24, 2002, as amended at 72 FR 262, Jan. 4, 2007; 78 FR 52854, Aug. 27, 2013; 82 FR 12169, Mar. 1, 2017]

§ 520.960 Flumethasone.

(a) *Specifications*. Each tablet contains 0.0625 milligram of flumethasone.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs:* Administer orally from 0.0625 to 0.25 milligram daily in divided doses.

(ii) *Cats:* Administer orally from 0.03125 to 0.125 milligram daily in divided doses.

(2) *Indications for use*—(i) *Dogs:* It is used for musculoskeletal conditions due to inflammation of muscles or joints and accessory structures, where permanent structural changes do not exist, such as arthritis, the disc syndrome, and myositis.

(ii) *Dogs and cats:* It is used in certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

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

[44 FR 7131, Feb. 6, 1979, as amended at 61 FR 5506, Feb. 13, 1996; 79 FR 28821, May 20, 2014]

§ 520.970 Flunixin.

(a) *Specifications*. (1) Each 10-gram (g) packet of granules contains flunixin meglumine equivalent to 250 milligrams (mg) of flunixin.

(2) Each 30-g syringe of paste contains flunixin meglumine equivalent to 1,500 mg of flunixin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of products described in paragraph (a).

(2) No. 061133 for use of the product described in paragraph (a)(2).

(c) *Conditions of use in horses*—(1) *Amount*. 0.5 mg per pound of body weight per day for up to 5 days.

(2) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders.

(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.

[76 FR 53051, Aug. 25, 2011, as amended at 79 FR 74020, Dec. 15, 2014; 84 FR 8972, Mar. 13, 2019]

§ 520.980 Fluoxetine.

(a) *Specifications.* Each chewable tablet contains 8, 16, 32, or 64 milligrams (mg) fluoxetine hydrochloride.

(b) *Sponsor.* See No. 055246 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 1 to 2 mg per kilogram body weight once daily.

(2) *Indications for use.* For the treatment of canine separation anxiety in conjunction with a behavior modification plan.

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

[72 FR 6463, Feb. 12, 2007, as amended at 79 FR 74020, Dec. 15, 2014; 82 FR 21690, May 10, 2017]

§ 520.998 Fluralaner.

(a) *Specifications.* (1) Each chewable tablet contains 112.5, 250, 500, 1,000, or 1,400 milligrams (mg) fluralaner.

(2) Each chewable tablet contains 45, 100, 200, 400, or 560 mg fluralaner.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose with food:

(i) *Chewable tablets described in paragraph (a)(1) of this section.* Administer every 12 weeks, an appropriate combination of tablets to provide a minimum dose of 11.4 mg per pound (lb) (25 mg per kilogram (kg)) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(ii) *Chewable tablets described in paragraph (a)(2) of this section.* Administer monthly, an appropriate combination of tablets to provide a minimum dose of 4.5 mg/lb (10 mg/kg) body weight.

(2) *Indications for use*—(i) *Chewable tablets described in paragraph (a)(1) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater.

(ii) *Chewable tablets described in paragraph (a)(2) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*), and the treatment and control of tick infestations (*I. scapularis* (black-legged tick), *D. variabilis* (American dog tick), *R. sanguineus* (brown dog tick), and *H. longicornis* (Asian longhorned tick)) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 4.4 lb or greater; and for the treatment and control of *A. americanum* (lone star tick) infestations for 1 month in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

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

[86 FR 14818, Mar. 19, 2021, as amended at 88 FR 27698, May 3, 2023; 90 FR 6800, Jan. 21, 2025]

§ 520.1010 Furosemide.

(a) *Specifications.* (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use of dosage forms and strengths listed in paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000061 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and

powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

(3) Nos. 058829 and 069043 for use of syrup in paragraph (a)(4) of this section for conditions of use in paragraph (d)(2)(i) and (d)(2)(ii)(A) of this section.

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

(d) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount.* 1 to 2 mg per pound (/lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) *Indications for use.* For treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) *Dogs*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use.* (A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) *Cats*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use.* For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

[66 FR 47960, Sept. 17, 2001, as amended at 69 FR 74419, Dec. 14, 2004; 70 FR 50182, Aug. 26, 2005; 70 FR 76396, Dec. 27, 2005; 74 FR 61516, Nov. 25, 2009; 78 FR 17596, Mar. 22, 2013; 81 FR 17607, Mar. 30, 2016]

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications.* Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

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

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*

(3) *Limitations.* Do not slaughter treated swine for food for at least 3 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997; 71 FR 13542, Mar. 16, 2006; 81 FR 94989, Dec. 27, 2016; 88 FR 84700, Dec. 6, 2023]

§ 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications.* Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use.* In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations.* For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment. Federal law restricts

this drug to use by or on the order of a licensed veterinarian.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997; 78 FR 17596, Mar. 22, 2013; 81 FR 22523, Apr. 18, 2016; 88 FR 27698, May 3, 2023]

§ 520.1044c Gentamicin sulfate powder.

(a) *Specifications.* Each gram of powder contains gentamicin sulfate equivalent to:

(1) 16.7, 66.7, or 333.3 milligrams (mg) gentamicin.

(2) 333.3 mg gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) No. 000061 for products described in paragraph (a)(1) of this section.

(2) Nos. 016592 and 061133 for product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water for 3 consecutive days as follows:

(i) For colibacillosis: Gentamicin sulfate equivalent to 25 mg of gentamicin per gallon of drinking water to provide 0.5 mg per pound of body weight per day;

(ii) For swine dysentery: Gentamicin sulfate equivalent to 50 mg of gentamicin per gallon of drinking water to provide 1 mg per pound of body weight per day. Treatment may be repeated if dysentery recurs.

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Brachyspira hyodysenteriae.*

(3) *Limitations.* Withdrawal period: 10 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 4226, Jan. 27, 2012, as amended at 81 FR 94989, Dec. 27, 2016; 83 FR 48945, Sept. 28, 2018; 84 FR 8972, Mar. 13, 2019; 87 FR 10968, Feb. 28, 2022]

§ 520.1060 Glucose and glycine.

(a) *Specifications.* Each packet of powder contains 8.82 grams sodium chloride, 4.20 grams potassium phosphate, 0.5 gram citric acid anhydrous, 0.12 gram potassium citrate, 6.36 grams aminoacetic acid (glycine), and 44.0 grams glucose.

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

(c) *Conditions of use in calves*—(1) *Amount.* Dissolve each packet in 2 quarts of warm water and administer to each calf as follows:

(i) *Scouring and/or dehydrated calves.* Feed 2 quarts of solution, twice daily for 2 days (four feedings). No milk or milk replacer should be fed during this period. For the next four feedings (days 3 and 4), use 1 quart of solution together with 1 quart of milk replacer. Thereafter, feed as normal.

(ii) *Newly purchased calves.* Feed 2 quarts of solution instead of milk as the first feed upon arrival. For the next scheduled feeding, use 1 quart of solution mixed together with 1 quart of milk or milk replacer. Thereafter, feed as normal.

(2) *Indications for use.* For control of dehydration associated with diarrhea (scours); and as an early treatment at the first signs of scouring. It may also be used as followup treatment following intravenous fluid therapy.

(3) *Limitations.* The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. A veterinarian should be consulted in severely scouring calves. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

[79 FR 28821, May 20, 2014]

§ 520.1084 Grapiprant.

(a) *Specifications.* Each tablet contains 20, 60, or 100 milligrams (mg) grapiprant.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.9 mg/lb (2 mg/kg) once daily by mouth.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in dogs.

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

[81 FR 36789, June 8, 2016, as amended at 83 FR 14587, Apr. 5, 2018]

§ 520.1100 Griseofulvin.

(a) *Specifications.* (1) The powder complies with U.S.P. for griseofulvin, microsize.

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

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

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 061133 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

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

(d) *Conditions of use*—(1) *Horses*—(i) *Amount and indications for use.* (A) For equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of this section daily for not less than 10 days as follows: adults, 1 bolus; yearlings, one-half to 1 bolus; and foals, one-half bolus.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(A) Daily (single or divided) dose as follows: For animals weighing up to 6 pounds: 62.5 milligrams; for animals weighing 6 to 18 pounds: 125 milligrams; for animals weighing 18 to 36 pounds: 250 milligrams; for animals weighing 36 to 48 pounds: 375 milligrams; for animal weighing 48 to 75 pounds: 500 milligrams.

(B) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight × body weight × number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes, T. rubrum, T. schoenleini, T. sulphurem, T. verrucosum, T. interdigitale, Epidermophyton floccosum, Microsporum gypseum, M. canis, M. audouini.*

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989; 71 FR 38073, July 5, 2006; 77 FR 28253, May 14, 2012; 78 FR 28822, May 20, 2014; 84 FR 8972, Mar. 13, 2019]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Specifications.* Each packet contains 141.5 grams haloxon.

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

(c) *Special considerations.* Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(d) *Related tolerances.* See § 556.310 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Dissolve each packet in 32 fluid ounces of water and administer as follows: For animals weighing up to 100 pounds: ½ fluid ounce; for animals weighing 100 to 150 pounds: ¾ fluid ounce; for animals weighing 150 to 200 pounds: 1 fluid ounce; for animals weighing 200 to 300 pounds: 1 ½ fluid ounces; for animals weighing 300 to 450 pounds: 2 fluid ounces; for animals weighing 450 to 700 pounds: 3 fluid ounces; for animals weighing 700 to 1,000 pounds: 4 fluid ounces; for animals weighing 1,000 to 1,200 pounds: 5 fluid ounces; for animals weighing over 1,200 pounds: 6 fluid ounces. Retreat in 3 to 4 weeks.

(2) *Indications for use.* For control of gastrointestinal roundworms of the

genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations*. Do not treat dairy animals of breeding age. Do not treat within 1 week of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997; 78 FR 28822, May 20, 2014]

§ 520.1120b Haloxon boluses.

(a) *Specifications*. Each bolus contains 10.1 grams of haloxon.

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

(c) *Related tolerances*. See § 556.310 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Administered one bolus per 500 pounds body weight (35 to 50 milligrams per kilogram of body weight). Retreat in 3 to 4 weeks.

(2) *Indications for use*. For control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(3) *Limitations*. Do not treat dairy animals of breeding age or older. Do not treat within 1 week of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 61591, Oct. 29, 1979; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 78 FR 28822, May 20, 2014]

§ 520.1136 Ilunocitinib.

(a) *Specifications*. Each tablet contains 4.8, 6.4, 8.5, and 15 milligrams (mg) ilunocitinib.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer orally 0.27 to 0.36 mg ilunocitinib/lb (0.6 to 0.8 mg ilunocitinib/kg) body weight, once daily, with or without food.

(2) *Indications for use*. For the control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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

[89 FR 95103, Dec. 2, 2024]

§ 520.1150 Imepitoin.

(a) *Specifications*. Each tablet contains 100 or 400 milligrams (mg) imepitoin.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer orally twice daily, approximately 12 hours apart, at a dose of 13.6 mg per pound (30 mg/kg) of body weight. Initiate therapy starting 2 days prior to the day of the expected noise event and continuing through the noise event.

(2) *Indications for use*. For the treatment of noise aversion in dogs.

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

[84 FR 12494, Apr. 2, 2019]

§ 520.1156 Imidacloprid.

(a) *Specifications*. Each chewable tablet contains 7.5 or 37.5 milligrams (mg) imidacloprid.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer daily one 7.5-mg chewable tablet to dogs weighing 4 to 22 pounds (lb) or one 37.5-mg chewable table to dogs weighing 23 to 110 lb.

(2) *Indications for use*. Kills adult fleas and is indicated for the treatment of flea infestations on dogs and puppies 10 weeks of age and older and weighing 4 lb or greater.

(3) *Limitations*. Do not give to puppies younger than 10 weeks of age or to dogs weighing less than 4 lb. Do not give more than one tablet a day.

[80 FR 18775, Apr. 8, 2015, as amended at 86 FR 14818, Mar. 19, 2021]

§ 520.1157 Iodinated casein.

(a) *Specifications*. Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor*. See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. ⅕ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use*. For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

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

[49 FR 22469, May 30, 1984, as amended at 78 FR 28822, May 20, 2014]

§ 520.1158 Iodochlorhydroxyquin.

(a) *Specifications.* Each bolus contains 10 grams of iodochlorhydroxyquin.

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

(c) *Conditions of use*—(1) *Amount.* 1 bolus (10 grams) daily for a 1,000-pound horse.

(2) *Indications for use.* For treatment of equine diarrhea.

(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.

[48 FR 8054, Feb. 25, 1983, as amended at 50 FR 41489, Oct. 11, 1985; 78 FR 28822, May 20, 2014]

§ 520.1189 Itraconazole.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) of itraconazole.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 5 mg/kilogram (kg) (0.5 mL/kg) of body weight once daily on alternating weeks for 3 treatment cycles.

(2) *Indications for use.* For the treatment of dermatophytosis caused by *Microsporum canis* in cats.

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

[82 FR 12169, Mar. 1, 2017, as amended at 86 FR 57996, Oct. 20, 2021]

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 000010 for use of a 1.87 percent paste as in (e)(1) of this section and a 0.153 percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311, 054925, 058198, and 061133 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. Including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. Including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. Including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. Including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. Including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. Including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata*, *Haemonchus placei*,

Trichostrongylus axei, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); and sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*).

(iii) *Limitations.* For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000; 67 FR 71820, Dec. 3, 2002; 68 FR 43294, July 22, 2003; 69 FR 59131, Oct. 4, 2004; 70 FR 8514, Feb. 22, 2005; 71 FR 40010, July 14, 2006; 71 FR 67298, Nov. 21, 2006; 73 FR 34184, June 17, 2008; 74 FR 6542, Feb. 10, 2009; 78 FR 17596, Mar. 22, 2013; 84 FR 8972, Mar. 13, 2019; 84 FR 39183, Aug. 9, 2019; 86 FR 14818, Mar. 19, 2021]

§ 520.1193 Ivermectin tablets and chewables.

(a) *Specifications.* (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000010 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 069043 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

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

(d) *Conditions of use*—(1) *Dogs.* For use in dogs 6 weeks of age and older as follows:

(i) *Amount.* 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound (lb)), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(2) *Cats.* For use in cats 6 weeks of age and older as follows:

(i) *Amount.* Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use.* To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense.*

[67 FR 11230, Mar. 13, 2002, as amended at 67 FR 21996, May 2, 2002; 69 FR 43735, July 22, 2004; 81 FR 17607, Mar. 30, 2016; 84 FR 39183, Aug. 9, 2019]

§ 520.1194 Ivermectin meal.

(a) *Specifications.* Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount.* Administer 136 micrograms (mcg) ivermectin per pound (/lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. Including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. Including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. Including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. Including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C.*

brevicapsulatus, *Cylicodontophorus* spp., *Cylicostephanus* spp. Including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large Mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): G*asterophilus* spp. Including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. Cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Limitations. Do not use in horses intended for human consumption.

[70 FR 1817, Jan. 11, 2005, as amended at 70 FR 19262, Apr. 13, 2005]

§ 520.1195 Ivermectin liquid.

(a) *Specifications.* (1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

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

(1) Nos. 058005 and 058198 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) No. 058829 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) Nos. 000010 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms (mcg) per kilogram (/kg) of body weight as a single dose by stomach tube or as an oral drench.

(ii) *Indications for use.* For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. Including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. Including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. Including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. Including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. Including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. Including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults), *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. Cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(B) Large Strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. endentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); Small Strongyles including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); Ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); Hairworms (*Trichostongylus axei* (adult)); Large mouth Stomach Worms (*Habronema muscae* (adult)); Stomach Bots (*Gastrophilus* spp. (oral and gastric stages)); Lungworms (*Dictyocaulus arnfieldi* (adult and fourth-stage larvae)); intestinal threadworms

(*Strongyloides westeri* (adult)); Summer Sores caused by *Habronema* and *Draschia* spp. Cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(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.

(2) *Sheep*—(i) *Amount.* 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) *Indications for use.* For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (*Haemonchus contortus, H. placei* (adults only), *Ostertagia circumcincta, Trichostrongylus axei, T. colubriformis, Cooperia oncophora* (adults only), *C. curticei, Oesophagostomum columbianum, O. venulosum* (adults only), *Nematodirus battus, N. spathiger, S. papillosus* (adults only), *Chabertia ovina* (adult only), *Trichuris ovis* (adults only)); lungworms (*D. filaria*); and all larval stages of the nasal bot *Oestrus ovis.*

(iii) *Limitations.* For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

[67 FR 50597, Aug. 5, 2002, as amended at 69 FR 57173, Sept. 24, 2004; 71 FR 13542, Mar. 16, 2006; 71 FR 38072, July 5, 2006; 72 FR 9456, Feb. 21, 2008; 78 FR 17596, Mar. 22, 2013; 79 FR 10964, Feb. 27, 2014; 84 FR 39183, Aug. 9, 2019; 86 FR 14818, Mar. 19, 2021; 88 FR 27698, May 3, 2023; 88 FR 84700, Dec. 6, 2023]

§ 520.1196 Ivermectin and pyrantel tablets.

(a) *Specifications.* Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg and 114 mg, or 272 µg and 227 mg, respectively.

(b) *Sponsors.* See Nos. 000010, 051311, and 053701 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer a minimum of 6 µg of ivermectin and 5 mg of pyrantel per kilogram (2.72 µg and 2.27 mg per pound) of body weight monthly.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for up to a month (30 days) after infection and treatment and control of adult roundworms *Toxocara canis* and *Toxascaris leonina,* and adult hookworms *Ancylostoma caninum, A. braziliense,* and *Uncinaria stenocephala.*

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

(2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997; 66 FR 35756, July 9, 2001; 67 FR 21996, May 2, 2002; 68 FR 55823, Sept. 29, 2003; 78 FR 28822, May 20, 2014; 84 FR 39183, Aug. 9, 2019; 88 FR 16547, Mar. 20, 2023; 89 FR 42357, May 15, 2024]

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances. See § 556.344 of this chapter.*

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms *Haemonchus placei, Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei, T. colubriformis, Cooperia* spp., *Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum;* lungworms *Dictyocaulus viviparus;* grubs *Hypoderma* spp.; sucking lice *Linognathus vituli, Solenopotes capillatus;* mange mites *Psoroptes ovis, Sarcoptes scabiei,* and ticks *Amblyomma americanum.*

(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do

not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000; 84 FR 39183, Aug. 9, 2019]

§ 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains:

(1) 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(2) 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.—

(1) No. 000010 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.

(2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount.* (i) 200 micrograms (mcg) per kilogram (/kg) ivermectin (91 mcg per pound (/lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.

(ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.

(iii) 200 mcg/kg ivermectin (91 mcg/lb) and 2.5 mg/kg praziquantel (1.14 mg/lb).

(2) *Indications for use.* (i) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp. Including *T. brevicauda* and *T. serratus,* and *Craterostomum acuticaudatum;* Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. Including *C. coronatus, C. labiatus,* and *C. labratus; Cyathostomum* spp. Including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. Including *C. insigne, C. leptostomum, C. nassatus,* and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. Including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus,* and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Largemouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp. Including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. Cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

(ii) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp.; *Cylicocyclus* spp.; *Cylicostephanus* spp., *Cylicodontophorus* spp.; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Largemouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp.; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. Cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) For treatment and control of the following parasites in horses over 5 months of age: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp. Including *T. brevicauda* and *T. serratus,* and

Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. Including *C. coronatus*, *C. labiatus*, and *C. labratus; Cyathostomum* spp. Including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Largemouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

(3) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

[68 FR 55309, Sept. 25, 2003, as amended at 69 FR 49808, Aug. 12, 2004; 70 FR 65835, Nov. 1, 2005; 79 FR 37619, July 2, 2014; 84 FR 39183, Aug. 9, 2019; 89 FR 42357, May 15, 2024]

§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet or soft chewable tablet contains:

(1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;

(2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;

(3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or

(4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer monthly according to body weight as follows:

(i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.

(ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.

(iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(3) of this section.

(iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(4) of this section.

(v) Greater than 100 lb: use the appropriate combination of tablets.

(2) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis*, *Toxascaris leonina*), hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*) and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections.

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

[71 FR 65052, Nov. 7, 2006, as amended at 78 FR 28822, May 20, 2014; 83 FR 14587, Apr. 5, 2018]

§ 520.1200 Ivermectin, fenbendazole, and praziquantel tablets.

(a) *Specifications.* Each chewable tablet contains either:

(1) 68 micrograms (μg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or

(2) 27 μg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer tablets to provide 6 μg per kilogram (/kg) ivermectin, 100 mg/kg fenbendazole, and 5 mg/kg praziquantel.

(2) *Indications for use.* For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.

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

[73 FR 33692, June 13, 2008, as amended at 74 FR 61516, Nov. 25, 2009]

§ 520.1204 Kanamycin, bismuth subcarbonate, activated *attapulgite.*

(a) *Specifications.* (1) Each 5 milliliters (mL) of suspension contains 100 milligrams (mg) kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite (aluminum magnesium silicate).

(2) Each tablet contains 100 mg kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mL of suspension or 1 tablet per 20 pounds body weight every 8 hours. Maximum dose: 5 mL of suspension or 3 tablets every 8 hours. Dogs under 10 pounds: 2.5 mL of suspension or ½ tablet every 8 hours. A recommended initial loading dose should be twice the amount of a single dose.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of the associated diarrhea.

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

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999; 71 FR 43968, Aug. 3, 2006; 78 FR 28822, May 20, 2014]

§ 520.1242 Levamisole.

§ 520.1242a Levamisole powder.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, 362.7, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 054771 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 016592 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section.

(4) No. 061133 for use of 46.8-, 362.7-, and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), (e)(1)(iii), (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for use of an 18.15-g package as in paragraph (e)(3) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* It is used as an anthelmintic as follows:

(1) *Cattle*—(i) *Amount.* 8 milligrams per kilogram (mg/kg) body weight as a drench.

(ii) *Indications for use.* (A) Effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*); intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus placei, Ostertagia ostertagi, Trichostrongylus axei*); intestinal worms (*T. longispicularis, Cooperia oncophora, C. punctata, Nematodirus spathiger, Bunostomum phlebotomum, Oesophagostomum radiatum*); and lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult your veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* 8 mg/kg body weight as a drench.

(ii) *Indications for use.* (A) Effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*); intestinal

worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*); intestinal worms (*Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), and lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Do not slaughter for food within 72 hours of treatment. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult veterinarian before using in severely debilitated animals.

(3) *Swine*—(i) *Amount.* 8 mg/kg body weight in drinking water.

(ii) *Indications for use.* Effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(iii) *Limitations.* Do not administer within 72 hours of slaughter for food. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine.

[69 FR 9753, Mar. 2, 2004, as amended at 69 FR 33839, June 17, 2004; 70 FR 2353, Jan. 13, 2005; 77 FR 28253, May 14, 2012; 78 FR 28822, May 20, 2014; 84 FR 8972, Mar. 13, 2019; 87 FR 58961, Sept. 29, 2022]

§ 520.1242b Levamisol boluses or oblets.

(a) *Specifications.* Each bolus contains 2.19 grams levamisol hydrochloride. Each oblet contains 0.184 grams levamisol hydrochloride.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Required labeling.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Related tolerances.* See § 556.350 of this chapter.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer orally 2.19-gram boluses as a single dose as follows: 250 to 450 pounds, ½ bolus; 450 to 750 pounds, 1 bolus; and 750 to 1,050 pounds, 1½ boluses.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Consult veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* Administer orally one 0.184-gram oblet for each 50 pounds of body weight.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult a veterinarian before using in severely debilitated animals.

[78 FR 28822, May 20, 2014]

§ 520.1242c Levamisol and piperazine.

(a) *Specifications.* (1) Each ounce of solution contains 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) A soluble powder which when constituted with water contains in each fluid ounce 0.45 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 5.0 grams of piperazine base.

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

(c) *Conditions of use in horses*—(1) *Amount.* Aqueous solution: administer by stomach tube or drench 1 fluid ounce per 100 pounds of body weight. Reconstituted soluble powder: administer by stomach tube 1 fluid ounce per 125 pounds of body weight. If reinfection occurs, re-treat animals at 6- to 8-week intervals.

(2) *Indications for use.* An anthelmintic effective against infections of large strongyles (*Strongylus vulgaris, S. edentatus*), small strongyles (*Cylicocercus* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp., *Cylicotetrapedon* spp.), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equi*).

(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.

[78 FR 28823, May 20, 2014]

§ 520.1242d Levamisole resinate.

(a) *Specifications.* The drug is levamisole adsorbed on a resin, in a concentration equivalent to 10 percent levamisole hydrochloride. Each 2.05-ounce (58.1 gram) packet contains levamisole equivalent to 5.806 grams of levamisole hydrochloride.

(b) *Sponsor.* See No. 043781 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* In swine it is used as follows:

(1) *Amount.* The equivalent of 8 milligrams per kilogram of body weight, as a single dose, mixed in the animal's ration.

(2) *Indications for use.* For the removal of and control of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and swine kidney worms (*Stephanurus dentatum*).

(3) *Limitations.* For pigs from weaning to market weight, mix one 58.1-gram packet of levamisole resinate containing the equivalent of 10-percent levamisole hydrochloride in 40 pounds of feed and administer 1 pound of medicated feed per 40 pounds of body weight as sole ration. For breeding swine, mix 1 packet of the 10-percent resinate in 16 pounds of feed and administer 1 pound of medicated feed per 100 pounds of body weight as sole ration. Administer as single doses. Withhold regular feed overnight and administer medicated feed the following morning. Do not withhold water during fasting. Do not treat within 72 hours of slaughter. Salivation or muzzle foam may be observed. The reaction will disappear a short time after feeding. If pigs are infected with mature lungworms, coughing and vomiting may be observed. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 18171, Apr. 28, 1978, as amended at 45 FR 3574, Jan. 18, 1980]

§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) *Specifications.* Each tablet contains 907 milligrams of levamisole hydrochloride.

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

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount.* The equivalent of 8 milligrams of levamisole hydrochloride per kilogram of body weight, as a single dose.

(2) *Indications for use.* See § 520.1242a(f)(3)(ii).

(3) *Limitations.* Withholding water from pigs before treatment is not necessary. Add one tablet for each 2½ gallons of water; mix thoroughly. Allow 1 gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[45 FR 6087, Jan. 25, 1980, as amended at 67 FR 63055, Oct. 10, 2002; 78 FR 28823, May 20, 2014]

§ 520.1242f Levamisol gel.

(a) *Specifications.* Each gram of gel contains 115 milligrams (11.5 percent) levamisol hydrochloride.

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

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Eight milligrams of levamisole hydrochloride per kilogram of body weight, as a single oral dose.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not administer to cattle within 6 days of slaughter for food; do not administer to dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) *Breeding swine*—(i) *Amount.* Eight milligrams per kilogram of body weight (3.6 milligrams per pound) as a single oral dose.

(ii) *Conditions of use.* For treating breeding swine infected with the following nematodes: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and kidney worms (*Stephanurus dentatus*).

(iii) *Limitations.* May require retreatment in 4 to 5 weeks. Do not use within 11 days of slaughter for food. Consult your veterinarian for assistance before using in severely debilitated animals and in the diagnosis, treatment, and control of parasitism.

[47 FR 22517, May 25, 1982; 47 FR 30242, July 13, 1982, as amended at 48 FR 11429, Mar. 18, 1983; 51 FR 29215, Aug. 15, 1986; 67 FR 63055, Oct. 10, 2002; 78 FR 28823, May 20, 2014]

§ 520.1242g Levamisole resinate and famphur paste.

(a) *Specifications.* The drug is a paste containing 11.6 percent levamisole resinate (50 percent potency) and 23.6 percent famphur.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Do not use any cholinesterase-inhibiting drugs, pesticides, insecticides, or chemicals on cattle simultaneously or within a few days before or after treatment with this product.

(d) *Related tolerances.* See §§ 556.273 and 556.350 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* 8 milligrams of levamisole hydrochloride (equivalent) and 30 milligrams of famphur activity per kilogram of body weight.

(2) *Indications for use.* For treatment of cattle infected with the following parasites: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), lungworms (*Dictyocaulus*), cattle grubs (*Hypoderma*), biting lice (*Bovicola*), and sucking lice (*Linognathus*, *Solenoptes*).

(3) *Limitations.* Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54 FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992; 62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997; 78 FR 28823, May 20, 2014]

§ 520.1248 Levothyroxine.

(a) *Specifications.* Each tablet contains 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, or 1.0 milligrams (mg) levothyroxine sodium.

(b) *Sponsors.* See Nos. 059051 and 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by mouth as follows:

(i) No. 061690: 0.1 mg/10 pounds (lb) body weight (0.022 mg/kilogram (kg)) as a single dose every 24 hours or as a divided dose every 12 hours.

(ii) No. 059051: 0.1 mg/10 lb (0.01 mg/lb, 0.022 mg/kg) body weight twice daily.

(2) *Indications for use.* For replacement therapy for diminished thyroid function in dogs.

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

[81 FR 22523, Apr. 18, 2016, as amended at 86 FR 57996, Oct. 20, 2021]

§ 520.1263 Lincomycin.

§ 520.1263a Lincomycin tablets and syrup.

(a) *Specifications.* (1) Each ounce of syrup contains lincomycin hydrochloride equivalent to either 25 or 50 milligrams (mg) lincomycin.

(2) Each tablet contains lincomycin hydrochloride equivalent to either 25 or 50 mg lincomycin.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 10 mg per pound of body weight every 12 hours, or 7 mg per pound of body weight every 8 hours, for up to 12 days.

(2) *Indications for use.* For infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

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

[78 FR 28823, May 20, 2014]

§ 520.1263b Lincomycin powder.

(a) *Specifications.* Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.

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

(1) Nos. 054771 and 061133 for use as in paragraph (d) of this section.

(2) Nos. 016592 and 076475 for use as in paragraphs (d)(1) and (2) of this section.

(c) *Tolerances.* See § 556.360 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.

(ii) *Indications for use.* For the treatment of swine dysentery (bloody scours).

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Chickens*—(i) *Amount.* 64 milligrams per gallon of drinking water.

(ii) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Honey bees*—(i) *Amount.* Mix 100 milligrams lincomycin with 20 grams confectioners'/powdered sugar and dust 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 late in the 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000; 67 FR 17284, Apr. 10, 2002; 67 FR 71819, Dec. 3, 2002; 67 FR 78356, Dec. 24, 2002; 68 FR 3817, Jan. 27, 2003; 70 FR 1818, Jan. 11, 2005; 77 FR 20988, Apr. 9, 2012; 77 FR 29217, May 17, 2012; 78 FR 28823, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 94989, Dec. 27, 2016; 83 FR 48945, Sept. 28, 2018; 84 FR 8972, Mar. 13, 2019. Redesignated at 85 FR 18119, Apr. 1, 2020, as amended at 88 FR 16547, Mar. 20, 2023; 88 FR 84700, Dec. 6, 2023]

§ 520.1265 Lincomycin and spectinomycin powder.

(a) *Specifications*. The following salts of lincomycin and spectinomycin are present in a soluble powder in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base:

(1) Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate.

(2) Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use of product described in paragraph (a)(1) of this section.

(2) Nos. 016592, 061133, and 066104 for use of product described in paragraph (a)(2) of this section.

(c) *Tolerances*. See §§ 556.360 and 556.600 of this chapter.

(d) *Conditions of use in chickens*—(1) *Amount*. 2 grams of antibiotic activity per gallon of drinking water; administer as the sole source of water for the first 5 to 7 days of life.

(2) *Indications for use*. As an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

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

[69 FR 13220, Mar. 22, 2004, as amended at 70 FR 40881, July 15, 2005; 71 FR 71038, Dec. 8, 2006; 77 FR 56770, Sept. 14, 2012; 78 FR 28823, May 20, 2014; 81 FR 94989, Dec. 27, 2016; 83 FR 48945, Sept. 28, 2018; 84 FR 8972, Mar. 13, 2019]

§ 520.1284 Liothyronine.

(a) *Specifications*. Each tablet contains 60 or 120 micrograms (μg) liothyronine as the sodium salt.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally to dogs at levels up to 12.8 μg per kilogram (/kg) of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8 μg/kg of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(2) *Indications for use*. For treatment of hypothyroidism in dogs.

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

[78 FR 28823, May 20, 2014]

§ 520.1286 Lotilaner.

(a) *Specifications*. Each chewable tablet contains:

(1) For use in dogs: 56.25, 112.5, 225, 450, or 900 milligrams (mg) lotilaner; or

(2) For use in cats: 12 or 48 mg lotilaner.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer orally once a month at the recommended minimum dosage of 9 mg/lb (20 mg/kg).

(ii) *Indications for use*. Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs and puppies 8 weeks of

age or older and weighing 4.4 pounds or greater.

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

(2) *Cats*—(i) *Amount.* Administer orally once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg).

(ii) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 1 month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater; and for the treatment and control of *Ixodes scapularis* (black-legged tick) for 1 month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.

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

[85 FR 18119, Apr. 1, 2020, as amended at 86 FR 61685, Nov. 8, 2021]

§ 520.1287 Lotilaner, moxidectin, praziquantel, and pyrantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 56.25 milligrams (mg) lotilaner, 0.056 mg moxidectin, 14.25 mg praziquantel, and 14.25 mg pyrantel (as pamoate salt);

(2) 112.5 mg lotilaner, 0.113 mg moxidectin, 28.5 mg praziquantel, and 28.5 mg pyrantel (as pamoate salt);

(3) 225 mg lotilaner, 0.225 mg moxidectin, 57 mg praziquantel, and 57 mg pyrantel (as pamoate salt);

(4) 450 mg lotilaner, 0.45 mg moxidectin, 114 mg praziquantel, and 114 mg pyrantel (as pamoate salt); or

(5) 900 mg lotilaner, 0.9 mg moxidectin, 228 mg praziquantel, and 228 mg pyrantel (as pamoate salt).

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally once a month, at the minimum dosage of 9 mg/lb (20 mg/kg) lotilaner, 0.009 mg/lb (0.02 mg/kg) moxidectin, 2.28 mg/lb (5 mg/kg) praziquantel, and 2.28 mg/lb (5 mg/kg) pyrantel (as pamoate salt).

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*), hookworm (adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum, Taenia pisiformis* and *Echinococcus granulosus*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

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

[90 FR 6800, Jan. 21, 2025]

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) Tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) Flavored tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A) or (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(3) Flavored tablets containing 90 or 204.9 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A) or (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(4) Flavored tablets containing 135 or 270 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Minimum of 10 mg lufenuron per kilogram (4.5 mg per pound (lb)) of body weight, once a month.

(ii) *Indications for use*—(A) For the prevention and control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in dogs and puppies 4 weeks of age and older.

(2) *Cats*—(i) *Amount.* Minimum of 30 mg lufenuron per kilogram (13.6 mg/lb) of body weight, once a month.

(ii) *Indications for use*—(A) For the control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(3) of this section as in paragraph (c)(2)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in cats and kittens 4 weeks of age and older.

[68 FR 51905, Aug. 29, 2003]

§ 520.1289 Lufenuron suspension.

(a) *Specifications.* Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

[60 FR 20402, Apr. 26, 1995, as amended at 62 FR 8371, Feb. 25, 1997]

§ 520.1310 Marbofloxacin.

(a) *Specifications.* Each tablet or chewable tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Nos. 017033, 054771, and 086117 for use of tablets.

(2) No. 086101 for use of chewable tablets.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 1.25 mg per pound (/lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use.* For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[64 FR 39919, July 23, 1999, as amended at 66 FR 46369, Sept. 5, 2001; 78 FR 28823, May 20, 2014; 85 FR 45307, July 28, 2020; 88 FR 27698, May 3, 2023]

§ 520.1315 Maropitant.

(a) *Specifications.* Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsors.* See Nos. 054771, 086101, and 086117 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Indications for use and amount.* (i) For prevention of acute vomiting in dogs 2 to 7 months of age, administer a minimum dose of 2.0 mg per kilogram (/kg) body weight once daily for up to 5 consecutive days.

(ii) For prevention of acute vomiting in dogs 7 months of age and older, administer a minimum dose of 2.0 mg/kg body weight once daily until resolution of acute vomiting.

(iii) For prevention of vomiting due to motion sickness in dogs 4 months of age and older, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

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

[72 FR 9243, Mar. 1, 2007, as amended at 78 FR 28823, May 20, 2014; 80 FR 53459, Sept. 4, 2015; 88 FR 27699, May 3, 2023; 89 FR 85426, Oct. 28, 2024]

§ 520.1320 Mebendazole.

(a) *Specifications.* (1) Each gram of powder contains either 40 or 166.7 milligrams of mebendazole.

(2) Each gram of paste contains 200 milligrams of mebendazole.

(3) Each milliliter of suspension contains 33.3 milligrams of mebendazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use.* For treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*); small strongyles; and mature and immature (4th larval stage) pinworms (*Oxyuris equi*).

(iii) *Limitations.* The drug is compatible with carbon disulfide. 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.

(2) *Dogs*—(i) *Amount.* Administer 100 milligrams of mebendazole per 10 pounds of body weight, once daily for 3 days, as an oral powder by mixing with a small quantity of food, preferably before the regular meal.

(ii) *Indications for use.* The drug is used for treatment of infections of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

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

[78 FR 28823, May 20, 2014]

§ 520.1326 Mebendazole and trichlorfon oral dosage forms.

§ 520.1326a Mebendazole and trichlorfon powder.

(a) *Specifications.* Each gram of powder contains 83.3 milligrams of mebendazole and 375.0 milligrams of trichlorofon.

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

(c) *Conditions of use in horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorofon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for the treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi.*)

(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.

[45 FR 10759, Feb. 19, 1980, as amended at 46 FR 52330, Oct. 27, 1981. Redesignated at 51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997; 78 FR 28824, May 20, 2014]

§ 520.1326b Mebendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams of mebendazole and 454 milligrams of trichlorfon.

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

(c) *Conditions of use in horses*—(1) *Amount.* 8.8 milligrams of mebendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* It is used in horses for treatment of infections of bots (*Gastrophilus intestinalis* and *G. nasalis*), large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Do not administer more than once every 30 days. Do not treat sick or debilitated animals, foals under 4 months of age, or mares in the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not administer simultaneously or within a few days before or after treatment with, or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not administer intravenous anesthetics, especially muscle relaxants, concurrently. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 13212, Apr. 18, 1986, as amended at 62 FR 61625, Nov. 19, 1997; 78 FR 28824, May 20, 2014]

§ 520.1330 Meclofenamic acid granules.

(a) *Specifications.* Each gram of granules contains 5 milligrams (5 percent) meclofenamic acid.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milligram per pound of body weight (1 gram per 1000 pounds) once daily for 5 to 7 days by addition to the daily grain ration.

(2) *Indications for use.* For the treatment of acute or chronic inflammatory diseases involving the musculoskeletal system.

(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.

[78 FR 28824, May 20, 2014]

§ 520.1331 Meclofenamic acid tablets.

(a) *Specifications.* Each tablet contains either 10 or 20 milligrams of meclofenamic acid.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 1.1 milligrams per kilogram (0.5 milligram per pound) daily for 5 to 7 days.

(2) *Indications for use.* For the relief of signs and symptoms of chronic inflammatory disease involving the musculoskeletal system.

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

[50 FR 43385, Oct. 25, 1985, as amended at 53 FR 23390, June 22, 1988; 78 FR 28824, May 20, 2014]

§ 520.1341 Megestrol.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams of megestrol acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally, intact, or crushed and mixed with food as follows:

(i) For the postponement of estrus by proestrus treatment: 1 milligram per pound of body weight per day for 8 days.

(ii) For the postponement of estrus by anestrus treatment: 0.25 milligram per pound of body weight per day for 32 days.

(iii) For alleviation of false pregnancy: 1 milligram per pound of body weight per day for 8 days.

(2) *Indications for use.* For the postponement of estrus and the alleviation of false pregnancy in female dogs.

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

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 78 FR 28824, May 20, 2014]

§ 520.1367 Meloxicam.

(a) *Specifications*—(1) Each milliliter of suspension contains 0.5 milligrams (mg) meloxicam.

(2) Each milliliter of suspension contains 1.5 mg meloxicam.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section:

(1) No. 000010 for use of the products described in paragraph (a) of this section; and

(2) Nos. 013744 and 055529 for use of the product described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

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

[68 FR 42968, July 21, 2003, as amended at 69 FR 69523, Nov. 30, 2004. Redesignated and amended at 78 FR 57058, Sept. 17, 2013; 80 FR 53459, Sept. 4, 2015]

§ 520.1375 Methimazole tablets.

(a) *Specifications.* Each tablet contains 2.5 or 5 milligrams (mg) methimazole.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* The starting dose is 2.5 mg every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 levels and clinical response.

(2) *Indications for use.* For the treatment of hyperthyroidism.

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

[74 FR 27707, June 11, 2009. Redesignated and amended at 89 FR 95103, Dec. 2, 2024]

§ 520.1376 Methimazole solution.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) methimazole.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer a starting dose of 2.5 mg every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 (TT4) levels and clinical response. Dose adjustments should be made in 2.5 mg increments with a maximum dosage of 20 mg per day divided, not to exceed 10 mg as a single dose.

(2) *Indications for use.* For the treatment of hyperthyroidism.

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

[89 FR 95103, Dec. 2, 2024]

§ 520.1380 Methocarbamol.

(a) *Specifications.* Each tablet contains 500 milligrams (mg) of methocarbamol.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer 60 mg per pound of body weight in two or three equally divided doses, followed each following day by 30 to 60 mg per pound of body weight, usually not to exceed 14 to 21 days.

(2) *Indications for use.* As an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

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

[78 FR 28824, May 20, 2014]

§ 520.1408 Methylprednisolone.

(a) *Specifications.* Each tablet contains 1, 2, or 4 milligrams (mg) of methylprednisolone.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 5 to 15 pounds (lbs): 2 mg; 15 to 40 lbs: 2 to 4 mg; 40 to 80 lbs: 4 to 8 mg. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed.

(2) *Indications for use.* As an anti-inflammatory agent.

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

[78 FR 28824, May 20, 2014, as amended at 83 FR 48946, Sept. 28, 2018; 89 FR 14410, Feb. 27, 2024]

§ 520.1409 Methylprednisolone and aspirin.

(a) *Specifications.* Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Under 15 pounds, ¼ to 1 tablet daily; 15 to 60 pounds, 1 to 2 tablets daily; 60 pounds and over, 2 tablets daily. Administer total daily dose in divided doses 6 to 10 hours apart, with a light feeding. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* As an anti-inflammatory and analgesic agent.

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

[48 FR 21566, May 13, 1983, as amended at 78 FR 28824, May 20, 2014]

§ 520.1422 Metoserpate hydrochloride.

(a) *Chemical name.* Methyl-*o*-methyl-18-epireserpate hydrochloride.

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

(c) *Related tolerances.* See § 556.410 of this chapter.

(d) *Conditions of use.* It is used in drinking water for replacement chickens as follows:

(1) *Amount.* 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use.* As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations.* To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount.* 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use.* As an aid in control of hysteria.

(ii) *Limitations.* To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

[40 FR 13838, Mar. 27, 1975, as amended at 76 FR 17337, Mar. 29, 2011; 78 FR 28824, May 20, 2014]

§ 520.1425 Metronidazole.

(a) *Specifications.* Each milliliter of suspension contains 125 milligrams (mg) metronidazole.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 25 mg per kilogram (11.3 mg per pound) of body weight twice daily for 5 consecutive days.

(2) *Indications for use.* For the treatment of *Giardia duodenalis* infection in dogs.

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

[89 FR 14410, Feb. 27, 2024]

§ 520.1430 Mibolerone.

(a) *Specifications.* Each milliliter contains 100 micrograms of mibolerone.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 30 micrograms for animals weighing 1 to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, German Shepherds, or German Shepherd mix. Administer daily, orally or in a small amount of food, at least 30 days before expected initiation of heat, and continue daily as long as desired, but not for more than 24 months.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

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

[43 FR 15625, Apr. 14, 1978, as amended at 78 FR 28824, May 20, 2014]

§ 520.1441 Milbemycin.

(a) *Specifications.* Each flavored tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams (mg) of milbemycin oxime.

(b) *Sponsors.* See Nos. 013744 and 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* For hookworm, roundworm, and whipworm, administer 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)). For heartworm, administer 0.05 mg/lb of body weight (0.1 mg/kg). Administer once a month.

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis,* control of hookworm infections caused by *Ancylostoma caninum,* and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and puppies 4 weeks of age or greater and 2 pounds body weight or greater.

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

(2) *Cats*—(i) *Amount.* Administer 0.91 mg/lb of body weight (2.0 mg/kg) once a month.

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

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

[84 FR 12494, Apr. 2, 2019]

§ 520.1443 Milbemycin oxime and lufenuron.

(a) *Specifications.* (1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use.* (A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

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

(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998; 68 FR 51905, Aug. 29, 2003. Redesignated at 77 FR 47512, Aug. 9, 2012, as amended at 80 FR 18776, Apr. 8, 2015; 86 FR 13184, Mar. 8, 2021]

§ 520.1445 Milbemycin oxime and praziquantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime and 228 mg praziquantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally, once a month, a minimum dosage of 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)) milbemycin oxime and 2.28 mg/lb of body weight (5 mg/kg) praziquantel.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, *E. granulosus*, and *Dipylidium caninum*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

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

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012, as amended at 82 FR 58556, Dec. 13, 2017]

§ 520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime, 46 mg lufenuron, and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime, 115 mg lufenuron, and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime, 230 mg lufenuron, and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime, 460 mg lufenuron, and 228 mg praziquantel.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.5 mg milbemycin oxime, 10

mg lufenuron, and 5 mg of praziquantel per kilogram of body weight, once a month.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis;* for the prevention and control of flea populations (*Ctenocephalides felis*); and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

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

(2) [Reserved]

[77 FR 4225, Jan. 27, 2012, as amended at 80 FR 18776, Apr. 8, 2015; 83 FR 13635, Mar. 30, 2018; 86 FR 13184, Mar. 8, 2021]

§ 520.1450 Morantel tartrate oral dosage forms.

§ 520.1450a Morantel tartrate bolus.

(a) *Specifications.* Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.

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

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* One bolus per 500 pounds of body weight (4.4 milligrams per pound of body weight) as a single oral dose. Boluses may be divided in half for more accurate dosing as follows: up to 325 pounds, ½ bolus; 326 to 600 pounds, 1 bolus; 601 to 900 pounds, 1½ boluses; and 901 to 1,200 pounds, 2 boluses.

(2) *Indications for use.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(3) *Limitations.* Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. Do not treat within 14 days of slaughter.

[46 FR 50949, Oct. 16, 1981. Redesignated at 49 FR 47831, Dec. 7, 1984, and amended at 51 FR 9005, Mar. 17, 1986; 78 FR 28825, May 20, 2014]

§ 520.1450b Morantel tartrate cartridge.

(a) *Specifications.* The drug product consists of a stainless-steel cylinder having both ends closed with polyethylene diffusing discs and containing a morantel tartrate paste. The paste contains 22.7 grams of morantel tartrate equivalent to 13.5 grams of morantel base.

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

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum.*

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 106 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 47831, Dec. 7, 1984, as amended at 51 FR 23415, June 27, 1986; 51 FR 41081, Nov. 13, 1986; 78 FR 28825, May 20, 2014]

§ 520.1450c Morantel tartrate sustained-release trilaminate cylinder/sheet.

(a) *Specifications.* The drug product consists of a trilaminated, perforated, plastic sheet formed into a cylinder having plastic plugs in its ends. The core lamina contains 19.8 grams of morantel tartrate equivalent to 11.8 grams of morantel base.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Grazing cattle: Administer 1 cartridge to each animal at the start of the grazing season.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum.*

(3) *Limitations.* Administer orally with the dosing gun to all cattle that will be grazing the same pasture. Effectiveness of the drug product is dependent upon continuous control of the gastrointestinal parasites for approximately 90 days following administration. Therefore, treated cattle should not be moved to pastures grazed in the same grazing season/calendar year by untreated cattle. Do not administer to cattle within 102 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

[56 FR 13396, Apr. 2, 1991, as amended at 78 FR 28825, May 20, 2014]

§ 520.1451 Moxidectin tablets.

(a) *Specifications.* Each tablet contains 30, 68, or 136 micrograms of moxidectin.

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

(c) *Conditions of use*—(1) *Amount.* 3 micrograms per kilogram (1.36 micrograms per pound) of body weight.

(2) *Indications for use.* To prevent infection by the canine heartworm *Dirofilaria immitis* and the subsequent development of canine heartworm disease.

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

[62 FR 37713, July 15, 1997, as amended at 78 FR 28825, May 20, 2014]

§ 520.1452 Moxidectin gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (2 percent) moxidectin.

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

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus.* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. radiatus; Cyliocostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Gyalocephalus capitatus*; and *Petrovinema poculatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); and horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Do not use in horses intended for human consumption.

[62 FR 42902, Aug. 11, 1997, as amended at 64 FR 66105, Nov. 24, 1999; 68 FR 51445, Aug. 27, 2003; 69 FR 24959, May 5, 2004; 70 FR 75017, Dec. 19, 2005; 78 FR 28825, May 20, 2014]

§ 520.1453 Moxidectin and praziquantel gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (mg) (2.0 percent) moxidectin and 125 mg (12.5 percent) praziquantel.

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

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* Administer by mouth as a single dose: 0.4 mg moxidectin per kilogram and 2.5 mg praziquantel per kilogram (2.2 pounds) body weight.

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): (*Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp., including *C. insigne, C. leptostomum, C. nassatus*, and *C. radiatus*; *Cylicostephanus* spp., including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus*; *Coronocyclus* spp., including *C. coronatus, C. labiatus,* and *C. labratus*; *Gyalocephalus capitatus*; and *Petrovinema poculatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars); and tapeworms: *Anoplocephala perfoliata* (adults). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Do not use in horses intended for human consumption.

[68 FR 51446, Aug. 27, 2003, as amended at 69 FR 21956, Apr. 23, 2004; 70 FR 75017, Dec. 19, 2005; 78 FR 28825, May 20, 2014]

§ 520.1454 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in sheep*—(1) *Amount.* Administer 1 mL per 11 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) *Indications for use.* For the treatment and control of the adult and L4 larval stages of *Haemonchus contortus*, *Teladorsagia circumcincta*, *T. trifurcata*, *Trichostrongylus axei*, *T. colubriformis*, *T. vitrinus*, *Cooperia curticei*, *C. oncophora*, *Oesophagostomum columbianum*, *O. venulosum*, *Nematodirus battus*, *N. filicollis*, and *N. spathiger*.

(3) *Limitations.* Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use in female sheep providing milk for human consumption.

[70 FR 76163, Dec. 23, 2005, as amended at 76 FR 48714, Aug. 9, 2011; 82 FR 21690, May 10, 2017; 86 FR 14818, Mar. 19, 2021]

§ 520.1468 Naproxen.

(a) *Specifications.* Each gram of granules contains 500 milligrams (mg) (50 percent) naproxen.

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

(c) *Conditions of use in horses*—(1) *Amount.* 10 mg per kilogram of body weight twice daily top dressed on feed for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system.

(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.

[78 FR 28825, May 20, 2014]

§ 520.1484 Neomycin.

(a) *Specifications.* (1) Each ounce of powder contains 20.3 grams (g) neomycin sulfate (equivalent to 14.2 g neomycin base).

(2) Each milliliter of solution contains 200 milligrams (mg) neomycin sulfate (equivalent to 140 mg neomycin base).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) Nos. 016592, 054771, 058005, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (e)(1) and (e)(2) of this section.

(3) Nos. 016592, 054771, and 058005 for use of product described in paragraph (a)(2) as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.430 of this chapter.

(d) *Special labeling considerations.* Labeling shall bear the following warning statements: ''A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Conditions of use*—(1) *Cattle, swine, sheep, and goats*—(i) *Amount.* 10 mg per pound (/lb) of body weight per day (22 mg per kilogram (/kg)) in divided doses for a maximum of 14 days.

(ii) *Indications for use.* For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

(iii) *Limitations.* Discontinue treatment prior to slaughter as follows: Cattle, 1 day; sheep, 2 days; swine and goats, 3 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* 10 mg/lb of body weight per day (22 mg/kg) for 5 days.

(ii) *Indications for use.* For the control of mortality associated with *E. coli* susceptible to neomycin sulfate in growing turkeys.

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

[71 FR 56866, Sept. 28, 2006, as amended at 71 FR 68738, Nov. 28, 2006; 78 FR 17596, Mar. 22, 2013; 78 FR 28825, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 94989, Dec. 27, 2016; 84 FR 8973, Mar. 13, 2019; 88 FR 55563, Aug. 16, 2023; 88 FR 84700, Dec. 6, 2023]

§ 520.1510 Nitenpyram.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

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

(1) No. 021091 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), and (d)(2) of this section.

(2) No. 000061 for use as in paragraphs (d)(1)(i)(B) and (d)(1)(ii)(B) of this section.

(c) *Special considerations.* The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* (A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use.* (A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1443(d)(1) is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount.* (A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use.* (A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003, as amended at 80 FR 18776, Apr. 8, 2015; 86 FR 13184, Mar. 8, 2021; 86 FR 57997, Oct. 20, 2021]

§ 520.1604 Oclacitinib.

(a) *Specifications.* Each tablet or chewable tablet contains 3.6, 5.4, or 16 milligrams (mg) of oclacitinib as oclacitinib maleate.

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

(c) *Conditions of use*—(1) *Amount.* Administer orally 0.18 to 0.27 mg/per pound of body weight (0.4 to 0.6 mg/kg body weight) twice daily for up to 14 days; then administered once daily for maintenance therapy.

(2) *Indications for use.* For control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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

[78 FR 42007, July 15, 2013, as amended at 88 FR 55563, Aug. 16, 2023]

§ 520.1615 Omeprazole.

(a) *Specifications.* Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Special considerations.* When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use in horses*—(1) *Amount.* (i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use.* (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations.* Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004, as amended at 71 FR 59374, Oct. 10, 2006; 84 FR 39183, Aug. 9, 2019]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

[71 FR 14643, Mar. 23, 2006, as amended at 75 FR 26646, May 12, 2010]

§ 520.1618 Orbifloxacin suspension.

(a) *Specifications.* Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

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

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) *Indications for use.* For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Proteus mirabilis*, *Escherichia coli*, and *Enterococcus faecalis* and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus*

pseudintermedius, *Staphylococcus aureus*, coagulase-positive staphylococci, *Pasteurella multocida*, *Proteus mirabilis*, *Pseudomonas* spp., *Klebsiella pneumoniae*, *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *E. faecalis*, β-hemolytic streptococci (Group G), and *Streptococcus equisimilis*.

(2) *Cats*—(i) *Amount*. 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *S. aureus*, *E. coli*, and *P. multocida*.

[75 FR 26646, May 12, 2010]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications*—(1) *Powder for suspension*. Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets*. Each gram of pellets contains 6.49 percent oxfendazole.

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

(c) *Conditions of use*—(1) *Amount*. 10 milligrams per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations*—(i) *Powder for suspension*. For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets*. The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior to administration is not necessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[44 FR 35211, June 19, 1979, as amended at 46 FR 26301, May 12, 1981; 46 FR 60570, Dec. 11, 1981; 49 FR 28549, July 13, 1984; 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1629 Oxfendazole paste.

(a)(1) *Specifications*. Each gram of paste contains 0.375 gram oxfendazole (37.5 percent).

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

(3) *Conditions of use*—(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications*. Each gram of paste contains 185 milligrams of oxfendazole (18.5 percent).

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

(3) *Related tolerances*. See § 556.495 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use*. The drug is used in cattle for the removal and control of the following worms: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata*, *C. oncophora*,

and *C. mcmasteri*—adult, L4); and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations.* For use in cattle only. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 11 days after treatment. Do not use in female dairy cattle of breeding age. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 38250, Sept. 28, 1984, as amended at 58 FR 39443, July 23, 1993; 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1630 Oxfendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains:

(1) 90.6 milligrams (mg) oxfendazole (9.06 percent).

(2) 225.0 mg oxfendazole (22.5 percent).

(b) *Sponsor.* See Nos. 000010 and 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances. See* § 556.495 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter. If labeled for administration by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 10 mg per kilogram (/kg) of body weight by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks.

(ii) *Indications for use.* For removal of large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus, S. vulgaris,* and *S. equinus*), and small strongyles.

(iii) *Limitations.* Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for human consumption.

(2) *Cattle.* Use the products described in paragraphs (a)(1) and (a)(2) of this section as follows:

(i) *Amount.* 4.5 mg/kg of body weight by dose syringe. Treatment may be repeated in 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms (*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata, C. oncophora,* and *C. surnabada*—adult, L4), and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations.* Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[55 FR 46943, Nov. 8, 1990, as amended at 56 FR 8710, Mar. 1, 1991; 61 FR 5506, Feb. 13, 1996; 72 FR 10596, Mar. 9, 2007; 73 FR 45610, Aug. 6, 2008; 75 FR 10166, Mar. 5, 2010; 78 FR 28825, May 20, 2014]

§ 520.1631 Oxfendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 28.5 milligrams oxfendazole and 454.5 milligrams trichlorfon.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2.5 milligrams of oxfendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of bots (*Gasterophilus intestinalis,* 2nd and 3rd instars; *G. nasalis,* 3rd instar) and the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), pinworms (*Oxyuris equi*), adult and 4th stage larvae; large strongyles (*Strongylus edentatus, S. vulgaris,* and *S. equinus*); and small strongyles.

(3) *Limitations.* Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water before use is unnecessary. Administer with caution to sick or debilitated horses. Not for use in horses intended for food. Do not administer to mares during the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not use this product in animals simultaneously with, or within a few days before or after treatment with

or exposure to, cholinesterase-inhibiting drugs, pesticides, or chemicals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 50291, Dec. 10, 1985, as amended at 61 FR 5506, Feb. 13, 1996; 78 FR 28825, May 20, 2014]

§ 520.1638 Oxibendazole.

(a) *Specifications.* (1) Each gram of paste contains 227 milligrams (mg) (22.7 percent) oxibendazole.

(2) Each milliliter of suspension contains 100 mg (10 percent) oxibendazole.

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

(c) *Special considerations.* (1) See § 500.25 of this chapter.

(2) Suspension product described in paragraph (a)(2) of this section shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use in horses*—(1) *Amount.* For uses other than for threadworms (*Strongyloides westeri*), 10 mg oxibendazole per kilogram (/kg) body weight; for threadworms (*Strongyloides westeri*), 15 mg/kg. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Administer suspension product by stomach tube in 3 to 4 pints of warm water, or by top dressing or mixing into a portion of the normal grain ration.

(2) *Indications for use.* For removal and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*); small strongyles (genera *Cylicostephanus, Cylicocyclus, Cyathostomum, Triodontophorus, Cylicodontophorus,* and *Gyalocephalus*); large roundworms (*Parascaris equorum*); pinworms (*Oxyuris equi*) including various larval stages; and threadworms (*Strongyloides westeri*).

(3) *Limitations.* Do not use in horses intended for human consumption.

[78 FR 28825, May 20, 2014]

§ 520.1660 Oxytetracycline.

§ 520.1660a [Reserved]

§ 520.1660b Oxytetracycline capsules.

(a) *Specifications.* Each capsule contains 125 or 250 milligrams (mg) oxytetracycline hydrochloride.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 25 to 50 mg per pound of body weight per day in divided doses at 12-hour intervals.

(2) *Indications for use.* For the treatment of bacterial pneumonia caused by *Brucella bronchiseptica,* tonsilitis caused by *Streptococcus hemolyticus,* bacterial enteritis caused by *Escherichia coli,* urinary tract infections caused by *Escherichia coli,* and wound infections caused by *Staphylococcus aureus.*

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

[40 FR 13838, Mar. 27, 1975, as amended at 78 FR 28825, May 20, 2014; 88 FR 55563, Aug. 16, 2023]

§ 520.1660c Oxytetracycline tablets.

(a) *Specifications.* Each tablet contains 250 or 500 milligrams (mg) oxytetracycline hydrochloride.

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

(c) *Tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1) *Amounts.* 10 mg per pound of body weight every 12 hours for treatment; 5 mg per pound of body weight every 12 hours for control.

(2) *Indications for use.* For treatment and control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida.*

(3) *Limitations.* Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts

this drug to use by or on the order of a licensed veterinarian.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998; 70 FR 16394, Apr. 4, 2005; 78 FR 28825, May 20, 2014; 88 FR 14897, Mar. 10, 2023; 88 FR 55563, Aug. 16, 2023]

§ 520.1660d Oxytetracycline powder.

(a) *Specifications.* The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz, 3.09 and 3.91 lb; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 oz.; pail: 5 lb). Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz).

(7) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 and 9.6 oz.; pails: 2 and 5 lb); each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb).

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and, 19.75 oz, and 3.91 lb; pails: 3.09 and 5 lb).

(10) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.74 oz; pails: 5 lb).

(b) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 016592 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

(3) No. 066104 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 016592 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 061133 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, sheep, and honeybees.

(6) No. 069254 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(7) No. 061133 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use.* (1) It is used in drinking water as follows:

(i) *Chickens*—(A)(*1*) *Amount.* Administer 200 to 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

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

(B)(*1*) *Amount.* Administer 400 to 800 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

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

(ii) *Turkeys*—(A)(*1*) *Amount.* Administer 200 to 400 milligrams/gallon for 7

to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061133 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B)(*1*) *Amount.* Administer 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061133 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(C)(*1*) *Amount.* Administer 25 milligrams per pound of body weight daily for 7 to 14 days. Not to be used for more than 14 consecutive days.

(*2*) *Indications for use.* Growing turkeys. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061133 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Swine*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily in drinking water. Administer up to 14 days; do not use for more than 14 consecutive days those products sponsored by Nos. 054771, 061133, and 069254. Administer up to 5 days; do not use for more than 5 consecutive days those products sponsored by Nos. 016592 and 061133.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

(C) *Limitations.* Withdraw zero days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Do not use for more than 14 consecutive days.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(v) *Sheep*—(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Not to be used for more than 14 consecutive days.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) Withdraw 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) It is used in the food of honey bees as follows:

(i) *Amount.* 200 milligrams per colony, administered via either a 1:1 sugar

syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture. The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals.

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

(iii) The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1660d, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 520.1664 Oxytetracycline and carbomycin.

(a) *Specifications.* (1) Oxytetracycline: The antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(2) Carbomycin: The antibiotic substance produced by growth of *Streptomyces halstedii* or the same antibiotic substance produced by any other means.

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

(c) *Special considerations.* The quantities of oxytetracycline in paragraph (e) of this section refer to the activity of oxytetracycline hydrochloride and the quantities of carbomycin listed refer to the activity of an appropriate standard.

(d) *Related tolerances.* See §§ 556.110 and 556.500 of this chapter.

(e) *Conditions of use.* It is used as oxytetracycline hydrochloride plus carbomycin base in drinking water of chickens as follows:

(1) *Amount.* Administer 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon for not more than 5 days.

(2) *Indications for use.* As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by *Mycoplasma gallisepticum* and secondary bacterial organisms associated with chronic respiratory disease such as *E. coli.*

(3) *Limitations.* Not for use in chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 78 FR 28825, May 20, 2014; 81 FR 94989, Dec. 27, 2016. Redesignated at 88 FR 55563, Aug. 16, 2023]

§ 520.1696 Penicillin.

§ 520.1696a Penicillin G powder.

(a) *Specifications.* Each gram of powder contains penicillin G potassium equivalent to 1.54 million units of penicillin G.

(b) *Sponsors.* See Nos. 016592, 042791, 054771, 061133, and 076475 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use in turkeys*—(1) *Amount.* 1,500,000 units per gallon drinking water for 5 days.

(2) *Indications for use.* Treatment of erysipelas caused by *Erysipelothrix rhusiopathiae.*

(3) *Limitations.* Discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992, as amended at 59 FR 42493, Aug. 18, 1994; 60 FR 26359, May 17, 1995; 62 FR 55160, Oct. 23, 1997; 65 FR 10705, Feb. 29, 2000; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 68 FR 26204, May 15, 2003; 69 FR 9946, Mar. 3, 2004; 69 FR 41428, July 9, 2004; 77 FR 20988, Apr. 9, 2012; 78 FR 28825, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 36789, June 8, 2016; 81 FR 94990, Dec. 27, 2016; 84 FR 8973, Mar. 13, 2019. Redesignated at 85 FR 18119, Apr. 1, 2020, as amended at 86 FR 57997, Oct. 20, 2021]

§ 520.1696c Penicillin V tablets.

(a) *Specifications.* Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

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

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994; 78 FR 28826, May 20, 2014; 84 FR 39183, Aug. 9, 2019. Redesignated at 85 FR 18119, Apr. 1, 2020; 88 FR 27699, May 3, 2023]

§ 520.1705 Pergolide.

(a) *Specifications.* Each tablet contains 1 milligram (mg) peroglide (as pergolide mesylate).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally at a starting dose of 2 micrograms/kilograms (μ/kg) once daily. Dosage may be adjusted to effect, not to exceed 4 μg/kg daily.

(2) *Indications for use.* For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

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

[77 FR 15960, Mar. 19, 2012, as amended at 81 FR 22523, Apr. 18, 2016]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams (mg), or 1 gram (g) phenylbutazone. Each bolus contains 1, 2, or 4 g phenylbutazone.

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

(1) No. 000061 for use of 100- or 400-mg or 1-g tablets, or 2- or 4-g boluses, in dogs and horses.

(2) No. 069043 for use of 100- or 200-mg or 1-g tablets in dogs and horses.

(3) Nos. 054771 and 061133 for use of 100-mg or 1-g tablets in dogs and horses.

(4) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses.

(5) No. 058198 for use of 1-g tablets in horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 20 mg per pound of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount.* 1 to 2 g per 500 pounds of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 8192, Feb. 13, 2008, as amended at 74 FR 1146, Jan. 12, 2009; 76 FR 11331, Mar. 2, 2011; 76 FR 17777, Mar. 31, 2011; 78 FR 21060, Apr. 9, 2013; 78 FR 28826, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8973, Mar. 13, 2019; 85 FR 45307, July 28, 2020; 86 FR 14819, Mar. 19, 2021; 87 FR 58961, Sept. 29, 2022]

§ 520.1720b Phenylbutazone granules.

(a) *Specifications.* Each package of granules contains 1 or 8 grams of phenylbutazone.

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

(1) No. 000061 for 8-gram package.

(2) No. 059320 for 1-gram package.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily as required. by adding to a portion of the usual grain ration.

(2) *Indications for use.* For the treatment of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug

to use by or on the order of a licensed veterinarian.

[78 FR 28826, May 20, 2014]

§ 520.1720c Phenylbutazone paste.

(a) *Specifications.* (1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

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

(1) No. 000061 for use of product described in paragraph (a)(1) of this section.

(2) No. 017030 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007; 77 FR 4897, Feb. 1, 2012; 78 FR 28826, May 20, 2014; 79 FR 74020, Dec. 15, 2014]

§ 520.1720d Phenylbutazone gel.

(a) *Specifications.* Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter. require bioequivalency and safety information.

(c) *Conditions of use in horses*—(1) *Amount.* 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use.* For relief of inflammatory conditions associated with the musculoskeletal system of horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 78 FR 28826, May 20, 2014; 84 FR 8973, Mar. 13, 2019]

§ 520.1720e Phenylbutazone powder.

(a) *Specifications.* (1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

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

(1) No. 086119 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.

(2) *Indications for use.* For the relief of inflammatory conditions associated with the musculosketetal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27956, May 18, 2007, as amended at 90 FR 6800, Jan. 21, 2025]

§ 520.1760 Phenylpropanolamine.

(a) *Specifications.* (1) Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(2) Each extended-release tablet contains 18, 38, 74, or 145 mg phenylpropanolamine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) Nos. 055246 and 086117 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) and (3) of this section.

(2) No. 055246 for use of product described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii) and (c)(2) and)(3) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally as follows:

(i) Chewable tablet: 2 mg/kg of body weight twice daily.

(ii) Extended-release tablet: 2 to 4 mg/kg of body weight once daily with food.

(2) *Indications for use*. For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

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

[77 FR 15961, Mar. 19, 2012, as amended at 84 FR 39183, Aug. 9, 2019; 89 FR 85426, Oct. 28, 2024]

§ 520.1780 Pimobendan tablets.

(a) *Specifications*. Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) *Sponsors*. See Nos. 000010 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use*. For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (*e.g.*, furosemide, etc.) as appropriate on a case-by-case basis.

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

[72 FR 27733, May 17, 2007, as amended at 79 FR 18158, Apr. 1, 2014; 87 FR 10968, Feb. 28, 2022; 89 FR 42357, May 15, 2024; 89 FR 85426, Oct. 28, 2024]

§ 520.1782 Pimobendan solution.

(a) *Specifications*. Each milliliter of solution contains 1.5 milligrams (mg) pimobendan.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally at a total daily dose of 0.23 mg/lb (0.5 mg/kg) body weight. The total daily dose should be divided into two equal portions administered approximately 12 hours apart (*i.e.*, morning and evening).

(2) *Indications for use*. For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (*e.g.*, furosemide, etc.) as appropriate on a case-by-case basis.

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

[89 FR 42357, May 15, 2024]

§ 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

§ 520.1802a Piperazine-carbon disulfide complex suspension.

(a) *Specifications*. Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

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

(c) *Conditions of use in horses and ponies*—(1) *Amount*. Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum)*, bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongyles* spp.), and pinworms (*Oxyuris equi*).

(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.

[45 FR 52781, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications*. Each bolus contains 20 grams of piperazine-carbon disulfide complex.

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

(c) *Conditions of use in horses and ponies*—(1) *Amount.* For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).

(3) *Limitations.* Withhold feed overnight or for 8 to 10 hours. Give water just before and/or after treatment. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics or other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[45 FR 52782, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.

(a) *Specifications.* Each fluid ounce contains 5 grams of piperazine-carbon disulfide complex and 0.83 gram of phenothiazine.

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

(c) *Conditions of use in horses and ponies*—(1) *Amount.* Administer 1 fluid ounce per 100 pounds of body weight by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, and large strongyles (*Strongylus* spp.).

(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.

[45 FR 52782, Aug. 8, 1980, as amended at 78 FR 28826, May 20, 2014]

§ 520.1803 Piperazine citrate capsules.

(a) *Specifications.* Each capsule contains piperazine citrate equivalent to 140 milligrams of piperazine base.

(b) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in 1/2 of the regular feeding and when the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfection may occur. Repeat treatment if indicated.

(2) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(3) *Limitations.* Severely debilitated animals should not be treated except on the advice of a veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 54 FR 38515, Sept. 19, 1989; 78 FR 28826, May 20, 2014]

§ 520.1805 Piperazine phosphate with thenium closylate tablets.

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate) or 500 milligrams piperazine hexahydrate (as piperazine phosphate) and 250 milligrams thenium (as thenium closylate).

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

(c) *Conditions of use*—(1) *Amount.* Administer orally to dogs as follows:

NUMBER OF TABLETS AT EACH OF THE TWO DOSES

Animal weight (lb)	375 mg	750 mg
2 but less than 5	½	

NUMBER OF TABLETS AT EACH OF THE TWO DOSES—Continued

Animal weight (lb)	375 mg	750 mg
5 but less than 10	1	½
10 or heavier	2	1

(2) *Indications for use.* For removal of immature (fourth stage larvae) and adult hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) and ascarids (*Toxocara canis*) from weaned pups and adult dogs.

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

[43 FR 32747, July 28, 1978, as amended at 47 FR 55476, Dec. 10, 1982; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 78 FR 28826, May 20, 2014]

§ 520.1806 Piperazine suspension.

(a) *Specifications.* Each milliliter of suspension contains piperazine monohydrochloride equivalent to 33.5 milligrams (mg) piperazine base.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25(c) of this chapter.

(d) *Conditions of use in dogs*—(1) *Indications for use.* For the removal of roundworms (*Toxocara canis*and *Toxascaris leonina*).

(2) *Dosage.* Administer 20 to 30 mg piperazine base per pound body weight as a single dose.

(3) *Limitations.* Administer by mixing into the animal's ration to be consumed at one feeding. For animals in heavily contaminated areas, reworm at monthly intervals. Not for use in unweaned pups or animals less than 3 weeks of age.

[70 FR 17319, Apr. 6, 2005]

§ 520.1840 Poloxalene.

(a) *Specifications.* Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use as in paragraphs (d)(1) and (d)(3) of this section.

(2) No. 067949 for use as in paragraph (d)(2) of this section.

(3) No. 066104 for use as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.517 of this chapter.

(d) *Conditions of use.* (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 oz. of block (1.5 grams poloxalene) per 100 lbs. of body weight per day.

(3) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle. A 53-percent poloxalene top dressing on individual rations of ground feed. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat use of the drug if animals are exposed to bloat-producing conditions for more than 12 hours after the last treatment. Do not exceed the double dose in any 24-hour period.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39857, Aug. 29, 1975; 42 FR 41854, Aug. 19, 1977; 50 FR 5385, Feb. 8, 1985; 54 FR 33501, Aug. 15, 1989; 56 FR 50653, Oct. 8, 1991; 58 FR 26523, May 4, 1993; 60 FR 55659, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001; 69 FR 62811, Oct. 28, 2004; 70 FR 32489, June 3, 2005; 78 FR 28826, May 20, 2014; 83 FR 48946, Sept. 28, 2018; 84 FR 32992, July 11, 2019]

§ 520.1855 Ponazuril.

(a) *Specifications.* Each gram of paste contains 150 milligrams (mg) ponazuril.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 15 mg per kilogram (kg) (6.81 mg per pound (lb)) body weight as the first dose, followed by 5 mg/kg (2.27 mg/lb) body weight once daily for a period of 27 additional days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*.

(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.

[66 FR 43774, Aug. 21, 2001, as amended at 79 FR 28827, May 20, 2014; 80 FR 34278, June 16, 2015; 80 FR 53459, Sept. 4, 2015; 84 FR 39183, Aug. 9, 2019]

§ 520.1860 Pradofloxacin.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) pradofloxacin.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 3.4 mg/lb (7.5 mg/kg) body weight once daily for 7 consecutive days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*, *Streptococcus canis*, *Staphylococcus aureus*, *Staphylococcus felis*, and *Staphylococcus pseudintermedius*.

(3) *Limitations.* Federal law prohibits the extralabel use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 76863, Dec. 31, 2012, as amended at 79 FR 28827, May 20, 2014; 86 FR 14819, Mar. 19, 2021]

§ 520.1870 Praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 34 milligrams (mg) praziquantel.

(2) 11.5 or 23 mg praziquantel.

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

(1) No. 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (c)(1) of this section and for use of product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

(2) Nos. 069043 and 086101 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 pounds (lb) and under, ½ tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1½ tablets (51 mg); 16 to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 3 tablets (102 mg); 46 to 60 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.

(ii) *Indications for use*—(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(B) For removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*—(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(ii) *Dosage.* Cats 4 pounds and under, 11.5 mg; 5 to 11 pounds, 23 mg; over 11 pounds, 34.5 mg.

(iii) *Limitations.* Administer directly by mouth or crumbled and in feed. Not intended for use in kittens less than 6 weeks of age. For over the counter use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 60570, Dec. 11, 1981, as amended at 47 FR 26377, June 18, 1982; 55 FR 2234, Jan. 23, 1990; 58 FR 7864, Feb. 10, 1993; 58 FR 42853, Aug. 12, 1993; 68 FR 57351, Oct. 3, 2003; 69 FR 62181, Oct. 25, 2004; 78 FR 17596, Mar. 22, 2013; 81 FR 17607, Mar. 30, 2016; 86 FR 14819, Mar. 19, 2021; 87 FR 58961, Sept. 29, 2022; 88 FR 27699, May 3, 2023]

§ 520.1871 Praziquantel and pyrantel.

(a) *Specifications.* (1) Each tablet contains 13.6 milligrams (mg) praziquantel and 54.3 mg pyrantel base (as pyrantel pamoate), 18.2 mg praziquantel and 72.6 mg pyrantel base (as pyrantel pamoate), or 27.2 mg praziquantel and 108.6 mg pyrantel base (as pyrantel pamoate).

(2) Each chewable tablet contains 30 mg praziquantel and 30 mg pyrantel pamoate or 114 mg praziquantel and 114 mg pyrantel pamoate.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as in paragraph (d) of this chapter.

(1) See No. 058198 for use of tablets described in paragraph (a)(1) of this section for use as in paragraph (d)(1) of this section.

(2) See No. 051311 for use of tablets described in paragraph (a)(2) of this section for use as in paragraph (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Cats*—(i) *Dosage.* Administer a minimum dose of 2.27 mg praziquantel and 9.2 mg pyrantel pamoate per pound of body weight according to the dosing tables on labeling. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated.

(ii) *Indications for use.* For removal of tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*), hookworms (*Ancylostoma tubaeforme*), and large roundworms (*Toxocara cati*) in cats and kittens.

(iii) *Limitations.* Not for use in kittens less than 2 months of age or weighing less than 2.0 pounds. Consult your veterinarian before giving to sick or pregnant animals.

(2) *Dogs*—(i) *Amount.* Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) *Indications for use.* For the treatment and control of roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) in dogs and puppies.

[58 FR 58652, Nov. 3, 1993, as amended at 72 FR 16270, Apr. 4, 2007; 75 FR 54018, Sept. 3, 2010; 86 FR 14819, Mar. 19, 2021]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) *Specifications.* Each tablet or chewable tablet contains either:

(1) Tablet No. 1: 22.7 milligrams praziquantel, 22.7 milligrams pyrantel base, and 113.4 milligrams febantel; or

(2) Tablet No. 2: 68 milligrams praziquantel, 68 milligrams pyrantel base, and 340.2 milligrams febantel.

(3) Tablet No. 3: 136 milligrams (mg) praziquantel, 136 mg pyrantel base, and 680.4 mg febantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer as a single dose directly by mouth or in a small amount of food as follows:

Weight of animal		Number of tablets per dose		
Kilograms	Pounds	Tablet no. 1	Tablet no. 2	Tablet no. 3
0.9 to 1.8	2 to 4	1/2.		
2.3 to 3.2	5 to 7	1.		
3.6 to 5.4	8 to 12	1 1/2.		
5.9 to 8.2	13 to 18	2.		
8.6 to 11.4	19 to 25	2 1/2.		
11.8 to 13.6	26 to 30	.....	1.	
14.1 to 20.0	31 to 44	.....	1 1/2.	
20.4 to 27.2	45 to 60	.....	2	1
27.7 to 40.9	61 to 90	.....	.....	1 1/2
41.3 to 54.5	91 to 120	.....	.....	2

(ii) *Indications for use.* For the removal of tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*); hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*); ascarids (*Toxocara canis*, *Toxascaris leonina*); and whipworms (*Trichuris vulpis*) and for the removal and control of tapeworm *Echinococcus multilocularis* in dogs.

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

(2) [Reserved]

[59 FR 33908, July 1, 1994, as amended at 61 FR 29651, June 12, 1996; 68 FR 22293, Apr. 28, 2003; 71 FR 6677, Feb. 9, 2006; 86 FR 14819, Mar. 19, 2021; 87 FR 58961, Sept. 29, 2022]

§ 520.1880 Prednisolone.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams prednisolone.

(b) *Sponsor.* See No. 061690 in § 510.600(c)(2) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 2.5 milligrams per 4.5 kilograms (10 pounds) body weight per day. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7

days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* For use as an anti-inflammatory agent.

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

[57 FR 4718, Feb. 7, 1992, as amended at 60 FR 57832, Nov. 22, 1995; 63 FR 148, Jan. 5, 1998; 79 FR 28827, May 20, 2014]

§ 520.1892 Pregabalin.

(a) *Specifications.* Each milliliter (mL) of solution contains 50 milligrams (mg) pregabalin.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally as a single dose of 5 mg/kg (0.1 mL/kg) approximately 1.5 hours before the start of the transportation or veterinary visit.

(2) *Indications for use.* For alleviation of acute anxiety and fear associated with transportation and veterinary visits.

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

[89 FR 14410, Feb. 27, 2024]

§ 520.1900 Primidone.

(a) *Specifications.* Each tablet contains 50 or 250 milligrams of primidone.

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

(1) No. 069043 for use of 250 milligram tablets.

(2) No. 054771 for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs*—(1) *Amount.* Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.

(2) *Indications for use.* For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.

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

[42 FR 61594, Dec. 6, 1977, as amended at 43 FR 55386, Nov. 28, 1978; 46 FR 8467, Jan. 27, 1981; 46 FR 57477, Nov. 24, 1981; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35076, June 30, 1997; 78 FR 21060, Apr. 9, 2013; 79 FR 28827, May 20, 2014; 83 FR 48946, Sept. 28, 2018]

§ 520.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each capsules contains either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide); or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

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

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Capsules described in paragraph (a)(1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a)(2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(2) *Indications for use.* For the treatment of gastrointestinal disturbances associated with emotional stress.

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

[79 FR 28827, May 20, 2014]

§ 520.1921 Prochlorperazine, isopropamide, and neomycin.

(a) *Specifications.* Each capsule contains either:

(1) Capsule No. 1: 3.33 milligrams of prochlorperazine (as the dimaleate), 1.67 milligrams of isopropamide (as the iodide), and 25 milligrams of neomycin base (as the sulfate); or

(2) Capsule No. 3: 10 milligrams of prochlorperazine (as the dimaleate), 5

milligrams of isopropamide (as the iodide), and 75 milligrams of neomycin base (as the sulfate).

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer capsules orally twice daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 3
10 to 20	1	
20 to 30	2	
Over 30	3	1
Over 60		2

(2) *Indications for use*. For the treatment infectious bacterial gastroenteritis associated with emotional stress.

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

[49 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 79 FR 28827, May 20, 2014]

§ 520.1962 Promazine.

(a) *Specifications*. Conforms to N.F. XII for promazine hydrochloride.

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

(c) *Conditions of use in horses*—(1) *Amount*. Administer 0.45 to 0.9 milligrams per pound of body weight mixed with an amount of feed that will be readily consumed.

(2) *Indications for use*. For quieting excitable, unruly, or intractable 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.

[79 FR 28827, May 20, 2014]

§ 520.2002 Propiopromazine.

(a) *Specifications*. Each chewable tablet contains 10 or 20 milligrams of propiopromazine hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer 0.5 to 2.0 milligrams per pound of body weight once or twice daily, depending upon the degree of tranquilization desired.

(2) *Indications for use*. For oral administration as a tranquilizer. As an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking, car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

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

[79 FR 28827, May 20, 2014]

§ 520.2041 Pyrantel pamoate chewable tablets.

(a) *Specifications*. Each tablet contains pyrantel pamoate equivalent to 22.7 or 113.5 milligrams pyrantel base.

(b) *Sponsor*. See Nos. 017135 and 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Provides at least 2.27 milligrams pyrantel base per pound body weight for dogs weighing more than 5 pounds, and at least 4.54 milligrams of pyrantel base per pound body weight for dogs weighing 5 pounds or less.

(2) *Indications for use*—(i) *In dogs and puppies*. For removal of ascarids (*Toxocara canis; Toxascaris leonina*) and hookworms (*Ancylostoma caninum; Uncinaria stenocephala*).

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis*.

(3) *Limitations*. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001; 67 FR 21996, May 2, 2002; 81 FR 22523, Apr. 18, 2016; 82 FR 12169, Mar. 1, 2017; 84 FR 8973, Mar. 13, 2019]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications*. Each tablet contains pyrantel pamoate equivalent to 22.7, 45.4, or 113.5 milligrams of pyrantel base.

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used for dogs as follows:

(1) *Amount.* For dogs weighing over 5 pounds, use at least 2.27 milligrams of pyrantel base per pound of body weight; for dogs weighing 5 pounds or less, use at least 4.54 milligrams of pyrantel base per pound of body weight.

(2) *Indications for use.* For removal and control of large roundworms (ascarids) (*Toxocara canis* and *Toxascaris leonina*), and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(3) *Limitations.* Administer orally directly or in a small amount of food. To prevent reinfection of *T. canis* in puppies, lactating bitches after whelping, and adult dogs; treat puppies 2, 3, 4, 6, 8, and 10 weeks of age; treat lactating bitches 2 to 3 weeks after whelping; routinely treat adult dogs monthly. Do not withhold food prior to or after treatment. The presence of these parasites should be confirmed by laboratory fecal examination. A followup fecal examination should be conducted 2 to 4 weeks after first treatment regimen to determine the need for re-treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 52700, Nov. 14, 1978, as amended at 49 FR 22073, May 25, 1984; 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993]

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications.* (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 054771, 058829, and 069043 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 054771, 058198, and 058829 for use of the products described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses and ponies.* It is used as follows:

(i) *Amount.* 3 mg per pound (/lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

(iii) *Limitations.* Do not use in horses intended for human consumption. When the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(2) *Dogs.* It is used as follows:

(i) *Dogs and puppies*—(A) *Amount.* 2.27 mg/lb body weight as a single dose in the animal's feed bowl by itself or mixed in a small quantity of food.

(B) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(C) *Limitations.* Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) *Dogs, puppies, and lactating bitches after whelping*—(A) *Amount.* 2.27 mg/lb body weight.

(B) *Indications for use.* To prevent reinfections of *T. canis.*

(C) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

[67 FR 43248, June 27, 2002, as amended at 68 FR 54803, Sept. 19, 2003; 68 FR 55199, Sept. 23, 2003; 68 FR 55825, Sept. 29, 2003; 75 FR 52622, Aug. 27, 2010; 76 FR 17337, Mar. 29, 2011; 78 FR 17596, Mar. 22, 2013; 79 FR 28827, May 20, 2014; 80 FR 76386, Dec. 9, 2015; 81 FR 17607, Mar. 30, 2016; 86 FR 14819, Mar. 19, 2021]

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications*—(1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).

(2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

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

(1) No. 054771 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

(2) No. 017135 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

(3) No. 061133 for use of product described in paragraph (a)(3) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use.* It is used in horses and ponies as follows:

(1) *Amounts and indications for use.* (i) 3 mg per pound (/lb) body weight as single oral dose for removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

(ii) 6 mg/lb body weight as single oral dose for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*).

(2) *Limitations.* Do not use in horses intended for human consumption.

[70 FR 29447, May 23, 2005, as amended at 76 FR 17337, Mar. 29, 2011; 78 FR 17596, Mar. 22, 2013; 79 FR 28827, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 84 FR 8973, Mar. 13, 2019]

§ 520.2045 Pyrantel tartrate powder.

(a) *Specifications.* Each gram of powder contains 106 milligrams (10.6 percent) or 113 milligrams (11.3 percent) pyrantel tartrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of 11.3 percent powder as in paragraph (d)(1) and 10.6 percent powder as in paragraph (d)(2) and of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration. Do not administer by stomach tube or dose syringe.

(ii) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(iii) *Limitations.* Do not treat severely debilitated animals with this drug. Do not use in horses intended for human consumption.

(2) *Swine*—(i) *Amount.* Add to feed at 0.4 gram pyrantel tartrate per pound of non-pelleted ration. The ration is administered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(ii) *Indications for use.* For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(iii) *Limitations.* Consult veterinarian before using in severely debilitated animals. Do not treat within 24 hours of slaughter.

[79 FR 28827, May 20, 2014]

§ 520.2046 Pyrantel tartrate pellets.

(a) *Specifications.* (1) Each gram of pellets contains 12.5 milligrams (mg) (1.25 percent) pyrantel tartrate; or

(2) Each gram of pellets contains 21.1 mg (2.11 percent) pyrantel tartrate.

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

(1) No. 054771 for use of products described in paragraph (a) as in paragraph (c) of this section.

(2) No. 061133 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(c) *Conditions of use in horses*—(1) *Amount.* Administer as a single dose at 12.5 mg per 2.2 pounds of body weight mixed with the usual grain ration.

(2) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*),

pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(3) *Limitations*. Do not treat severely debilitated animals with this drug. Do not use in horses intended for human consumption.

[79 FR 28828, May 20, 2014, as amended at 84 FR 8973, Mar. 13, 2019]

§ 520.2075 Robenacoxib.

(a) *Specifications*. Each tablet contains 10, 20, or 40 milligrams (mg) robenacoxib for use in dogs, or 6 mg robenacoxib for use in cats.

(b) *Sponsors*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.91 mg/lb (2 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs weighing at least 5.5 lb (2.5 kg) and at least 4 months of age for a maximum of 3 days.

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

(2) *Cats*—(i) *Amount*. Administer 0.45 mg/lb (1 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 4 months of age for a maximum of 3 days.

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

[76 FR 18648, Apr. 5, 2011, as amended at 79 FR 10964, Feb. 27, 2014; 81 FR 59133, Aug. 29, 2016]

§ 520.2086 Sarolaner.

(a) *Specifications*. Each chewable tablet contains 5, 10, 20, 40, 80, or 120 milligrams (mg) sarolaner.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg).

(2) *Indications for use*. Kills adult fleas, and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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

[81 FR 22523, Apr. 18, 2016, as amended at 82 FR 12169, Mar. 1, 2017; 86 FR 61685, Nov. 8, 2021; 90 FR 6800, Jan. 21, 2025]

§ 520.2090 Sarolaner, moxidectin, and pyrantel.

(a) *Specifications*. Each chewable tablet contains:

(1) 3.0 milligrams (mg) sarolaner, 0.06 mg moxidectin, and 12.5 mg pyrantel (as pamoate salt);

(2) 6.0 mg sarolaner, 0.12 mg moxidectin, and 25.0 mg pyrantel (as pamoate salt);

(3) 12.0 mg sarolaner, 0.24 mg moxidectin, and 50.0 mg pyrantel (as pamoate salt);

(4) 24.0 mg sarolaner, 0.48 mg moxidectin, and 100 mg pyrantel (as pamoate salt);

(5) 48.0 mg sarolaner, 0.96 mg moxidectin, and 200 mg pyrantel (as pamoate salt); or

(6) 72.0 mg sarolaner, 1.44 mg moxidectin, and 300 mg pyrantel (as pamoate salt).

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally, once a month, at the recommended minimum dose of 0.54 mg/lb (1.2 mg/kg) sarolaner, 0.011 mg/lb (24 µg/kg) moxidectin, and 2.27 mg/lb (5 mg/kg) pyrantel (as pamoate salt).

(2) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and hookworm

(L4, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*) infections. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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

[85 FR 45307, July 28, 2020, as amended at 86 FR 57997, Oct. 20, 2021; 87 FR 17945, Mar. 29, 2022; 89 FR 95103, Dec. 2, 2024; 90 FR 6800, Jan. 21, 2025]

§ 520.2098 Selegiline.

(a) *Specifications.* Each tablet contains 2, 5, 10, 15, or 30 milligrams (mg) selegiline hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amounts and indications for use.* (i) Administer 1 mg per kilogram (0.45 mg per pound) of body weight once daily for control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) Administer 0.5 to 1.0 mg per kilogram of body weight once daily for the control of clinical signs associated with canine cognitive dysfunction syndrome.

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

[79 FR 28828, May 20, 2014]

§ 520.2100 Selenium and vitamin E.

(a) *Specifications.* Each capsule contains:

(1) 2.19 milligrams (mg) sodium selenite (equivalent to 1 mg selenium) and 56.2 mg (68 I.U.) vitamin E as d-alpha tocopheryl acid succinate; or

(2) 0.548 mg sodium selenite (equivalent to 0.25 mg selenium) and 14 mg (17 I.U.) vitamin E as d-alpha tocopheryl acid succinate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Dogs over 20 pounds: Administer 1 capsule described in paragraph (a)(1) per 20 pounds of body weight to a maximum of 5 capsules. Repeat at 3 day intervals until a satisfactory therapeutic response is observed. Maintenance dosage is 1 capsule per 40 pounds of body weight every 3 to 7 days, or longer, as required.

(ii) Dogs under 20 pounds: Administer 1 capsule described in paragraph (a)(2) per 5 pounds of body weight with a minimum of 1 capsule. Repeat at 3-day intervals until a satisfactory response is observed. Maintenance dosage is 1 capsule per 10 pounds of body weight every 3 to 7 days, or longer, as required.

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

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

[79 FR 28828, May 20, 2014]

§ 520.2123 Spectinomycin oral dosage forms.

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 054771 and 061133 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

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

[73 FR 6607, Feb. 5, 2008, as amended at 79 FR 28828, May 20, 2014; 84 FR 8973, Mar. 13, 2019]

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts.* (i) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(ii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008, as amended at 81 FR 94990, Dec. 27, 2016; 84 FR 8973, Mar. 13, 2019]

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 016592, 054771, and 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008, as amended at 78 FR 17596, Mar. 22, 2013; 79 FR 28828, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 84 FR 8973, Mar. 13, 2019; 88 FR 14897, Mar. 10, 2023]

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

(b) *Sponsor.* See No. 058198 in § 510.600 of this chapter.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer tablets once a month at a recommended minimum dosage of 13.5 mg per pound (30 mg per kilogram) of body weight.

(ii) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) for 1 month on dogs and puppies 14 weeks of age and older and 5.0 pounds of body weight or greater.

(2) *Cats*—(i) *Amount.* Administer tablets once a month at a minimum dosage of 22.5 mg per pound (50 mg per kilogram) of body weight.

(ii) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*C. felis*) for 1 month on cats and kittens 14 weeks of age and older and 4.1 pounds of body weight or greater.

[77 FR 60623, Oct. 4, 2012, as amended at 81 FR 48702, July 26, 2016; 87 FR 10968, Feb. 28, 2022; 89 FR 85426, Oct. 28, 2024]

§ 520.2134 Spinosad and milbemycin.

(a) *Specifications.* Each chewable tablet contains 140 milligrams (mg) spinosad and 2.3 mg milbemycin oxime, 270 mg spinosad and 4.5 mg milbemycin oxime, 560 mg spinosad and 9.3 mg milbemycin oxime, 810 mg spinosad and 13.5 mg milbemycin oxime, or 1,620 mg spinosad and 27 mg milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer once a month at a minimum dosage of 13.5 mg/pound (lb) (30 mg/kilogram (kg)) of body weight spinosad and 0.2 mg/lb (0.5 mg/kg) of body weight milbemycin oxime.

(2) *Indications for use.* To kill fleas; for the prevention and treatment of flea infestations (*Ctenocephalides felis*); for the prevention of heartworm disease (*Dirofilaria immitis*); and for the treatment and control of adult hookworm (*Ancylostoma caninum*), adult roundworm (*Toxocara canis* and *Toxascaris leonina*), and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and 5 lbs of body weight or greater.

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

[76 FR 12563, Mar. 8, 2011, as amended at 81 FR 48702, July 26, 2016]

§ 520.2138 Spironolactone and benazepril.

(a) *Specifications.* Each chewable tablet contains 20 milligrams (mg) spironolactone and 2.5 mg benazepril hydrochloride, 40 mg spironolactone and 5 mg benazepril hydrochloride, or 80 mg spironolactone and 10 mg benazepril hydrochloride.

(b) *Sponsor.* See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once daily, with food, at a dose of 0.9 mg per pound (lb) (2 mg per kilogram (kg)) spironolactone and 0.11 mg/lb (0.25 mg/kg) benazepril hydrochloride, according to dog body weight using a suitable combination of whole and/or half tablets.

(2) *Indications for use.* With concurrent therapy (*e.g.*, furosemide, etc.) for the management of clinical signs of mild, moderate, or severe congestive heart failure in dogs due to atrioventricular valvular insufficiency (AVVI).

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

[86 FR 14819, Mar. 19, 2021]

§ 520.2150 Stanozolol.

(a) *Specifications.* Each tablet or chewable tablet contains 2 milligrams stanozolol.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs:* Administered orally to small breeds, ½ to 1 tablet twice daily for several weeks; to large breeds, 1 to 2 tablets twice daily for several weeks. The tablets may be crushed and administered in feed.

(ii) *Cats:* Administered orally ½ to 1 tablet twice daily for several weeks.

(2) *Indications for use.* As an anabolic steroid treatment.

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

[79 FR 28828, May 20, 2014]

§ 520.2158 Streptomycin.

(a) *Specifications.* Each milliliter of solution contains 250 milligrams (25 percent) streptomycin sulfate.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.610 of this chapter.

(d) *Conditions of use.* Use in drinking water as follows:

(1) *Calves*—(i) *Amount.* 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

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

(2) *Swine*—(i) *Amount.* 10 to 15 mg/pound of body weight (1.0 to 1.5 grams per gallon) for up to 4 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

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

(3) *Chickens*—(i) *Amount.* 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.

(iii) *Limitations.* Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Federal law restricts this

drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 58 FR 47211, Sept. 8, 1993; 63 FR 51821, Sept. 29, 1998. Redesignated and amended at 79 FR 28828, May 20, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 18776, Apr. 8, 2015; 80 FR 61296, Oct. 13, 2015]

§ 520.2184 Sulfachloropyrazine.

(a) *Specifications.* Each gram of powder contains 476 milligrams of sodium sulfachloropyrazine monohydrate.

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

(c) *Related tolerance.* See § 556.625 of this chapter.

(d) *Conditions of use in chickens.* It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:

(1) *Amount.* Administer in drinking water as 0.03 percent solution for 3 days.

(2) *Indications for use.* For the treatment of coccidiosis.

(3) *Limitations.* Withdraw 4 days prior to slaughter. Do not use in chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28829, May 20, 2014, as amended at 81 FR 94990, Dec. 27, 2016]

§ 520.2200 Sulfachlorpyridazine.

(a) *Specifications.* (1) Sodium sulfachlorpyridazine powder.

(2) Each milliliter (mL) of suspension contains 50 milligrams (mg) of sodium sulfachlorpyridazine.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Calves*—(i) *Amount.* Administer 30 to 45 mg sulfachlorpyridazine powder per pound (/lb) of body weight per day in milk or milk replacer in divided doses twice daily for 1 to 5 days.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(iii) *Limitations.* Treated ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer 20 to 35 mg/lb body weight per day in divided doses twice daily for 1 to 5 days in drinking water or an oral suspension containing 50 mg per mL.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10166, Mar. 5, 2010, as amended at 79 FR 28829, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 94990, Dec. 27, 2016; 88 FR 27699, May 3, 2023]

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

(b) *Sponsor.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(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 70054, Dec. 2, 2004, as amended at 73 FR 53686, Sept. 17, 2008; 75 FR 69586, Nov. 15, 2010]

§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.

(a) *Specifications.* Each 195-gram (g) packet of powder contains 78 g sulfamerazine, 78 g sulfamethazine, and 39 g sulfaquinoxaline.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.660, 556.670, and 556.685 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amounts and indications for use.* (A) As an aid in the control of coccidiosis caused by *Eimeria tenella* and *E. necatrix* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. If bloody droppings appear, repeat at 0.025 percent level for 2 more days. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations.* Do not treat chickens within 14 days of slaughter for food. Do not medicate chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amounts and indications for use.* (A) As an aid in the control of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations.* Do not treat turkeys within 14 days of slaughter for food. Do not medicate turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 13001, Mar. 14, 2006, as amended at 79 FR 28829, May 20, 2014; 80 FR 34278, June 16, 2015; 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016; 85 FR 18119, Apr. 1, 2020]

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) *Specifications.* (1) Each ounce of solution contains 3.75 grams (12.5 percent) sulfadimethoxine.

(2) Each 107 grams of powder contains the equivalent of 94.6 grams sulfadimethoxine as sulfadimethoxine sodium.

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

(1) Nos. 016592, 054771, 054925, and 069043 for use of the product described in paragraph (a)(1) of this section.

(2) Nos. 016592, 054771, 054925, 058829, 061133, and 066104 for use of the product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use*—(1) *Broiler and replacement chickens*—(i) *Amount.* Administer 1.875 grams per gallon (0.05 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use.* For treatment of outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* Administer 0.938 grams per gallon (0.025 percent) of drinking water for 6 consecutive days.

(ii) *Indications for use.* Growing turkeys: For treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to turkeys over 24 weeks (168 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* 1.18 to 2.36 grams per gallon (0.031 to 0.062 percent) of drinking water. As a drench, administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days. If no improvement within 2 to 3 days, reevaluate diagnosis. Do not treat beyond 5 days.

(ii) *Indications for use.* Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

(iii) *Limitations.* Withdraw 7 days before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

[79 FR 28829, May 20, 2014, as amended at 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8973, Mar. 13, 2019; 87 FR 10968, Feb. 28, 2022]

§ 520.2220b Sulfadimethoxine suspension.

(a) *Specifications.* Each milliliter of suspension contains 50 milligrams (mg) sulfadimethoxine.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily until the animal is free of clinical signs for 48 hours.

(2) *Indications for use.* For the treatment of sulfadimethoxine-susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

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

[79 FR 28829, May 20, 2014, as amended at 88 FR 55564, Aug. 16, 2023]

§ 520.2220c Sulfadimethoxine tablet.

(a) *Specifications.* Each tablet contains 125, 250, or 500 milligrams (mg) sulfadimethoxine.

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily until the animal is free of clinical signs for 48 hours.

(2) *Indications for use.* For the treatment of sulfadimethoxine-susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

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

[79 FR 28829, May 20, 2014, as amended at 88 FR 55564, Aug. 16, 2023]

§ 520.2220d Sulfadimethoxine bolus.

(a) *Specifications.* Each bolus contains 2.5, 5, or 15 grams sulfadimethoxine.

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

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.

(2) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations.* Do not administer within 7 days of slaughter. Milk that has been taken from animals during treatment and 60 hours (five milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28829, May 20, 2014, as amended at 88 FR 16547, Mar. 20, 2023]

§ 520.2220e Sulfadimethoxine extended-release bolus.

(a) *Specifications.* Each extended-release bolus contains 12.5 grams sulfadimethoxine.

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

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use in beef cattle and non-lactating dairy cattle*—(1) *Amount.*

Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.

(2) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(3) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2220f Sulfadimethoxine and ormetoprim tablet.

(a) *Specifications.* Each tablet contains 120 milligrams (mg) (100 mg sulfadimethoxine and 20 mg ormetoprim), 240 mg (200 mg sulfadimethoxine and 40 mg ormetoprim), 600 mg (500 mg sulfadimethoxine and 100 mg ormetoprim), or 1200 mg (1000 mg sulfadimethoxine and 200 mg ormetoprim).

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

(c) *Conditions of use in dogs*—(1) *Amount.* On the first day of treatment, administer 25 mg per pound (55 mg per kilogram) of body weight. Then follow with a daily dosage of 12.5 mg per pound (27.5 mg per kilogram) of body weight. Do not exceed a total of 21 consecutive days.

(2) *Indications of use.* Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *E. coli, Staphylococcus* spp., and *Proteus mirabilus* susceptible to ormetoprim-potentiated sulfadimethoxine.

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

[79 FR 28830, May 20, 2014]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine solution.

(a) *Specifications.* Each milliliter of solution contains 62.5 milligrams (mg) sodium sulfaethoxypyridazine.

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

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Do not treat within 10 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* For use at 2.5 grams per gallon. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; and as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2240b Sulfaethoxypyridazine tablets.

(a) *Specifications.* (1) Each tablet contains 2.5 or 15 grams sulfaethoxypyridazine.

(2) Each extended-release tablet contains 5 grams sulfaethoxypyridazine.

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

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use in cattle*—(1) *2.5- or 15-gram tablets*—(i) *Amount.* Administer 25 milligrams per pound of body weight per day for 4 days. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *15-gram extended-release tablets*—(i) *Amount.* Administer 100 milligrams per pound of body weight. Use as the sole source of sulfonamide.

(ii) *Indications for use.* For treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (*E. coli*, *Streptococci*, *Staphylococci*, *Sphaerophorus necrophorus* and Gram-negative rods including *Pasteurella*); and for use prophylactically during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(iii) *Limitations.* Do not treat within 16 days of slaughter. Not for use in lactating dairy cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28830, May 20, 2014]

§ 520.2260 Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblets and boluses.

(a) *Specifications.* Each oblet or bolus contains:

(1) 2.5, 5, or 15 grams sulfamethazine.

(2) 5 grams sulfamethazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section.

(1) No. 016592 for use of products described in paragraph (a)(1) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use.* (1) Oblets and boluses described in paragraph (a)(1) of this section:

(i) *Amount.* Administer as a single dose 100 milligrams per pound (mg/lb) of body weight the first day and 50 mg/lb of body weight on each following day.

(ii) *Indications for use*—(A) *Beef cattle and nonlactating dairy cattle.* For the treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), and coccidiosis (*Eimeria bovis* and *E. zurnii*).

(B) *Horses.* For the treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus* equi), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat cattle within 10 days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. 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.

(2) Boluses described in paragraph (a)(2) of this section:

(i) *Amount.* Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use*—(A) *Ruminating beef and dairy calves.* For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacillosis) caused by *Escherichia coli;* necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium*

necrophorum; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(B) [Reserved]

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[87 FR 58961, Sept. 29, 2022, as amended at 88 FR 14897, Mar. 10, 2023; 88 FR 16547, Mar. 20, 2023]

§ 520.2260b Sulfamethazine sustained-release boluses.

(a) *Related tolerances.* See § 556.670 of this chapter.

(b) [Reserved]

(c)(1) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of a 27-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 27 grams (1 bolus) for each 150 pounds of body weight as a single dose.

(ii) *Indications for use.* For nonlactating cattle for the treatment of infections caused by organisms sensitive to sulfamethazine such as hemorrhagic septicemia (shipping fever complex), bacterial pneumonia, foot rot, and calf diphtheria and as an aid in the control of bacterial diseases usually associated with shipping and handling of cattle.

(iii) *Limitations.* If no response within 2 to 3 days, reevaluate therapy; do not crush tablets; treated animals must not be slaughtered for food within 28 days after the latest treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter for use of a 32.1-gram sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* 32.1 grams (1 bolus) per 200 pounds of body weight.

(ii) *Indications for use.* For beef and nonlactating dairy cattle for the treatment of diseases caused by sulfamethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *E. coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, and acute mastitis and acute metritis caused by *Streptococcus* spp.)

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Do not treat animals within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) [Reserved]

(f)(1) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter for use of an 8.02-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer 2 boluses (8.02 grams per bolus) per 100 pounds of body weight, as a single dose.

(ii) *Indications for use.* Administer orally to ruminating calves for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bacterial pneumonia (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), and calf diphtheria (*Fusobacterium necrophorum*).

(iii) *Limitations.* For use in ruminating replacement calves only. Do not slaughter animals for food for at least 12 days after the last dose. Exceeding two consecutive doses may cause violative tissue residue to remain beyond the withdrawal time. Do not use in calves under 1 month of age or calves being fed an all milk diet. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g)(1) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter for use of a 30-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer at the rate of 1 bolus (30 grams per bolus) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use.* Administer orally to beef cattle and nonlactating dairy cattle for the treatment of the following diseases when caused by one

or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; bacterial pneumonia associated with *Pasteurell* spp.; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; acute mastitis and metritis caused by *Streptococcus* spp.

(iii) *Limitations.* For use in beef cattle and nonlactating dairy cattle only. Do not slaughter animals for food for at least 8 days after the last dose. Do not use in lactating dairy cattle. Do not administer more than two consecutive doses. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 36132, July 14, 1981, as amended at 48 FR 18803, Apr. 26, 1983; 48 FR 32760, July 19, 1983; 49 FR 29057, July 18, 1984; 50 FR 49372, Dec. 2, 1985; 51 FR 30212, Aug. 25, 1986; 53 FR 40727, Oct. 18, 1988; 54 FR 14341, Apr. 11, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 70 FR 8290, Feb. 18, 2005; 78 FR 17596, Mar. 22, 2013; 79 FR 28830, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 84 FR 8973, Mar. 13, 2019; 85 FR 18119, Apr. 1, 2020; 86 FR 14819, Mar. 19, 2021; 87 FR 10969, Feb. 28, 2022; 88 FR 55564, Aug. 16, 2023]

§ 520.2260c Sulfamethazine sustained-release tablets.

(a) *Specifications.* Each extended-release tablet contains 8 grams sulfamethazine.

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

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 8 grams (1 tablet) per 45 pounds of body weight as a single dose.

(2) *Indications for use.* In calves for sustained treatment of pneumonia caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli;* and calf diptheria caused by *Fusobacterium necrophorum.*

(3) *Limitations.* Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 26763, June 10, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 79 FR 28830, May 20, 2014]

§ 520.2261 Sulfamethazine sodium oral dosage forms.

§ 520.2261a Sulfamethazine solution.

(a) *Specifications.* Each milliliter of solution contains 125 milligrams (12.5 percent) sulfamethazine sodium.

(b) *Sponsors.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Administer in drinking water to provide: Cattle and swine 112.5 milligrams of sulfamethazine sodium per pound of body weight per day on the first day and 56.25 milligrams per pound of body weight on subsequent days; Chickens, 61 to 89 milligrams of sulfamethazine sodium per pound of body weight per day, and turkeys 53 to 130 milligrams of sulfamethazine sodium per pound of body weight per day, depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors.

(2) *Indications for use.* For treatment and control of diseases caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine.* Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella, Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella* Pullorum). In turkeys for control of coccidiosis (*Eimeria*

meleagrimitis, *Eimeria adenoeides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease, in chickens, medicate for 6 consecutive days; coccidiosis, in chickens and turkeys, medicate as in paragraph (c) of this section, then reduce amount of medication to one-half for 4 additional days.

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982; 67 FR 78355, Dec. 24, 2002; 70 FR 32489, June 3, 2005; 74 FR 36112, July 22, 2009; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011; 79 FR 28831, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 36789, June 8, 2016; 81 FR 94990, Dec. 27, 2016]

§ 520.2261b Sulfamethazine powder.

(a) *Specifications.* A soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Sponsors.* See Nos. 016592 and 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* Administer in drinking water to provide 58 to 85 milligrams (mg) per pound (/lb) of body weight per day.

(ii) *Indications for use.* For control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *E. necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella* Pullorum).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate chickens producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated chickens must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* Administer in drinking water to provide 50 to 124 mg/lb of body weight per day

(ii) *Indications for use.* For control of coccidiosis (*E. meleagrimitis*, *E. adenoeides*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated turkeys must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Swine*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use.* For treatment of porcine colibacillosis (bacterial

scours) (*E. coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 15 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated swine must actually consume enough medicated water which provides the recommended dosages. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Cattle*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use in beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*F. necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.)

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated cattle must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 70303, Dec. 4, 2006, as amended at 75 FR 10166, Mar. 5, 2010; 79 FR 28831, May 20, 2014; 80 FR 61296, Oct. 13, 2015; 81 FR 17607, Mar. 30, 2016; 81 FR 94990, Dec. 27, 2016; 84 FR 8973, Mar. 13, 2019]

§ 520.2280 Sulfamethizole and methenamine.

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 1 tablet per 20 pounds of body weight 3 times per day until clinical signs are alleviated. To reduce the possibility of relapse, continue therapy for a week to 10 days.

(2) *Indications for use.* For treatment of urinary tract infections such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. As an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

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

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 13561, Apr. 5, 1985; 79 FR 28831, May 20, 2014]

§ 520.2325 Sulfaquinoxaline oral dosage forms.

§ 520.2325a Sulfaquinoxaline powder and solution.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) To No. 016592 for use of a 25-percent sulfaquinoxaline soluble powder and a 20-percent sulfaquinoxaline sodium solution as provided for in paragraph (c) of this section.

(2) To Nos. 016592 and 054771 for use of a 31.92-percent sulfaquinoxaline solution (sodium and potassium salts) as provided for in paragraphs (c)(1), (c)(2),

(c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) No. 054771 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(b) *Related tolerances.* See §556.685 of this chapter.

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

(1) *Chickens.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti.*

(ii) Administer at the 0.04 percent level for 2 or 3 days, skip 3 days then administer at the 0.025 percent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 percent level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(2) *Turkeys.* (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides.*

(ii) Administer at the 0.025 percent level for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(3) *Chickens and turkeys.* (i) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(ii) Administer at the 0.04 percent level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. If cholera has become established as the respiratory or chronic form, use feed medicated with sulfaquinoxaline. Poultry which have survived typhoid outbreaks should not be kept for laying house replacements or breeders unless tests show they are not carriers.

(4) *Cattle and calves.* (i) For the control and treatment of outbreaks of coccidiosis caused by *Eimeria bovis* or *E. zurnii.*

(ii) Administer at the 0.015-percent level for 3 to 5 days in drinking water medicated with sulfaquinoxaline solution.

(iii) In lieu of treatment as provided in paragraph (c)(4)(ii) of this section, administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) *Limitations.* A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys, or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 3964, Jan. 28, 1983, as amended at 48 FR 26762, June 10, 1983; 55 FR 29843, July 23, 1990; 59 FR 28769, June 3, 1994; 59 FR 33197, June 28, 1994; 61 FR 24443, May 15, 1996; 61 FR 63711, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 65 FR 10705, Feb. 29, 2000; 69 FR 41427, July 9, 2004; 69 FR 60547, Oct. 12, 2004; 74 FR 36112, July 22, 2009; 78 FR 17596, Mar. 22, 2013; 79 FR 28831, May 20, 2014; 81 FR 22523, Apr. 18, 2016; 81 FR 36789, June 8, 2016; 81 FR 59134, Aug. 29, 2016; 81 FR 94990, Dec. 27, 2016; 87 FR 58962, Sept. 29, 2022]

§ 520.2325b Sulfaquinoxaline drench.

(a) *Specifications.* A soluble powder containing 25 percent sulfaquinoxaline.

(b) *Sponsor.* See No. 016592 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.685 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 1 teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(2) *Indications for use.* For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zuernii.*

(3) *Limitations.* Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 28831, May 20, 2014, as amended at 82 FR 12169, Mar. 1, 2017; 84 FR 32992, July 11, 2019; 84 FR 53310, Oct. 7, 2019]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications.* Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

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

(c) *Conditions of use*—(1) *Amount.* Administer one tablet orally per 4 pounds of body weight.

(2) *Indications for use.* Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.

(3) *Limitations.* Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 60895, Dec. 29, 1978, as amended at 79 FR 28831, May 20, 2014; 87 FR 76421, Dec. 14, 2022]

§ 520.2335 Telmisartan.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) telmisartan.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 1.5 mg/kilogram (kg) (0.68 mg/pound (lb)) orally twice daily for 14 days, followed by 2 mg/kg (0.91 mg/lb) orally once daily.

(2) *Indications for use.* For the control of systemic hypertension in cats.

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

[83 FR 64740, Dec. 18, 2018]

§ 520.2340 Tepoxalin.

(a) *Specifications.* Each tablet contains 30, 50, 100, or 200 milligrams (mg) tepoxalin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 10 mg per kilogram (/kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

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

[68 FR 34795, June 11, 2003]

§ 520.2345 Tetracycline.

§ 520.2345a Tetracycline capsules.

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams (mg) tetracycline hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 25 mg per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

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

[70 FR 50182, Aug. 26, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 79 FR 28831, May 20, 2014]

§ 520.2345b Tetracycline tablets.

(a) *Specifications.* Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

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

(c) *Conditions of use. Dogs*—(1) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(3) *Limitations.* Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use

by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345c Tetracycline boluses.

(a) *Specifications.* Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

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

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations.* Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(2) *Amount.* 10 milligrams per pound of body weight per day in two divided doses.

(i) *Indications for use.* Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, bacterial enteritis caused by *E. coli,* and salmonella organisms susceptible to tetracycline.

(ii) *Limitations.* Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline.

[57 FR 37328, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002; 79 FR 28831, May 20, 2014; 81 FR 67151, Sept. 30, 2016]

§ 520.2345d Tetracycline powder.

(a) *Specifications.* Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors.* See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 054771: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) No. 066104: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(3) Nos. 016592 and 054771: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(4) Nos. 016592, 054925, 061133, and 076475: 324 grams per pound as in paragraph (d) of this section.

(5) No. 016592: 25 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

(d) *Conditions of use.* It is administered in drinking water as follows:

(1) *Calves*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae (Haemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 066104 and within 5 days of treatment for Nos. 016592, 054771, 054925, 057561, and 061133; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae (Haemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 066104 and within 4 days of treatment for Nos. 016592, 054771, 054925, 057561, and 061133; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Chickens*—(i) *Amount.* Chronic respiratory disease: 400 to 800 milligrams

per gallon. Infectious synovitis: 200 to 400 milligrams per gallon.

(ii) *Indications for use.* Control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Turkeys*—(i) *Amount.* For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 17693, Apr. 14, 1994, as amended at 59 FR 19133, Apr. 22, 1994; 62 FR 5319, Feb. 5, 1997; 62 FR 35076, June 30, 1997; 62 FR 46668, Sept. 4, 1997; 62 FR 55160, Oct. 23, 1997; 64 FR 37673, July 13, 1999; 67 FR 78355, Dec. 24, 2002; 70 FR 16934, Apr. 4, 2005; 70 FR 67353, Nov. 7, 2005; 71 FR 13542, Mar. 16, 2006; 75 FR 10166, Mar. 5, 2010; 75 FR 12981, Mar. 18, 2010; 76 FR 17338, Mar. 29, 2011; 77 FR 20988, Apr. 9, 2012; 78 FR 21060, Apr. 9, 2013; 79 FR 28831, May 20, 2014; 81 FR 17607, Mar. 30, 2016; 81 FR 22523, Apr. 18, 2016; 81 FR 94990, Dec. 27, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8973, Mar. 13, 2019]

§ 520.2345e Tetracycline solution.

(a) *Specifications.* Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *Escherichia coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(iii) *Limitations.* Administer orally; continue treatment until symptoms have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use.* Treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli.*

(iii) *Limitations.* Administer orally; continue treatment until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.

(a) *Specifications.* Each capsule contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic per pound of body weight (1 capsule for each 6 pounds) every 12 hours.

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli.*

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

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin, or 180 milligrams of tetracycline hydrochloride and 180 milligrams of novobiocin.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds).

(2) *Indications for use.* Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli.*

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

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28831, May 20, 2014]

§ 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.

(a) *Specifications.* Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride, 60 milligrams of novobiocin, and 1.5 milligrams of prednisolone or 180 milligrams of tetracycline hydrochloride, 180 milligrams of novobiocin, and 4.5 milligrams of prednisolone.

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

(c) *Conditions of use in dogs*—(1) *Amount.* 10 milligrams of each antibiotic and 0.25 milligram of prednisolone per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds) every 12 hours for 48 hours. Treatment is to be continued with novobiocin and tetracycline alone at the same dose schedule for an additional 3 days or longer as needed.

(2) *Indications for use.* Treatment of acute and chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli,* when it is necessary to initially reduce the severity of associated clinical signs.

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

[57 FR 37329, Aug. 18, 1992, as amended at 79 FR 28832, May 20, 2014]

§ 520.2362 Thenium closylate.

(a) *Specifications.* Each tablet contains thenium closylate equivalent to 500 milligrams thenium base.

(a) *Specifications.* Thenium closylate tablets contain thenium closylate equivalent to 500 milligrams thenium as base in each tablet.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Dogs weighing over 10 pounds: Administer 1 tablet as a single dose. Dogs weighing 5 to 10 pounds: Administered one-half tablet twice during a single day. Repeat treatment after 2 or 3 weeks.

(2) *Indications for use.* For treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms).

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 53477, Dec. 7, 1976; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 79 FR 28832, May 20, 2014]

§ 520.2382 Thiabendazole and triclorfon.

(a) *Specifications.* The drug contains 5 grams of thiabendazole with 4.5 grams of trichlorfon, or 20 grams of thiabendazole with 18 grams of trichlorfon.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 2 grams of thiabendazole with 1.8 grams of

trichlorfon per 100 pounds of body weight sprinkled on the animals' usual daily ration of feed, or may be mixed in 5 to 10 fluid ounces of water and administered by stomach tube or drench.

(2) *Indications for use.* For the treatment and control of bots (*Gasterophilus* spp.), large strongyles (*Strongylus* spp.), small strongyles (genera *Cyathostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*, *Poteriostomum*), pinworms (*Oxyuris* spp., *Strongyloides* spp.), and ascarids (*Parascaris* spp.).

(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.

[40 FR 23071, May 28, 1975, as amended at 48 FR 48229, Oct. 18, 1983; 79 FR 28832, May 20, 2014. Redesignated at 84 FR 39183, Aug. 9, 2019. Redesignated at 88 FR 27699, May 3, 2023]

§ 520.2455 Tiamulin.

(a) *Specifications.* (1) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(2) Each milliliter (mL) of solution contains 125 mg (12.5 percent) tiamulin hydrogen fumarate.

(3) Each mL of solution contains 123 mg (12.3 percent) tiamulin hydrogen fumarate.

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

(1) No. 058198 for products described in paragraph (a) of this section.

(2) No. 066104 for product described in paragraph (a)(1) of this section.

(3) Nos. 016592, 051072, 051311, and 061133 for product described in paragraph (a)(2) of this section.

(4) No. 054771 for product described in paragraph (a)(3) of this section.

(c) *Related tolerances.* See § 556.732 of this chapter.

(d) *Conditions of use in swine*—(1) *Amounts and indications for use.* Administer in drinking water for 5 consecutive days:

(i) 3.5 mg per (/) lb of body weight daily for treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin.

(ii) 10.5 mg/lb of body weight daily for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(2) *Limitations.* Use as only source of drinking water. Prepare fresh medicated water daily. Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramicin) as adverse reactions may occur. The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

[70 FR 75017, Dec. 19, 2005, as amended at 74 FR 7180, Feb. 13, 2009; 75 FR 54492, Sept. 8, 2010; 77 FR 56770, Sept. 14, 2012; 78 FR 17596, Mar. 22, 2013; 80 FR 13229, Mar. 13, 2015; 85 FR 18119, Apr. 1, 2020; 87 FR 17945, Mar. 29, 2022; 87 FR 58962, Sept. 29, 2022]

§ 520.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of concentrate solution contains 250 milligrams (mg) tilmicosin as tilmicosin phosphate.

(b) *Sponsors.* See Nos. 016592 and 058198 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water at a concentration of 200 mg per liter for 5 consecutive days.

(2) *Indications for use.* (i) For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(ii) For the control of swine respiratory disease associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(3) *Limitations.* Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this product. Federal

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

[79 FR 18158, Apr. 1, 2014, as amended at 81 FR 17608, Mar. 30, 2016; 81 FR 48702, July 26, 2016; 87 FR 58962, Sept. 29, 2022]

§ 520.2473 Tioxidazole oral dosage forms.

§ 520.2473a Tioxidazole granules.

(a) *Specifications.* Each gram of granules contains 200 milligrams of tioxidazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 milligrams per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus, S. equinus,* and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* For administration with feed: Sprinkle required amount of granules on a small amount of the usual grain ration and mix. Prepare for each horse individually. Withholding of feed or water not necessary. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[50 FR 52772, Dec. 26, 1985; 51 FR 2693, Jan. 21, 1986, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.2473b Tioxidazole paste.

(a) *Specifications.* Each plastic syringe contains 6.25 grams of tioxidazole.

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

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 milligrams of tioxidazole per pound of body weight as a single dose.

(ii) *Indications for use.* Removal of mature large strongyles (*Strongylus edentatus, S. equinus,* and *S. vulgaris*), mature ascarids (*Parascaris equorum*), mature and immature (4th larval stage) pinworms (*Oxyuris equi*), and mature small strongyles (*Triodontophorus* spp.).

(iii) *Limitations.* Administer orally by inserting the nozzle of the syringe through the space between front and back teeth and deposit the required dose on the base of the tongue. Before dosing, make sure the horse's mouth contains no feed. Not for use in horses intended for food. The reproductive safety of tioxidazole in breeding animals has not been determined. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. It is recommended that this drug be administered with caution to sick or debilitated horses.

(2) [Reserved]

[52 FR 43059, Nov. 9, 1987]

§ 520.2475 Toceranib.

(a) *Specifications.* Each tablet contains 10, 15, or 50 milligrams (mg) toceranib as toceranib phosphate.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer an initial dose of 3.25 mg per kilogram (1.48 mg per pound) body weight, orally every other day.

(ii) *Indications for use.* For the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement.

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

(2) [Reserved]

[74 FR 28875, June 18, 2009, as amended at 79 FR 28832, May 20, 2014]

§ 520.2520 Trichlorfon oral dosage forms.

§ 520.2520a Trichlorfon and atropine.

(a) *Specifications.* (1) For trichlorfon: O,O-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

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

(c) *Conditions of use in mice*—(1) *Amount.* Administer 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter continuously for 7 to 14 days as the sole source of drinking water.

(2) *Indications for use.* For the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.

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

[79 FR 28832, May 20, 2014]

§ 520.2520b Trichlorfon boluses.

(a) *Specifications.* Each bolus contains either 7.3, 10.9, 14.6, or 18.2 g of trichlorfon.

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

(c) *Conditions of use in horses*—(1) *Amount.* 18.2 milligrams per pound of body weight, except for strongyles use 36.4 milligrams per pound of body weight.

(2) *Indications for use.* For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(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.

[45 FR 48127, July 18, 1980. Redesignated and amended at 79 FR 28833, May 20, 2014]

§ 520.2520c Trichlorfon granules.

(a) *Specifications.* Each package contains either 18.2 or 36.4 g of trichlorfon.

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

(c) *Conditions of use in horses*—(1) *Amount.* 18.2 milligrams per pound of body weight.

(2) *Indications for use.* For horses for removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(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.

[45 FR 48128, July 18, 1980. Redesignated and amended at 79 FR 28833, May 20, 2014]

§ 520.2520d Trichlorfon, phenothiazine, and piperazine.

(a) *Specifications.* Each 54.10 grams (1.91 ounces) of water dispersible powder contains 9.10 grams of trichlorfon, 6.25 grams of phenothiazine, and the equivalent of 20.0 grams of piperazine base (as piperazine dihydrochloride).

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

(c) *Conditions of use in horses*—(1) *Amount.* 18.2 milligrams (mg) of trichlorfon, 12.5 mg of phenothiazine, and 40 mg of piperazine base per pound of body weight.

(2) *Indications for use.* For removal of bots (*Gastrophilus nasalis, Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(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.

[48 FR 2757, Jan. 21, 1983. Redesignated and amended at 79 FR 28833, May 20, 2014; 85 FR 4208, Jan. 24, 2020]

§ 520.2582 Triflupromazine.

(a) *Specifications.* Each tablet contains 10 or 25 milligrams (mg) triflupromazine hydrochloride.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 1 to 2 mg per pound of body weight daily, followed by 1 mg daily.

(2) *Indications for use.* For relief of anxiety, to help control psychomotor over-activity, and to increase the tolerance of animals to pain and pruritus. For use in various clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

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

[79 FR 28833, May 20, 2014]

§ 520.2598 Trilostane.

(a) *Specifications.* Each capsule contains 5, 10, 20, 30, 60, or 120 milligrams (mg) trilostane.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The starting dose is 1.0 to 3.0 milligrams per pound (2.2 to 6.7 milligrams per kilogram) once a day.

(2) *Indications for use.* For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism in dogs.

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

[74 FR 21767, May 11, 2009, as amended at 74 FR 30464, June 26, 2009; 80 FR 53460, Sept. 4, 2015; 87 FR 58962, Sept. 29, 2022; 89 FR 85426, Oct. 28, 2024]

§ 520.2604 Trimeprazine and prednisolone tablets.

(a) *Specifications.* Each tablet contains 5 milligrams (mg) trimeprazine tartrate and 2 mg prednisolone.

(b) *Sponsors.* See Nos. 054771 and 086117 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally an initial dosage: for dogs weighing up to 10 pounds, ½ tablet twice daily; for dogs weighing 11 to 20 pounds, 1 tablet twice daily; for dogs weighing 21 to 40 pounds, 2 tablets twice daily; and for dogs weighing over 40 pounds, 3 tablets twice daily. After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms.

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular, and nonspecific origins. As adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, infections, and coughs of nonspecific origin.

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

[79 FR 28833, May 20, 2014, as amended at 87 FR 10969, Feb. 28, 2022; 89 FR 85426, Oct. 28, 2024]

§ 520.2605 Trimeprazine and prednisolone capsules.

(a) *Specifications.* Each capsule contains:

(1) 3.75 milligrams (mg) trimeprazine in sustained released form (as trimeprazine tartrate) and 1 mg prednisolone (Capsule No. 1); or

(2) 7.5 mg trimeprazine in sustained release form (as trimeprazine tartrate) and 2 mg prednisolone (Capsule No. 2).

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once daily an initial dosage:

(i) For dogs weighing up to 10 pounds: one Capsule No. 1;

(ii) For dogs weighing 11 to 20 pounds, one Capsule No. 2 or two Capsule No. 1;

(iii) For dogs weighing 21 to 40 pounds, two Capsule No. 2 or four Capsule No. 1; and

(iv) For dogs weighing over 40 pounds, three Capsule No. 2 or six Capsule No. 1. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms.

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. As adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin.

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

[79 FR 28833, May 20, 2014]

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications.* Each tablet contains 30 milligrams (mg) (5 mg trimethoprim and 25 mg sulfadiazine), 120 mg (20 mg trimethoprim and 100 mg sulfadiazine), 480 mg (80 mg trimethoprim and 400 mg sulfadiazine) or 960 mg (160 mg trimethoprim and 800 mg sulfadiazine).

(b) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at 30 mg per kilogram of body weight (14 milligrams per pound) once daily. Alternatively, especially in severe infections, the initial dose may be followed by one-half

the recommended daily dose every 12 hours. Administer for 2 to 3 days after symptoms have subsided. Do not treat for more than 14 consecutive days.

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

[79 FR 28833, May 20, 2014]

§ 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. 054771 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, as amended at 79 FR 28834, May 20, 2014]

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

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

(1) No. 000061 for use of product described in paragraph (a)(1) for use as in paragraph (c)(1) of this section.

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) *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.

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

(2) *Horses*—(i) *Amount.* Administer orally at a dosage of 24 mg combined active ingredients per kilogram body weight (10.9 mg/lb) twice daily for 10 days. Administered by volume at 2.7 mL per 45.4 kilograms of body weight (2.7 mL/100 lb).

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus*.

(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.

[78 FR 63872, Oct. 25, 2013, as amended at 85 FR 4208, Jan. 24, 2020]

§ 520.2613 Trimethoprim and sulfadiazine powder.

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

(b) *Sponsors.* See Nos. 054771 and 059051 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 3.75 grams of powder per 110 pounds (50 kilograms) of body weight in a small amount of feed, as a single daily dose, for 5 to 7 days.

(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.* 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.

[58 FR 36135, July 6, 1993, as amended at 64 FR 68289, Dec. 7, 1999; 79 FR 28834, May 20, 2014; 79 FR 64116, Oct. 28, 2014]

§ 520.2640 Tylosin.

(a) *Specifications.* Each container of soluble powder contains tylosin tartrate equivalent to:

(1) 100 grams (g) tylosin base, or

(2) 256 g tylosin base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) Nos. 016592 and 058198 for use of the 100-g container as in paragraph (e) of this section

(2) No. 061133 for use of the 100-or 256-g container as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

(3) No. 061133 for use of a 100-g container as in paragraphs (e)(1)(i)(B) and (e)(1)(ii) of this section.

(c) *Related tolerances.* See § 556.746 of this chapter.

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

(e) *Conditions of use*—(1) *Chickens*—(i) *Amounts and indications for use.* (A) Administer 2 grams per gallon (528 parts per million (ppm)) for 1 to 5 days as an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *M. gallisepticum* at time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(B) Administer 851 to 1,419 mg/gallon (225 to 375 ppm) for 5 days for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.

(ii) *Limitations.* 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 (528 ppm) 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 the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum.*

(iii) *Limitations.* 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 (66 ppm) 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* when followed immediately by tylosin phosphate medicated feed; and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* when followed immediately by tylosin phosphate medicated feed.

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

(iii) *Limitations.* Do not administer within 48 hours of slaughter. As indicated in paragraph (d)(3)(ii)(A) of this section, 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; 76 FR 59024, Sept. 23, 2011; 77 FR 29217, May 17, 2012; 79 FR 37620, July 2, 2014; 79 FR 53136, Sept. 8, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 34278, June 16, 2015; 83 FR 14587, Apr. 5, 2018; 84 FR 8973, Mar. 13, 2019; 84 FR 32992, July 11, 2019; 87 FR 76421, Dec. 14, 2022; 88 FR 16547, Mar. 20, 2023]

§ 520.2645 Tylvalosin.

(a) *Specifications.* Granules containing 62.5 percent tylvalosin (w/w) as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 50 parts per million (ppm) tylvalosin continuously in drinking water for 5 consecutive days.

(2) *Indications for use.* For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Glaesserella (Haemophilus) parasuis, Pasteurella multocida, Streptococcus suis,* and *Mycoplasma hyopneumoniae* in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of SRD.

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

[77 FR 55415, Sept. 10, 2012, as amended at 83 FR 13635, Mar. 30, 2018; 86 FR 57997, Oct. 20, 2021; 89 FR 14410, Feb. 27, 2024]

§ 520.2654 Velagliflozin.

(a) *Specifications.* Each milliliter of solution contains 15 milligrams (mg) velagliflozin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally 0.45 mg per pound of body weight (1 mg per kilogram) velagliflozin once daily.

(2) *Indications for use.* To improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.

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

[88 FR 84700, Dec. 6, 2023]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.