

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

[68 FR 26995, May 19, 2003, as amended at 76 FR 79064, Dec. 21, 2011; 87 FR 76422, Dec. 14, 2022]

**§ 522.2694 Zinc, copper, manganese, and selenium.**

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) zinc as zinc oxide, 15 mg copper as copper carbonate, 10 mg manganese as manganese carbonate, and 5 mg selenium as sodium selenite.

(b) *Sponsor.* See No. 066679 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer a single dose by subcutaneous injection to cattle up to 1 year of age, 1 mL/100 lb bodyweight; to cattle from 1 to 2 years of age, 1 mL/150 lb bodyweight, and to cattle over 2 years of age, 1 mL/200 lb bodyweight.

(2) *Indications for use.* As a supplemental source of zinc, copper, manganese, and selenium in cattle.

(3) *Limitations.* Cattle must not be slaughtered for human food consumption within 14 days of the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[89 FR 85428, Oct. 28, 2024]

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

Sec.

524.86 Amitraz.  
524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.  
524.155 Bacitracin, neomycin, polymyxin B, and hydrocortisone ophthalmic ointment.  
524.230 Buprenorphine.  
524.390 Chloramphenicol ophthalmic ointment.  
524.402 Chlorhexidine.  
524.450 Clotrimazole.  
524.463 Copper naphthenate.  
524.575 Cyclosporine ophthalmic ointment.  
524.590 Diclofenac.  
524.660 Dimethyl sulfoxide.  
524.770 Doramectin.  
524.775 Emodepside and praziquantel.  
524.802 Enrofloxacin and silver sulfadiazine otic emulsion.  
524.814 Eprinomectin.  
524.815 Eprinomectin and praziquantel.

524.838 Esafoxolaner, eprinomectin, and praziquantel.  
524.900 Famphur.  
524.920 Fenthion.  
524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.  
524.957 Florfenicol, terbinafine, and mometasone otic solution.  
524.960 Flumethasone, neomycin, and polymyxin B ophthalmic solution.  
524.970 Flunixin.

**FLUOCINOLONE TOPICAL AND OTIC DOSAGE FORMS**

524.981 [Reserved]  
524.981a Fluocinolone cream.  
524.981b Fluocinolone solution.  
524.981c Fluocinolone and neomycin cream.  
524.981d Fluocinolone and dimethyl sulfoxide solution.  
524.981e Fluocinolone and dimethyl sulfoxide otic solution.  
524.998 Fluralaner.  
524.1001 Fluralaner and moxidectin.  
524.1005 Furazolidone powder.  
524.1044 Gentamicin ophthalmic and topical dosage forms.  
524.1044a Gentamicin ophthalmic solution.  
524.1044b Gentamicin and betamethasone otic solution.  
524.1044c Gentamicin ophthalmic ointment.  
524.1044d Gentamicin and betamethasone ointment.  
524.1044e Gentamicin spray.  
524.1044f Gentamicin and betamethasone spray.  
524.1044g Gentamicin, betamethasone, and clotrimazole ointment.  
524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.  
524.1044i Gentamicin and betamethasone ophthalmic solution.  
524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.  
524.1140 Imidacloprid and ivermectin.  
524.1146 Imidacloprid and moxidectin.  
524.1193 Ivermectin topical solution.  
524.1195 Ivermectin otic suspension.  
524.1200 Kanamycin ophthalmic and topical dosage forms.  
524.1200a Kanamycin ophthalmic ointment.  
524.1200b Kanamycin ophthalmic solution.  
524.1204 Kanamycin, amphotericin, and hydrocortisone ointment.  
524.1240 Levamisole.  
524.1376 2-Mercaptobenzothiazole solution.  
524.1443 Miconazole.  
524.1445 Miconazole, polymyxin B, and prednisolone suspension.  
524.1446 Milbemycin otic solution.  
524.1448 Mirtazapine transdermal ointment.  
524.1450 Moxidectin.  
524.1465 Mupirocin.  
524.1484 Neomycin ophthalmic and topical dosage forms.  
524.1484b Neomycin, isoflupredone, and tetracaine powder.

## § 524.86

524.1484c Neomycin, isoflupredone, and tetracaine ointment.  
524.1484d Neomycin, hydrocortisone, and tetracaine otic ointment.  
524.1484e Neomycin and polymyxin B ophthalmic solution.  
524.1484f Neomycin, prednisolone, and tetracaine otic suspension.  
524.1484g Neomycin, thiabendazole, and dexamethasone solution.  
524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.  
524.1484i Neomycin and hydrocortisone ointment.  
524.1484k Neomycin and prednisolone suspension.  
524.1580 Nitrofurazone topical dosage forms.  
524.1580a Nitrofurazone ointment.  
524.1580b Nitrofurazone soluble powder.  
524.1600 Nystatin ophthalmic and topical dosage forms.  
524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ointment.  
524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone ophthalmic ointment.  
524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.  
524.1662 Oxytetracycline ophthalmic and topical dosage forms.  
524.1662a Oxytetracycline and hydrocortisone spray.  
524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.  
524.1742 Phosmet emulsifiable liquid.  
524.1982 Proparacaine ophthalmic solution.  
524.2080 Ropinirole.  
524.2098 Selamectin.  
524.2099 Selamectin and sarolaner.  
524.2101 Selenium disulfide suspension.  
524.2338 Terbinafine and betamethasone acetate.  
524.2350 Tolnaftate cream.  
524.2482 Triamcinolone spray.  
524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

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

SOURCE: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

## § 524.86 Amitraz.

(a) *Specifications.* Amitraz liquid contains 19.9 percent amitraz in an organic solvent.

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

(c) *Conditions of use*—(1) *Indications for use.* For dogs for the treatment of generalized demodicosis (*Demodex canis*).

(2) *Amount.* One 10.6 milliliter bottle per 2 gallons of warm water (250 parts per million) for each treatment, for a

## 21 CFR Ch. I (4–1–25 Edition)

total of 3 to 6 treatments, 14 days apart.

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

[47 FR 18589, Apr. 30, 1982, as amended at 79 FR 10967, Feb. 27, 2014]

## § 524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains:

(1) 500 units bacitracin, 3.5 milligrams (mg) neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate; or

(2) 400 units bacitracin zinc, 5 mg neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate.

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

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(2) Nos. 000061, 043264, and 086189 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

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

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014; 80 FR 61297, Oct. 13, 2015; 88 FR 84701, Dec. 6, 2023]

## § 524.155 Bacitracin, neomycin, polymyxin B, and hydrocortisone ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 400 units of bacitracin zinc, 5 milligrams (mg) of neomycin sulfate (equivalent to 3.5 mg of neomycin sulfate), 10,000 units of polymyxin B sulfate, and 10 mg of hydrocortisone.

(b) *Sponsors.* See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

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

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997; 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014]

#### § 524.230 Buprenorphine.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 milligrams (mg) buprenorphine. The drug is supplied in tubes containing 0.4 mL (8 mg) or 1.0 mL (20 mg).

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

(c) *Conditions of use in cats*—(1) *Amount.* Administer topically to the dorsal cervical area at the base of the skull a single dose of 1.2 to 3.1 mg/lb (2.7 to 6.7 mg/kg) approximately 1 to 2 hours before surgery.

(2) *Indications for use.* For the control of postoperative pain associated with surgical procedures in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Buprenorphine is a Schedule III controlled substance.

[87 FR 58962, Sept. 29, 2022]

#### § 524.390 Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol.

(b) *Sponsors.* See Nos. 043264 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Apply every 3 hours around the clock for 48 hours, after which night instillations may be omitted.

(2) *Indications for use.* For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

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

[77 FR 4897, Feb. 1, 2012, as amended at 77 FR 64717, Oct. 23, 2012; 79 FR 10967, Feb. 27, 2014]

#### § 524.402 Chlorhexidine.

(a) *Specifications.* Each gram of ointment contains 10 milligrams chlorhexidine acetate.

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

(c) *Conditions of use in dogs, cats, and horses*—(1) *Indications for use.* For use as a topical antiseptic ointment for surface wounds.

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

[72 FR 265, Jan. 4, 2007, as amended at 79 FR 10967, Feb. 27, 2014]

#### § 524.450 Clotrimazole.

(a) *Specifications.* Each gram of cream contains 10 milligrams of clotrimazole.

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

(c) *Conditions of use*—(1) *Amount.* Apply ¼-inch ribbon of cream per square inch of lesion once daily for 2 to 4 weeks.

(2) *Indications for use.* For the treatment of fungal infections of dogs and cats caused by *Microsporum canis* and *Trichophyton mentagrophytes*.

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

[40 FR 48128, July 18, 1980, as amended at 79 FR 10967, Feb. 27, 2014; 86 FR 14820, Mar. 19, 2021]

#### § 524.463 Copper naphthenate.

(a) *Amount.* The drug is a 37.5 percent solution of copper naphthenate.

(b) *Sponsors.* See Nos. 017135, 054771, and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Apply daily to affected hooves until fully healed.

(2) *Indications for use.* As an aid in treating horses and ponies for thrush caused by organisms susceptible to copper naphthenate.

(3) *Limitations.* Use on horses and ponies only. Avoid contact around eyes. Do not contaminate feed. Do not use in horses intended for human consumption.

[47 FR 4250, Jan. 29, 1982, as amended at 68 FR 55825, Sept. 29, 2003; 71 FR 38074, July 5, 2006; 79 FR 10967, Feb. 27, 2014]

## § 524.575

### § 524.575 Cyclosporine ophthalmic ointment.

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

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

(c) *Conditions of use*—(1) *Amount.* Apply a ¼-inch strip of ointment directly on the cornea or into the conjunctival sac of the affected eye(s) every 12 hours.

(2) *Indications for use.* For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

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

[60 FR 48651, Sept. 20, 1995, as amended at 62 FR 48940, Sept. 18, 1997; 79 FR 10967, Feb. 27, 2014]

### § 524.590 Diclofenac.

(a) *Specifications.* Each gram of cream contains 10 milligrams diclofenac sodium.

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

(c) *Conditions of use in horses*—(1) *Amount.* Apply a 5-inch (5") ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use in horses.* For the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints.

(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 40767, July 7, 2004, as amended at 74 FR 26782, June 4, 2009; 74 FR 47436, Sept. 16, 2009]

### § 524.660 Dimethyl sulfoxide.

(a) *Specifications.* (1) Each milliliter (mL) of solution contains 90 percent dimethyl sulfoxide and 10 percent water.

(2) Each milliliter (mL) of gel product contains 90 percent dimethyl sulfoxide.

## 21 CFR Ch. I (4–1–25 Edition)

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

(c) *Conditions of use in horses and dogs*—(1) *Amount*—(i) *Horses.* Apply topically two to three times daily in an amount not to exceed 100 mL per day. Total duration of therapy should not exceed 30 days.

(ii) *Dogs.* Apply topically three to four times daily in an amount not to exceed 20 mL per day. Total duration of therapy should not exceed 14 days.

(2) *Indications for use.* To reduce acute swelling due to trauma.

(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 10967, Feb. 27, 2014]

### § 524.770 Doramectin.

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

(b) *Sponsors.* See Nos. 051072, 054771, and 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.222 of this chapter.

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

(e) *Conditions of use in cattle*—(1) *Amount.* Administer topically 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *Ostertagia ostertagi* (inhibited fourth-stage larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia pectinata* (adults), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and

*Solenopotes capillatus*; biting lice; *Bovicola (Damalinia) bovis*; mange mites; *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*; and to control infections and to protect from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Oesophagostomum radiatum* for 28 days; and with *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment; and to control infestations and to protect from reinfestation with *Linognathus vituli* for 42 days and with *Bovicola (Damalinia) bovis* for 77 days after treatment.

(3) *Limitations*. Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

[69 FR 48392, Aug. 10, 2004, as amended at 70 FR 43046, July 26, 2005; 79 FR 10967, Feb. 27, 2014; 84 FR 32993, July 11, 2019; 87 FR 10970, Feb. 28, 2022; 88 FR 27700, May 3, 2023; 90 FR 6801, Jan. 21, 2025]

#### § 524.775 Emodepside and praziquantel.

(a) *Specifications*. Each milliliter of solution contains 21.4 milligrams (mg) emodepside and 85.7 mg praziquantel.

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

(c) *Conditions of use in cats*—(1) *Amount*. The recommended minimum dose is 1.36 mg/pound (lb) (3 mg/kilogram (kg)) emodepside and 5.45 mg/lb (12 mg/kg) praziquantel applied as a single topical dose.

(2) *Indications for use*. For the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).

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

[72 FR 42291, Aug. 2, 2007, as amended at 86 FR 14820, Mar. 19, 2021]

#### § 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.

(a) *Specifications*. Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsors*. See Nos. 058198 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use—Dogs*—(1) *Amount*. 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

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

(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.

[65 FR 66620, Nov. 7, 2000, as amended at 79 FR 10967, Feb. 27, 2014; 86 FR 14821, Mar. 19, 2021; 89 FR 85428, Oct. 28, 2024]

#### § 524.814 Eprinomectin.

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

(b) *Sponsors*. See Nos. 000010, 051072, and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.227 of this chapter.

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

(e) *Conditions of use in cattle*—(1) *Amount*. Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) topically along backbone from withers to tailhead.

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*);

mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. viviparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

(3) *Limitations*. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

[76 FR 72619, Nov. 25, 2011, as amended at 83 FR 48946, Sept. 28, 2018; 84 FR 39184, Aug. 9, 2019; 88 FR 27700, May 3, 2023]

**§ 524.815 Eprinomectin and praziquantel.**

(a) *Specifications*. Each milliliter (mL) of solution contains 4 milligrams (mg) eprinomectin and 83 mg praziquantel.

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

(c) *Conditions of use in cats*—(1) *Amount*. Using the 0.3 mL and 0.9 mL unit applicators, administer a minimum dose of 0.23 mg eprinomectin per pound body weight and 4.55 mg praziquantel per pound body weight by topical application on the dorsal midline between the base of the skull and the shoulder blades.

(2) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*, and for the treatment and control of roundworms (adult and fourth stage larval *Toxocara cati*), hookworms (adult and fourth stage larval *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*), and tapeworms (adult *Dipylidium caninum* and *Echinococcus multilocularis*), in cats and kittens 7 weeks of age and older and 1.8 lbs or greater.

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

[83 FR 48946, Sept. 28, 2018, as amended at 84 FR 39184, Aug. 9, 2019]

**§ 524.838 Esafoxolaner, eprinomectin, and praziquantel.**

(a) *Specifications*. Each milliliter (mL) of topical solution contains 12 milligrams (mg) esafoxolaner, 4 mg eprinomectin, and 83 mg praziquantel.

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

(c) *Conditions of use*—(1) *Amount*. Administer the entire contents of a pro-

vided unit applicator topically once a month at a minimum dose of 0.055 mL/lb (0.12 mL/kg), which delivers a minimum dose of 0.66 mg/lb (1.45 mg/kg) esafoxolaner, 0.23 mg/lb (0.51 mg/kg) eprinomectin, and 4.55 mg/lb (10.0 mg/kg) praziquantel.

(2) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the treatment and control of *Ixodes scapularis* (black-legged tick) and *Amblyomma americanum* (lone star tick) infestations, and the treatment and control of roundworms (fourth-stage larval and adult *Toxocara cati*), hookworms (fourth-stage larval and adult *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*), and tapeworms (*Dipylidium caninum*) in cats and kittens 8 weeks of age and older, and weighing 1.8 lbs or greater.

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

[88 FR 55566, Aug. 16, 2023]

**§ 524.900 Famphur.**

(a) *Specifications*. The drug is in liquid form containing 13.2 percent famphur.

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

(c) *Special considerations*. Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Related tolerances*. See § 556.273 of this chapter.

(e) *Conditions of use*—(1) *Amount*. Apply 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, from the shoulder to the tail head as a single treatment. Apply as soon as possible after heel fly activity ceases.

(2) *Indications for use in beef and non-lactating dairy cattle*. For control of cattle grubs and to reduce cattle lice infestations.

(3) *Limitations*. Do not slaughter within 35 days after treatment. Do not use on lactating dairy cows or dry dairy cows within 21 days of freshening, calves less than 3 months old, animals

stressed from castration, overexcitement or dehorning, sick or convalescent animals. Animals may become dehydrated and under stress following shipment. Do not treat until they are in good condition. Brahman and Brahman crossbreeds are less tolerant of cholinesterase-inhibiting insecticides than other breeds. Do not treat Brahman bulls. Swine should be eliminated from area where runoff occurs.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 34352, Aug. 30, 1984; 57 FR 7652, Mar. 4, 1992; 59 FR 28769, June 3, 1994; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997; 69 FR 41427, July 9, 2004; 79 FR 10968, Feb. 27, 2014; 83 FR 48946, Sept. 28, 2018]

#### § 524.920 Fenthion.

(a) *Specifications.* (1) The drug is a liquid containing:

- (i) 3 percent of fenthion; or
- (ii) 20 percent fenthion.

(2) The drug is a solution containing either 5.6 or 13.8 percent fenthion. Each concentration is available in 2 volumes which are contained in single-dose applicators.

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

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

(2) No. 058198 for use of product described in paragraph (a)(1)(ii) of this section as in paragraph (d)(2) of this section.

(3) No. 058198 for use of products described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.280 of this chapter.

(d) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* It is used at the rate of one-half fluid ounce per 100 pounds of body weight applied topically on the backline of the animal. Only one application per season should be made for grub control and this will also provide initial control of lice. A second application for lice control may be made if animals become reinfested, but no sooner than 35 days after the first treatment. Proper timing of treatment is important for grub control; cattle

should be treated as soon as possible after heel-fly activity ceases.

(ii) *Indications for use.* For the control of grubs and lice in beef and nonlactating cattle.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Cattle should not be slaughtered within 35 days following a single treatment. If a second application is made for lice control, cattle should not be slaughtered within 45 days of the second treatment. The drug must not be used within 28 days of freshening of dairy cattle. If freshening should occur within 28 days after treatment, do not use milk as human food for the balance of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; or sick, convalescent, or stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious infectious diseases.

(2) *Beef cattle and dairy cattle not of breeding age*—(i) *Amount.* It is administered as a single, topical application placed on the backline of animals as follows: For animals weighing 150 to 300 pounds, apply 4 milliliters (mL); for animals weighing 301 to 600 pounds, apply 8 mL; for animals weighing 601 to 900 pounds, apply 12 mL; for animals weighing 901 to 1,200 pounds, apply 16 mL; and for animal weighing over 1,200 pounds, apply 20 mL. For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. A second application is required for animals heavily infested with lice or for those which become reinfested. A second application should be made no sooner than 35 days after the first treatment.

(ii) *Indications for use.* For control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(iii) *Limitations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Host-parasite reactions such as bloat, salivation, staggering and paralysis may

## § 524.955

sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gullet, or while the northern cattle grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated before these stages of grub development. Consult your veterinarian, extension livestock specialist, or extension entomologist regarding the timing of treatment. If it is impossible to determine the area from which the cattle came and/or exact stage of the grubs, it is recommended that the cattle receive only a maintenance ration of low-energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gullet. Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases. Do not slaughter within 45 days of treatment.

(3) *Dogs*—(i) *Amount*. Four to 8 milligrams per kilogram of body weight. Apply the contents of the proper size, single-dose tube directly to one spot on the dog's skin.

(ii) *Indications for use*. For flea control on dogs only.

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

[79 FR 10968, Feb. 27, 2014, as amended at 84 FR 32993, July 11, 2019; 86 FR 14821, Mar. 19, 2021]

## § 524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.

(a) *Specifications*. Each milliliter of gel contains 10 milligrams (mg) florfenicol, 10 mg terbinafine, and 1 mg betamethasone acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs associated with susceptible strains of bacteria (*Staphylococcus pseudintermedius*) and yeast (*Malassezia pachydermatis*).

## 21 CFR Ch. I (4–1–25 Edition)

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

[80 FR 13230, Mar. 13, 2015, as amended at 86 FR 14821, Mar. 19, 2021]

## § 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications*. Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 16.6 milligrams (mg) florfenicol, 14.8 mg terbinafine (equivalent to 16.6 mg terbinafine hydrochloride), and 2.2 mg mometasone furoate.

(b) *Sponsor*. See Nos. 017030 and 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer one dropperette (1 mL) per affected ear(s).

(2) *Indications for use*. For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

[80 FR 76387, Dec. 9, 2015, as amended at 83 FR 64740, Dec. 18, 2018; 86 FR 14821, Mar. 19, 2021; 88 FR 14901, Mar. 10, 2023]

## § 524.960 Flumethasone, neomycin, and polymyxin B ophthalmic solution.

(a) *Specifications*. Each milliliter of ophthalmic preparation contains 0.10 milligram flumethasone, 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 units of polymyxin B sulfate, with or without hydroxypropyl methylcellulose.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Preparation containing hydroxypropyl methylcellulose*. Dogs: 1 to 2 drops per eye, every 6 hours.

(ii) *Preparation without hydroxypropyl methylcellulose*. Dogs and cats: 2 to 3 drops per eye, every 4 hours.

(2) *Indications for use*. Treatment of the inflammation, edema, and secondary bacterial infections associated with topical ophthalmological conditions of the eye such as corneal injuries, incipient pannus, superficial keratitis, conjunctivitis, acute

## Food and Drug Administration, HHS

## § 524.981c

nongranulomatous anterior uveitis, kerato- conjunctivitis, and blepharitis.

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

[44 FR 16012, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10968, Feb. 27, 2013]

### § 524.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) flunixin (equivalent to 83 mg flunixin meglumine).

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

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Apply only once at a dose of 3.3 mg flunixin per kg body weight (1.5 mg/lb; 3 mL per 100 lbs) topically in a narrow strip along the dorsal midline from the withers to the tailhead.

(2) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease and acute bovine mastitis, and the control of pain associated with foot rot in beef cattle 2 months of age and older and dairy cattle.

(3) *Limitations.* Not for use in beef and dairy bulls intended for breeding over 1 year of age. Milk that has been taken during treatment and for 48 hours after treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days of treatment. Not for use in replacement dairy heifers 20 months of age or older or dry dairy cows; use in these cattle may cause drug residues in calves born to these cows or heifers. 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 pre-ruminating calves. Approved only as a single topical dose in cattle. Repeated treatments may result in violative residues in milk or in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[83 FR 13635, Mar. 30, 2018, as amended at 88 FR 16549, Mar. 20, 2023]

## FLUOCINOLONE TOPICAL AND OTIC DOSAGE FORMS

### § 524.981 [Reserved]

#### § 524.981a Fluocinolone cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* A small amount is applied to the affected area two or three times daily.

(2) *Indications for use.* For the relief of pruritis and inflammation associated with certain superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical burns and physical abrasions.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10968, Feb. 27, 2014]

#### § 524.981b Fluocinolone solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* A small amount of solution is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs.* For the relief of pruritis and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses.

(ii) *Cats.* For the relief of pruritis and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

#### § 524.981c Fluocinolone and neomycin cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide

## § 524.981d

and 0.5 percent neomycin sulfate (0.35 percent neomycin base).

(b) *Sponsor*. See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. A small amount is applied to the affected area two or three times daily.

(2) *Indications for use*—(i) *Dogs*. For the relief of pruritis and inflammation associated with superficial acute and chronic dermatoses. It is used in the treatment of allergic and acute moist dermatitis and nonspecific dermatoses.

(ii) *Dogs and cats*. Used in the treatment of wound infections.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997; 79 FR 10969, Feb. 27, 2014]

## § 524.981d Fluocinolone and dimethyl sulfoxide solution.

(a) *Specifications*. Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1 to 2 milliliters into each anal sac following expression of anal sac contents.

(2) *Indications for use*. For the relief of impaction commonly present in apparently normal anal sacs, for the reversal of inflammatory changes associated with abnormal anal sacs, and to counteract the offensive odor of anal sac secretions.

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

[79 FR 10969, Feb. 27, 2014]

## § 524.981e Fluocinolone and dimethyl sulfoxide otic solution.

(a) *Specifications*. Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 60 percent dimethyl sulfoxide.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total

## 21 CFR Ch. I (4–1–25 Edition)

dosage used should not exceed 17 milliliters.

(2) *Indications for use*. For the relief of pruritis and inflammation associated with acute and chronic otitis.

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

[79 FR 10969, Feb. 27, 2014]

## § 524.998 Fluralaner.

(a) *Specifications*. Each milliliter of solution contains 280 milligrams (mg) fluralaner.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(ii) *Indications for use*. 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), and *Rhipicephalus sanguineus* (brown dog tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of *A. americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb 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 topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 18.2 mg/lb (40 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *D. variabilis* ticks.

(ii) *Indications for use*. Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*) and the treatment and control of *I. scapularis* (black-legged tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater; for the treatment and control of *D. variabilis*

(American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater.

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

[81 FR 67152, Sept. 30, 2016, as amended at 82 FR 43485, Sept. 18, 2017; 88 FR 14901, Mar. 10, 2023]

#### § 524.1001 Fluralaner and moxidectin.

(a) *Specifications.* Each milliliter of solution contains 280 milligram (mg) fluralaner and 14 mg moxidectin. Each individually packaged tube contains either 112.5 mg fluralaner and 5.6 mg moxidectin; 250 mg fluralaner and 12.5 mg moxidectin; or 500 mg fluralaner and 25 mg moxidectin.

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

(c) *Conditions of use—(1) Amount.* Administer topically as a single dose every 2 months to provide a minimum dose of 18.2 mg/lb (40 mg/kg) fluralaner and 0.9 mg/lb (2 mg/kg) moxidectin.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*, fourth-stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme*, fourth-stage larvae, immature adults, and adults); kills adult fleas and is indicated 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), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

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

[85 FR 18120, Apr. 1, 2020, as amended at 87 FR 58963, Sept. 29, 2022; 88 FR 14901, Mar. 10, 2023]

#### § 524.1005 Furazolidone powder.

(a) *Specifications.* The product contains either 4 or 10 percent furazolidone in inert dispersing agent and propellant.

(b) *Sponsors.* (1) See No. 051031 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

(2) See No. 017135 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

(c) *Conditions of use—(1) Amount.* Hold container about 6 to 12 inches from the eye or affected area and apply only enough powder to impart a light yellow color.

(2) *Indications of use—(i) Dogs.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and pyogenic dermatitis.

(ii) *Horses.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, lacerations, and following firing (heat or electrocautery).

(iii) [Reserved]

(iv) *Horses and ponies.* For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* sensitive to furazolidone.

(3) *Limitations.* For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Do not use in horses intended for human consumption.

[45 FR 49543, July 25, 1980, as amended at 50 FR 30153, July 24, 1985; 56 FR 50653, Oct. 8, 1991; 57 FR 31314, July 15, 1992; 60 FR 55659, Nov. 2, 1995; 65 FR 41588, July 6, 2000; 79 FR 10969, Feb. 27, 2014; 82 FR 11508, Feb. 24, 2017]

#### § 524.1044 Gentamicin ophthalmic and topical dosage forms.

##### § 524.1044a Gentamicin ophthalmic solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

## § 524.1044b

(b) *Sponsors*. See Nos. 000061 and 086189 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*  
(1) *Amount*. Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

(2) *Indications for use*. For the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

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

[80 FR 18776, Apr. 8, 2015, as amended at 89 FR 14410, Feb. 27, 2024]

## § 524.1044b Gentamicin and betamethasone otic solution.

(a) *Specifications*. Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

(b) *Sponsors*. See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amounts and indications for use*. (i) For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

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

[71 FR 13542, Mar. 16, 2006]

## § 524.1044c Gentamicin ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) *Sponsors*. See Nos. 000061 and 017033 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*  
(1) *Amount*. Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(2) *Indications for use*. For treatment of conjunctivitis caused by susceptible bacteria.

## 21 CFR Ch. I (4–1–25 Edition)

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

[69 FR 47363, Aug. 5, 2004, as amended at 77 FR 64717, Oct. 23, 2012; 85 FR 4208, Jan. 24, 2020; 88 FR 16549, Mar. 20, 2023]

## § 524.1044d Gentamicin and betamethasone ointment.

(a) *Specifications*. Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone.

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

(c) *Conditions of use in dogs—*(1) *Amount—*(i) *Otitis externa*. Instill 3 to 8 drops into the ear canal twice daily for 7 days.

(ii) *Infected superficial lesions*. Apply to cover the treatment area twice daily for 7 to 14 days.

(2) *Indications for use*. For the treatment of acute and chronic otitis externa and infected superficial lesions caused by bacteria sensitive to gentamicin.

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

[47 FR 26378, June 18, 1982, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014]

## § 524.1044e Gentamicin spray.

(a) *Specification*. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 1.07 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 in cattle—*(1) *Amount*. Hold the sprayer upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pump once. Treat once daily for up to 3 days.

(2) *Indications for use*. For the treatment of pinkeye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*.

(3) *Limitations*. Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce

## Food and Drug Administration, HHS

## § 524.1044h

similar signs. If conditions persists or increases, discontinue use and consult a veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended at 52 FR 7833, Mar. 13, 1987; 79 FR 10969, Feb. 27, 2014; 84 FR 32993, July 11, 2019; 88 FR 27700, May 3, 2023]

### § 524.1044f Gentamicin and betamethasone spray.

(a) *Specifications.* Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) *Sponsors.* See Nos. 000061, 017033, 054925, 058005, and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use.* For the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

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

[71 FR 13542, Mar. 16, 2006, as amended at 72 FR 5929, Feb. 8, 2007; 74 FR 22822, May 15, 2009; 77 FR 3598, Jan. 25, 2012; 88 FR 16549, Mar. 20, 2023]

### § 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

(a) *Specifications.* Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

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

(1) No. 000061 for use of 7.5- or 15-gram (g) tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 054925 for use of 7.5- or 15-g tubes; 10-, 15-, 25-, or 215-g bottles.

(3) No. 069043 for use of 10-, 20-, 40-, or 215-g bottles.

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

(c) *Conditions of use in dogs—(1) Amount.* Instill ointment twice daily into the ear canal for 7 consecutive days.

(i) From 7.5- or 15-g tubes; 10-, 12.5-, 15-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 20-, 40-, or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

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

[58 FR 38973, July 21, 1993, as amended at 63 FR 31932, June 11, 1998; 68 FR 42970, July 21, 2003; 70 FR 8291, Feb. 18, 2005; 71 FR 13542, Mar. 16, 2006; 71 FR 16481, Apr. 3, 2006; 71 FR 38261, July 6, 2006; 71 FR 56867, Sept. 28, 2006; 78 FR 17597, Mar. 22, 2013; 79 FR 10969, Feb. 27, 2014; 81 FR 17608, Mar. 30, 2016]

### § 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

(a) *Specifications.* Each gram of suspension contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate or mometasone furoate anhydrous, USP, equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

(2) *Indications for use.* For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria

## § 524.1044i

(*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

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

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 15370, Mar. 31, 2003; 70 FR 36338, June 23, 2005; 79 FR 10969, Feb. 27, 2014; 81 FR 59134, Aug. 29, 2016]

## § 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) *Specifications*. Each milliliter (mL) of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) of gentamicin base and 1 mg betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use*. For treatment of external eye infections and inflammation.

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

[75 FR 54492, Sept. 8, 2010, as amended at 80 FR 13230, Mar. 13, 2015]

## § 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.

(a) *Specifications*. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) hydrocortisone aceponate, 17.4 mg miconazole nitrate, and 1.5 mg gentamicin (as gentamicin sulfate).

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1.0 mL in the affected ear once daily for 5 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

[76 FR 78150, Dec. 16, 2011, as amended at 83 FR 13635, Mar. 30, 2018]

## 21 CFR Ch. I (4–1–25 Edition)

## § 524.1140 Imidacloprid and ivermectin.

(a) *Specifications*. The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100 milligrams (mg) imidacloprid and 800 micrograms (µg) ivermectin.

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

(c) *Conditions of Use in Dogs*—(1) *Amount*. The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 µg/lb (80 µg/kg) of ivermectin, topically once a month.

(2) *Indications for Use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*).

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

[67 FR 78685, Dec. 26, 2002, as amended at 86 FR 14821, Mar. 19, 2021]

## § 524.1146 Imidacloprid and moxidectin.

(a) *Specifications*. Each milliliter of solution contains:

(1) 100 milligrams (mg) imidacloprid and 25 mg moxidectin; or

(2) 100 mg imidacloprid and 10 mg moxidectin.

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

(1) Nos. 017030, 051072, 051311, 055529, and 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030, 051072, 051311, 055529, and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) Nos. 051072, 055529, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(3) 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*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. (A) For the prevention of heartworm disease

caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(B) For treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*.

(2) *Cats*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(3) *Ferrets*—(i) *Amount*. Topically apply 9.0 mg/lb body weight (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

[72 FR 10597, Mar. 9, 2007, as amended at 78 FR 73698, Dec. 9, 2013; 85 FR 18120, Apr. 1, 2020; 86 FR 13185, Mar. 8, 2021; 86 FR 14821, Mar. 19, 2021; 87 FR 17946, Mar. 29, 2022; 87 FR 58963, Sept. 29, 2022; 88 FR 27700, May 3, 2023; 89 FR 14410, Feb. 27, 2024]

#### § 524.1193 Ivermectin topical solution.

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

(b) *Sponsors*. See Nos. 000010, 016592, 055529, 058829, and 061133 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*. It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum* (adults); *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenoptes capillatus*; and horn flies *Haematobia irritans*. It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *O. ostertagi*, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) *Limitations*. Do not treat cattle within 48 days of slaughter. Do not use on female dairy cattle of breeding age or on calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[55 FR 50551, Dec. 7, 1990, as amended at 62 FR 38908, July 21, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 44385, Aug. 19, 1998; 66 FR 13236, Mar. 5, 2001; 66 FR 63165, Dec. 5, 2001; 68 FR 3817, Jan. 27, 2003; 68 FR 4713, Jan. 30, 2003; 69 FR 501, Jan. 6, 2004; 69 FR 62181, Oct. 25, 2004; 71 FR 13542, Mar. 16, 2006; 72 FR 6464, Feb. 12, 2007; 74 FR 36112, July 22, 2009; 75 FR 26648, May 12, 2010; 76 FR 81807, Dec. 29, 2011; 78 FR 17597, Mar. 22, 2013; 78 FR 63872, Oct. 25, 2013; 81 FR 25328, Apr. 28, 2016; 83 FR 13635, Mar. 30, 2018; 84 FR 8974, Mar. 13, 2019; 84 FR 39184, Aug. 9, 2019; 86 FR 13185, Mar. 8, 2021; 88 FR 84701, Dec. 6, 2023; 89 FR 42360, May 15, 2024]

#### § 524.1195 Ivermectin otic suspension.

(a) *Specifications*. Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

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

(c) *Conditions of use*—(1) *Amount*. Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) *Indications for use*. For the treatment of adult ear mite (*Otodectes*

## § 524.1200

*cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.

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

[66 FR 7578, Jan. 24, 2001, as amended at 74 FR 26782, June 4, 2009]

### § 524.1200 Kanamycin ophthalmic and topical dosage forms.

#### § 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications*. Each gram of ointment contains 3.5 milligrams kanamycin activity as kanamycin sulfate.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) *Indications for use*. For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

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

[79 FR 10969, Feb. 27, 2014]

#### § 524.1200b Kanamycin ophthalmic solution.

(a) *Specifications*. Each milliliter of solution contains 10 milligrams kanamycin activity as kanamycin sulfate.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as frequently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal.

## 21 CFR Ch. I (4–1–25 Edition)

(2) *Indications for use*. For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

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

[79 FR 10970, Feb. 27, 2014]

### § 524.1204 Kanamycin, amphotericin, and hydrocortisone ointment.

(a) *Specifications*. Each gram of ointment contains 5 milligrams kanamycin activity as kanamycin sulfate, 5 milligrams of amphotericin activity as the calcium salt, and 10 milligrams of hydrocortisone acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Apply to the affected areas of the skin at least twice daily. In severe or widespread lesions it may be desirable to apply the ointment more than twice daily. After some improvement is observed, treatment can usually be reduced to once daily.

(2) *Indications for use*. For the treatment of acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcers, superficial wounds, and superficial abscesses associated with bacterial infections caused by organisms susceptible to one or both antibiotics.

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

[79 FR 10970, Feb. 27, 2014]

### § 524.1240 Levamisole.

(a) *Specifications*. The drug contains 200 milligrams of levamisole per milliliter of diethylene glycol monobutyl ether (DGME) solution.

(b) *Sponsors*. See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.350 of this chapter.

(d) *Conditions of use. Cattle*—(1) *Amount*. 2.5 milliliters per 110 pounds (10 milligrams of levamisole per kilogram) of body weight as a single dose topically to the back of the animal.

(2) *Indications for use.* Anthelmintic effective against stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(3) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Cattle must not be slaughtered within 9 days following last treatment. Do not administer to dairy animals of breeding age. Do not treat animals before dipping or prior to exposure to heavy rain. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before using in severely debilitated animals.

[52 FR 10887, Apr. 6, 1987, as amended at 53 FR 7504, Mar. 9, 1988; 62 FR 61626, Nov. 19, 1997; 67 FR 78355, Dec. 24, 2002; 79 FR 10970, Feb. 27, 2014]

#### § 524.1376 2-Mercaptobenzothiazole solution.

(a) *Specifications.* The drug contains 1.3 percent 2-mercaptobenzothiazole in a suitable solvent.

(b) *Sponsor.* See 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply twice daily to affected area.

(2) *Indications for use.* For dogs as an aid in the treatment of hot spots (moist dermatitis) and as first aid for scrapes and abrasions.

(3) *Limitations.* Clip hair from affected area before applying. If no improvement is seen within 1 week, consult a veterinarian.

[48 FR 15618, Apr. 12, 1983, as amended at 65 FR 50913, Aug. 22, 2000; 68 FR 33381, June 4, 2003]

#### § 524.1443 Miconazole.

(a) *Specifications.* (1) Each gram of cream contains miconazole nitrate equivalent to 20 milligrams miconazole base.

(2) Each gram of lotion or spray contains miconazole nitrate equivalent to 1 percent miconazole base.

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

(1) No. 000061 for use of cream, lotion, and spray;

(2) Nos. 054925 and 058829 for use of lotion and spray.

(c) *Conditions of use in dogs and cats*—

(1) *Amount.* Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(2) *Indications for use.* For topical treatment of infections caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

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

[71 FR 13542, Mar. 16, 2006]

#### § 524.1445 Miconazole, polymixin B, and prednisolone suspension.

(a) *Specifications.* Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Instill five drops in the ear canal twice daily for 7 consecutive days.

(2) *Indications for use.* For the treatment of canine otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

[ 75 FR 4693, Jan. 29, 2010, as amended at 77 FR 46613, Aug. 6, 2012; 81 FR 48703, July 26, 2016]

#### § 524.1446 Milbemycin otic solution.

(a) *Specifications.* Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

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

(c) *Conditions of use*—(1) *Amount.* One tube administered topically into each external ear canal.

## § 524.1448

(2) *Indications for use.* For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.

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

[65 FR 13905, Mar. 15, 2000, as amended at 66 FR 13849, Mar. 8, 2001]

### § 524.1448 Mirtazapine transdermal ointment.

(a) *Specifications.* Each gram of ointment contains 20 milligrams (mg) mirtazapine.

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

(c) *Conditions of use—(1) Amount.* Administer topically by applying a 1.5 inch ribbon of ointment (approximately 2 mg) on the inner pinna of the cat's ear once daily for 14 days. Alternate the daily application of ointment between the left and right inner pinna of the ears.

(2) *Indications for use.* For body weight gain in cats with a history of weight loss.

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

[83 FR 64740, Dec. 18, 2018, as amended at 85 FR 45308, July 28, 2020; 88 FR 16549, Mar. 20, 2023]

### § 524.1450 Moxidectin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 5 milligrams (mg) moxidectin (0.5 percent solution).

(2) 25 mg moxidectin (2.5 percent solution).

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

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

(2) No. 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.426 of this chapter.

## 21 CFR Ch. I (4–1–25 Edition)

(d) *Conditions of use—(1) Cattle—(i) Amount.* Administer topically 0.5 mg per kilogram (kg) of body weight.

(ii) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus* (adult and L4)); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

(iii) *Limitations.* A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. See § 500.25 of this chapter.

(2) *Dogs—(i) Amount.* Administer topically a minimum of 1.1 mg per pound (lb) (2.5 mg/kg) of body weight, once monthly using the appropriate pre-loaded applicator tube.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*, as well as the treatment and control of intestinal hookworm (*Ancylostoma caninum* (adult, immature adult, and L4 larvae) and *Uncinaria stenocephala* (adult, immature adult, and L4 larvae)), roundworm (*Toxocara canis* (adult and L4 larvae) and *Toxascaris leonina* (adult)), and whipworm (*Trichuris vulpis* (adult)) infections in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 lbs.

## Food and Drug Administration, HHS

## § 524.1484c

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

[63 FR 14036, Mar. 24, 1998, as amended at 65 FR 36617, June 9, 2000; 66 FR 46370, Sept. 5, 2001. Redesignated at 76 FR 48715, Aug. 9, 2011, as amended at 80 FR 53460, Sept. 4, 2015; 82 FR 21691, May 10, 2017; 86 FR 14821, Mar. 19, 2021]

### § 524.1465 Mupirocin.

(a) *Specifications.* Each gram of ointment contains 20 milligrams mupirocin.

(b) *Sponsors.* See Nos. 025463, 051672, and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Apply twice daily. Treatment should not exceed 30 days.

(2) *Indications for use.* For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *S. intermedius*.

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

[72 FR 18119, Apr. 11, 2007, as amended at 75 FR 79296, Dec. 20, 2010; 78 FR 52854, Aug. 27, 2013; 79 FR 10970, Feb. 27, 2014; 82 FR 11508, Feb. 24, 2017]

### § 524.1484 Neomycin ophthalmic and topical dosage forms.

#### § 524.1484b Neomycin, isoflupredone, and tetracaine powder.

(a) *Specifications.* Each 15-gram insufflator bottle contains 5 milligrams (mg) neomycin sulfate (equivalent to 3.5 mg neomycin base), 1 mg isoflupredone acetate, and 5 mg tetracaine hydrochloride in a powder base.

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

(c) *Conditions of use in horses, dogs, and cats—(1) Amount.* Apply to affected areas as a dusting powder.

(2) *Indications for use.* For the treatment or as adjunctive therapy of certain ear and skin conditions caused by or associated with neomycin-susceptible organisms and/or allergy; as a superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable; as a dusting powder following amputation of tails, claws, and dewclaws and fol-

lowing ear trimming, castrating, and such surgical procedures as ovariohysterectomies. For the treatment of acute otitis externa, acute moist dermatitis, and interdigital dermatitis in dogs.

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

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014; 85 FR 45308, July 28, 2020]

#### § 524.1484c Neomycin, isoflupredone, and tetracaine ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

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

(c) *Conditions of use in dogs—(1) Amount.* In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(2) *Indications for use.* For the treatment of acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

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

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 18172, Apr. 28, 1978; 79 FR 10970, Feb. 27, 2014]

**§ 524.1484d Neomycin, hydrocortisone, and tetracaine otic ointment.**

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

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

(c) *Conditions of use in dogs and cats—*

(1) *Amount.* Instill a quantity of ointment sufficient to fill the external ear canal; may be applied one to three times daily.

(2) *Indications for use.* For the treatment of ear canker and other inflammatory conditions of the external ear canal, acute otitis externa and, to a lesser degree, chronic otitis externa.

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

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984; 79 FR 10970, Feb. 27, 2014]

**§ 524.1484e Neomycin and polymyxin B ophthalmic solution.**

(a) *Specifications.* Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

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

(c) *Conditions of use in dogs—*(1) *Amount.* Instill 1 to 2 drops per eye every 6 hours.

(2) *Indications for use.* For the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis.

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

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996; 79 FR 10970, Feb. 27, 2014]

**§ 524.1484f Neomycin, prednisolone, and tetracaine otic suspension.**

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone

acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

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

(c) *Conditions of use in dogs and cats—*

(1) *Amount.* Instill 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use.* For the treatment of acute otitis externa and, to a lesser degree, chronic otitis externa; as treatment or adjunctive therapy of certain ear conditions caused by or associated with neomycin-susceptible organisms and/or allergy.

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

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10971, Feb. 27, 2014]

**§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.**

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) thiabendazole, 3.2 mg neomycin (from neomycin sulfate), and 1 mg dexamethasone.

(b) *Sponsors.* See Nos. 000010 and 017033 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*

(1) *Amount.* In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (2 to 4 drops per square inch) twice daily. In treating otitis externa, instill 5 to 15 drops in the ear twice daily. Treat for up to 7 days.

(2) *Indications for use.* As an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 10971, Feb. 27, 2014; 80 FR 61297, Oct. 13, 2015; 84 FR 39184, Aug. 9, 2019; 88 FR 16549, Mar. 20, 2023]

**§ 524.1484h Neomycin, penicillin, polymyxin B, and hydrocortisone suspension.**

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin

## Food and Drug Administration, HHS

## § 524.1580a

B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Rub a small amount into the affected area 1 to 3 times a day. After definite improvement, apply once daily or every other day.

(2) *Indications for use*. For the treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

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

(d) *Conditions of use—dogs*—(1) *Amount*. Rub a small amount into the involved area 1 to 3 times a day. After definite improvement, it may be applied once a day or every other day.

(2) *Indications for use*. Treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations*. For use in dogs only. Shake drug thoroughly and clean lesion before using. If redness, irritation, or swelling persists or increases, discontinue use and reevaluate diagnosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994, as amended at 79 FR 10971, Feb. 27, 2014]

### § 524.1484i Neomycin and hydrocortisone ointment.

(a) *Specifications*. The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, and 5 milligrams of hydrocortisone acetate in each gram of ointment.<sup>1</sup>

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Apply 3 or 4 times daily into the conjunctival sac. With improvement, frequency may be reduced to 2 or 3 times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal 1 to 3 times daily.

(2) *Indications for use*. For the treatment of infections, allergic and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa.

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

[43 FR 40456, Sept. 12, 1978, as amended at 79 FR 10971, Feb. 27, 2014]

### § 524.1484k Neomycin and prednisolone suspension.

(a) *Specifications*. Each milliliter of suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base.

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

(c) *Conditions of use in dogs and cats*—(1) *Amount*. For beginning treatment of acute ocular inflammations place 1 or 2 drops in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, reduce the dosage to 1 drop 2 to 4 times daily. For otitis externa, place 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use*. For the treatment of treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa.

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

[79 FR 10971, Feb. 27, 2014]

### § 524.1580 Nitrofurazone topical dosage forms.

#### § 524.1580a Nitrofurazone ointment.

(a) *Specifications*. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

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

(1) See Nos. 058005, 059051, 061133, and 069043 for use on dogs, cats, or horses.

(2) See No. 017135 for use on dogs and horses.

(3) See Nos. 017153 and 058829 for use on horses.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain

## § 524.1580b

on the lesion for at least 24 hours. Use of a bandage is optional.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.

(3) *Limitations.* For use only on dogs, cats, and horses. Do not use on horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[46 FR 43402, June 27, 1980. Redesignated at 79 FR 10971, Feb. 27, 2014]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 524.1580a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.govinfo.gov](http://www.govinfo.gov).

## § 524.1580b Nitrofurazone soluble powder.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor.* See Nos. 059051 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.

(3) *Limitations.* In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian. For use only on dogs, cats, and horses (not for food use).

[45 FR 43402, June 27, 1980, as amended at 47 FR 43368, Oct. 1, 1982; 48 FR 28984, June 24, 1983; 53 FR 40728, Oct. 18, 1988; 54 FR 30542, July 21, 1989; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997; 76 FR 17778, Mar. 31, 2011; 78 FR 21060, Apr. 9, 2013. Redesignated at 79 FR 10971, Feb. 27, 2014, as amended at 79 FR 64117, Oct. 28, 2014; 83 FR 48947, Sept. 28, 2018]

## 21 CFR Ch. I (4–1–25 Edition)

## § 524.1600 Nystatin ophthalmic and topical dosage forms.

### § 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thiostrepton; and 1.0 milligram of triamcinolone acetonide.

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

(1) For petrolatum base ointments: Nos. 025463 and 054771; or

(2) For vanishing cream base ointments: Nos. 025463 and 054771.

(c) *Conditions of use*—(1) *Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

## Food and Drug Administration, HHS

## § 524.1662a

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

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 29770, July 11, 1978; 50 FR 41490, Oct. 11, 1985; 53 FR 39257, Oct. 6, 1988; 54 FR 5431, Feb. 3, 1989; 54 FR 48090, Nov. 21, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 61 FR 63712, Dec. 2, 1996; 64 FR 42831, Aug. 6, 1999; 67 FR 67521, Nov. 6, 2002; 68 FR 55201, Sept. 23, 2003; 70 FR 50183, Aug. 26, 2005; 71 FR 13542, Mar. 16, 2006; 79 FR 10972, Feb. 27, 2014; 88 FR 84701, Dec. 6, 2023]

### § 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thiostrepton, and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.430 and 556.470 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Apply 1 drop of ointment to the affected eye(s) 2 or 3 times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis.

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

(2) *Cattle*—(i) *Amount.* Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) *Indications for use.* For infectious kerato-conjunctivitis (pinkeye).

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

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985; 79 FR 10972, Feb. 27, 2014; 84 FR 32993, July 11, 2019]

### § 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.

(a) *Specifications.* Each gram of suspension contains 10 milligrams (mg) orbifloxacin, mometasone furoate

monohydrate equivalent to 1 mg mometasone furoate, and 1 mg posaconazole.

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

(c) *Conditions of use in dogs*—(1) *Amount.* For dogs weighing less than 30 lbs. instill 4 drops once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops into the ear canal. Therapy should continue for 7 consecutive days.

(2) *Indications for use.* For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

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

[75 FR 16346, Apr. 1, 2010]

### § 524.1662 Oxytetracycline ophthalmic and topical dosage forms.

#### § 524.1662a Oxytetracycline and hydrocortisone spray.

(a) *Specifications.* Each 3-ounce unit of oxytetracycline hydrochloride and hydrocortisone spray contains 300 milligrams of oxytetracycline hydrochloride and 100 milligrams of hydrocortisone with an inert freon propellant such that a 1-second spray treatment will deliver approximately 2.5 milligrams of oxytetracycline hydrochloride and 0.8 milligram of hydrocortisone.

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

(c) *Conditions of use in dogs and cats*—

(1) *Amount.* A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds. Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon

§ 524.1662b

after the initial favorable response has been obtained.

(2) *Indications for use.* For the relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions; for the prevention of bacterial infections in superficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus.

(3) *Limitations.* Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10972, Feb. 27, 2014]

§ 524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate.

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

(c) *Conditions of use in dogs and cats—*(1) *Amount.* Administer topically to the eye two to four times daily.

(2) *Indications for use.* For the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms including ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pink-eye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

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

[40 FR 13873, Mar. 27, 1975, as amended at 79 FR 10972, Feb. 27, 2014; 88 FR 14901, Mar. 10, 2023]

21 CFR Ch. I (4–1–25 Edition)

§ 524.1742 Phosmet emulsifiable liquid.

(a) *Specifications.* The emulsifiable liquid contains 11.6 percent *N*-(mercaptomethyl) phthalimide *S*-(*O*,*O*-dimethyl phosphorodithioate).

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

(c) *Related tolerances.* See 40 CFR 180.261.

(d) *Conditions of use—*(1) *Methods of application.* Methods of application to control the following conditions on beef cattle:

TABLE 1 TO PARAGRAPH (d)(1)

To control/method of use	Dilution rate (gal. drug: gal. of water)
Grubs:	
Dip .....	1:60
Pour-on .....	1:2
Spray .....	1:49
Lice:	
Dip .....	1:60
Pour-on .....	1:2 or 1:5
Spray .....	1:49 or 1:100
Hornflies:	
Dip .....	1:60
Spray .....	1:49 or 1:100
Cattle Ticks:	
Dip .....	1:60 or 1:240
Spray .....	1:49
Southern cattle ticks:	
Dip .....	1:60 or 1:240
Spray .....	1:49
Scabies mites:	
Dip .....	1:60
Lone Star Ticks:	
Dip .....	1:60
Spray .....	1:49 or 1:100

(i) *Dip vat procedure.* (A) Prior to charging vat, empty old contents and thoroughly clean the vat. Dip vats should be calibrated to maintain an accurate dilution. Add water, then drug to the vat according to the dilution rate indicated in the table. Add super phosphate at a rate of 100 pounds per 1,000 gallons of vat solution. Super phosphate is added to control the pH of the solution and ensure vat stability. Super phosphate is usually available at most fertilizer dealers as 0-45-0 or 0-46-0. Stir the dip thoroughly, preferably with a compressed air device; however, any form of thorough mixing is adequate. Re-stir vat contents prior to each use. During the dipping operation, each time the dip's volume is reduced by  $\frac{1}{8}$  to  $\frac{1}{4}$  of its initial volume, replenish with water and add the drug at a

rate of 1 gallon for each 50 or 200 gallons water added—depending on dilution rate 1:60 or 1:240. Also add super phosphate as necessary to maintain pH between 4.5 and 6.5. Stir well and resume dipping. Repeat replenishment process as necessary. For evaporation, add additional water accordingly. For added water due to rainfall, merely replenish dip with the product according to directions. If overflow occurs, either analyze for drug concentration and adjust accordingly or dispose of vat contents and recharge. Check pH after each addition of water or super phosphate to assure proper pH controls.

(B) *Dip maintenance.* (1) With use of dip vat tester, dipping may continue as long as the drug concentration is maintained between 0.15 and 0.25 percent, and the dip is not too foul for satisfactory use as indicated by foul odor or excessive darkening (i.e., color changes from beige to very dark brown).

(2) Without use of dip vat tester, vat should be emptied, cleaned, and recharged each time one of the following occurs: When the dip has been charged for 120 days; when the dip becomes too foul for satisfactory use, within the 120-day limit; if the number of animals dipped equals twice the number of gallons of the initial dip volume, within the 120-day limit.

(ii) *Spray method.* To prepare the spray, mix drug with water according to table and stir thoroughly. Apply the fresh mixture as a high-pressure spray, taking care to wet the skin, not just the hair. Apply to the point of "run-off," about 1 gallon of diluted spray per adult animal. Lesser amounts will permit runoff for younger animals.

(iii) *Pour-on method.* Dilute the drug with water according to table by slowly adding water to the product while stirring. Apply 1 ounce of the diluted mixture per 100 pounds of body weight (to a maximum of 8 ounces per head) down the center line of the back.

(2) *Timing of applications for cattle grub control.* For optimum cattle grub control, it is important to treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal, as the rapid kill of large numbers of larvae in these tissues may cause toxic side effects, such

as bloat, salivation, staggering, and paralysis.

(3) *Treatment regimens.* (i) Control of scabies mites requires two treatments, 10 to 14 days apart.

(ii) Control of Lone Star Ticks and hornflies requires two treatments, 7 days apart.

(4) *Warnings.* The drug is a cholinesterase inhibitor. Do not use this drug on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not apply within 21 days of slaughter. For use on beef cattle only. Do not treat sick, convalescent, or stressed cattle, or calves less than 3 months old except in Federal or State eradication programs where immediate treatment of all animals in an infested herd is mandatory. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty animals. Do not dip animals when overheated. Repeat treatment as necessary but not more often than every 7 to 10 days. Treatment for lice, ticks, hornflies, and scabies mites may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Treatment for lice, ticks, and scabies mites may be made any time 7 to 10 days following treatment for grubs. Do not treat grubs when the grub larvae are in the gullet or spinal canal. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear rubber gloves, goggles, and protective clothing. In case of skin contact, wash immediately with soap and water; for eyes, flush with water. Wash all contaminated clothing with soap and hot water before re-use.

[40 FR 13873, Mar. 27, 1975, as amended at 46 FR 27914, May 22, 1981; 48 FR 39607, Sept. 1, 1983; 54 FR 51021, Dec. 12, 1989; 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997; 63 FR 5255, Feb. 2, 1998; 85 FR 18120, Apr. 1, 2020]

#### § 524.1982 Proparacaine ophthalmic solution.

(a) *Specifications.* The drug is an aqueous solution containing 0.5 percent proparacaine hydrochloride, 2.45 percent glycerin as a stabilizer, and 0.2 percent chlorobutanol (choral derivative) and 1:10,000 benzalkonium chloride as preservatives.

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

(c) *Conditions of use in dogs and cats—*  
(1) *Amount.* It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to ten drops in the ear; for nasal use, instill five to ten drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(2) *Indications for use.* For use as a topical ophthalmic anesthetic. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected; as an aid in the removal of foreign bodies from the nose and ear canal; as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(3) *Limitations.* Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

(d) *Conditions of use.* (1) The drug is indicated for use as a topical ophthalmic anesthetic in animals. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in

minor surgery, and prior to catheterization.

(2) It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid in treatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

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

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985; 79 FR 10972, Feb. 27, 2014]

#### § 524.2080 Ropinirole.

(a) *Specifications.* Each milliliter of solution contains 30 milligrams (mg) ropinirole (equivalent to 34.2 mg ropinirole hydrochloride).

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* Using the table provided in labeling, administer the number of eye drops topically, corresponding to body weight, that results in a target dose of 3.75 mg per square meter (mg/m<sup>2</sup>) (dose band 2.7 to 5.4 mg/m<sup>2</sup>). If the dog does not vomit within 20 minutes of the first dose, then a second dose may be administered.

(2) *Indications for use.* For the induction of vomiting in dogs.

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

[86 FR 13185, Mar. 8, 2021]

**§ 524.2098 Selamectin.**

(a) *Specifications.* Each milliliter contains 60 or 120 milligrams (mg) of selamectin.

(b) *Sponsors.* See Nos. 051072, 051311, 054771, 055529, 061133, and 086117 of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer topically 2.7 mg of selamectin per pound (6 mg per kilogram) of body weight.

(2) *Indications for use.* Kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and control of tick (*Dermacentor variabilis*) infestations in dogs. Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. For dogs 6 weeks of age and older, and cats 8 weeks of age and older.

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

[64 FR 37401, July 12, 1999, as amended at 64 FR 48707, Sept. 8, 1999; 65 FR 45282, July 21, 2000; 74 FR 19878, Apr. 30, 2009; 79 FR 10972, Feb. 27, 2014; 86 FR 17064, Apr. 1, 2021; 87 FR 58963, Sept. 29, 2022; 89 FR 14410, Feb. 27, 2024; 89 FR 42360, May 15, 2024]

**§ 524.2099 Selamectin and sarolaner.**

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) selamectin and 10 mg sarolaner. The drug is provided in single dose tubes containing 0.25, 0.5, or 1 mL of solution.

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

(c) *Conditions of use in cats*—(1) *Amount.* Administer 2.7 mg selamectin per pound (1b) (6 mg per kilogram (/kg)) of body weight and 0.45 mg/lb sarolaner (1 mg/kg) by emptying the contents of the tube on the back of the animal at the base of the neck in front of the shoulder blades.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*, the treatment and

control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the prevention of *Dipylidium caninum* (tapeworm) infections as a direct result of killing *Ctenocephalides felis* vector fleas on the treated cat, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), and *Ixodes scapularis* (black-legged tick) for 1 month in cats and kittens 8 weeks and older, and weighing 2.8 pounds or greater.

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

[84 FR 12494, Apr. 2, 2019, as amended at 89 FR 14410, Feb. 27, 2024; 90 FR 6801, Jan. 21, 2025]

**§ 524.2101 Selenium disulfide suspension.**

(a) *Specifications.* The product contains 0.9-percent weight in weight (w/w) selenium disulfide (1-percent weight in volume (w/v)).

(b) *Sponsors.* See Nos. 000061 and 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use on dogs*—(1) *Indications for use.* For use as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and nonspecific dermatoses.

(2) *Amount.* One to 2 ounces per application.

(3) *Limitations.* Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if rash or irritation develops, discontinue use and consult a veterinarian.

[47 FR 53351, Nov. 26, 1982, as amended at 48 FR 32762, July 19, 1983; 54 FR 36962, Sept. 6, 1989; 56 FR 9623, Mar. 7, 1991; 58 FR 41025, Aug. 2, 1993; 63 FR 26981, May 15, 1998; 70 FR 50183, Aug. 26, 2005; 84 FR 39184, Aug. 9, 2019; 88 FR 27700, May 3, 2023]

## § 524.2338

### § 524.2338 Terbinafine and betamethasone acetate.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) terbinafine and 1 mg betamethasone acetate.

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

(c) *Conditions of use in dogs—(1) Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).

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

[89 FR 42360, May 15, 2024]

### § 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate in an anhydrous cream base.

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

(c) *Conditions of use—(1) Amount.* Apply a small amount of the cream to the affected areas once or twice a day for 2 to 4 weeks.

(2) *Indications for use.* For the treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypsum*.

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

[79 FR 10972, Feb. 27, 2014]

### § 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

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

(c) *Conditions of use in dogs—(1) Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

## 21 CFR Ch. I (4–1–25 Edition)

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

[68 FR 4916, Jan. 31, 2003, as amended at 78 FR 17868, Mar. 25, 2013]

### § 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a) *Specifications.* (1) Each gram of liquid or aerosol contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Each gram of liquid or aerosol contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

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

(1) No. 069043 for use of product described in paragraph (a)(1).

(2) No. 017135 for use of product described in paragraph (a)(2).

(c) *Conditions of use—(1) Amount.* Apply directly to the wound site.

(2) *Indications for use.* As an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate, and organic debris.

[79 FR 10973, Feb. 27, 2014, as amended at 88 FR 14901, Mar. 10, 2023]

## PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

526.88 Amoxicillin.

526.313 Ceftiofur.

526.363 Cephapirin benzathine.

526.365 Cephapirin sodium.

526.464 Cloxacillin benzathine.

526.465 Cloxacillin sodium.

526.820 Erythromycin.

526.1130 Hetacillin.

526.1590 Novobiocin.

526.1696 Penicillin G procaine.

526.1697 Penicillin G procaine and dihydrostreptomycin.

526.1698 Penicillin G procaine and novobiocin.

526.1810 Pirlimycin.

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

### § 526.88 Amoxicillin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains