calves. Do not use in calves to be processed for veal.

(3) Steers fed in confinement for slaughter—(i) Amount. 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) Indications for use. For increased rate of weight gain and improved feed efficiency.

(iii) Limitations. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(4) Pasture cattle (slaughter, stocker, feeder steers, and heifers)—(i) Amount. 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) Indications for use. For increased rate of weight gain.

(iii) Limitations. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.


§ 522.2690 Zinc gluconate.

(a) Specifications. Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) Sponsor. See No. 076175 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) Indications for use. Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(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]
§ 524.86 Amitraz liquid.

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

(b) Sponsor. See No. 000009 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 total of 3 to 6 treatments, 14 days apart.

(3) Limitations. Continue treatment until no viable mites are found in skin scrapings at 2 successive treatments, or until 6 treatments have been applied. Do not use for treatment of localized demodicosis or scabies. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 18589, Apr. 30, 1982]
§ 524.450 Clotrimazole cream.

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

(b) Sponsor. See 000859 in §510.600(c).

(c) Conditions of use—(1) Amount. Apply ½-inch ribbon of cream per square inch of lesion once daily for 2 to 4 weeks.

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

(3) Limitations. Wash hands thoroughly after use to avoid spread of infection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 48128, July 18, 1980]
§ 524.463 Copper naphthenate.

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

(b) Sponsors. See Nos. 000856, 017135, 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.


§ 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 1/4-inch strip of ointment to 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. Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 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.

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

§ 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

§ 524.660a Dimethyl sulfoxide solution.

(a) Specifications. Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For 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]

§ 524.660b Dimethyl sulfoxide gel.

(a) Specifications. Dimethyl sulfoxide gel, veterinary contains 90 percent of dimethyl sulfoxide in an aqueous gel.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. For use on horses and dogs as a topical application to reduce acute swelling due to trauma.
(2) **Amount**—(i) **Horses.** Administer 2 or 3 times daily in an amount not to exceed 100 grams per day. Total duration of therapy should not exceed 30 days.

(ii) **Dogs.** Administer 3 or 4 times daily in an amount not to exceed 20 grams per day. Total duration of therapy should not exceed 14 days.

(3) **Limitations.** Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food. Restricted to topical use on horses and dogs only. Due to rapid penetrating ability of dimethyl sulfoxide, rubber gloves should be worn when applying the drug. No other medications should be present on the skin prior to application of the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.770 Doramectin.

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

(b) **Sponsor.** See No. 000069 in § 510.600(c) of this chapter.

(c) **Related tolerances.** See § 556.225 of this chapter.

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

(e) **Conditions of use in cattle**—(1) **Amount.** Administer topically as a single dose 0.5 mg (1 mL) per kilogram (1 mL per 22 pounds) body weight.

(2) **Indications for use.** For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and 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 punctulata* (adults and fourth-stage larvae), *Cooperia pectinata* (adults), *Cooperia surinamensis* (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: *Choriopotes bovis* and *Sarcopes 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 punctulata* and *Haemonchus placei* for 35 days after treatment; and to control infestations and to protect from reinfection with *Linognathus vituli* for 42 days and with *Bovicola* (Damalinia) bovis for 77 days after treatment.

(3) **Limitations.** Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. 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]

§ 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. 000859 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/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]
§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.

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

(b) Sponsor. See No. 000859 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 extra-label use of this drug in food-producing animals.

[65 FR 66620, Nov. 7, 2000]

§ 524.814 Eprinomectin.

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

(b) Sponsor. See No. 050604 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) applied 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 (adults 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 re-infection 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]

§ 524.900 Famphur.

(a) Chemical name. O,O- Dimethyl O-[[p-(dimethylsulfamoyl)phenyl] phosphorothioate.

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

(c) Sponsor. See Nos. 000061 and 051311 in § 510.600(c) of this chapter.

(d) 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.

(e) Related tolerances. See § 556.273 of this chapter.

(f) Conditions of use. (1) The drug is used as a pour-on formulation for the control of cattle grubs and to reduce cattle lice infestations.

(2) It is used at the rate of 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, applied from the shoulder to the tail head as a single treatment. It is applied as soon as possible after heel fly activity ceases. 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, over-excitement 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.

(3) Do not slaughter within 35 days after treatment. Swine should be eliminated from area where run-off occurs.

§ 524.920 Fenthion.

(a) Chemical name. O,O-Dimethyl O-[4-(methylthio)-m-toly1] phosphorothioate.

(b) Specifications. (1) The drug is in a liquid form containing 3 percent of fenthion.

(2) Sponsor. See No. 000859 in § 510.600(c) of this chapter.

(3) 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.


(5) Conditions of use. (i) The drug is used for control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(ii) It is applied as a single application placed on the backline of animals as follows:

<table>
<thead>
<tr>
<th>Weight of animal</th>
<th>Dosage (milliliters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 to 300 lb</td>
<td>4</td>
</tr>
<tr>
<td>301 to 600 lb</td>
<td>8</td>
</tr>
<tr>
<td>601 to 900 lb</td>
<td>12</td>
</tr>
<tr>
<td>901 to 1,200 lb</td>
<td>16</td>
</tr>
<tr>
<td>Over 1,200 lb</td>
<td>20</td>
</tr>
</tbody>
</table>

For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. Host-parasite reactions such as bloat, salivation, staggering and paralysis may 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 on cattle on full feed when the common grub is killed while in the gullet. 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.

(iii) Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock.

(iv) Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases.

(v) Do not slaughter within 45 days of treatment.
§ 524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

(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. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(i) 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 nongranulomatous anterior uveitis, kerato-conjunctivitis, and blepharitis.

(3) Limitations. (i) In treating ophthalmological conditions associated with bacterial infections, the drug is contraindicated in those cases in which microorganisms are not susceptible to the antibiotics incorporated in the drug.

(ii) The drug is contraindicated in infectious tuberculous lesions of the eye, early acute stages of viral diseases of the cornea and conjunctiva, herpes simplex lesions of the eye, and fungal infections of the conjunctiva and eyelids.

(iii) The usual precautions and contraindications for corticosteroids and adrenocorticoids are applicable with this drug. Corticosteroids may inhibit essential inflammatory responses intrinsic to the fundamental healing mechanism. Adrenocorticoid compounds have been reported to cause an increase in intraocular pressure. Intraocular pressure should be checked frequently. Ocular reexaminations should be made at frequent intervals during long-term therapy.

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


§ 524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

§ 524.981a Fluocinolone acetonide 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. (1) The drug is indicated for the relief of pruritus and inflammation associated with certain superficial acute and chronic dermatoses in dogs. It is used in the treatment of allergic and acute moist
dermatitis and for the relief of superficial inflammation caused by chemical and physical abrasions and burns.

(2) A small amount is applied to the affected area two or three times daily.

(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]

§ 524.981b Fluocinolone acetonide solution.

(a) Specifications. The drug contains 0.01 percent fluocinolone acetonide in propylene glycol with citric acid.

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

(c) Conditions of use. (1) The drug is indicated for the relief of pruritus and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses in the dog. It is also indicated for the relief of pruritus and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses in the cat.

(2) A small amount of solution is applied to the affected area 2 or 3 times daily.

(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 61 FR 5507, Feb. 13, 1996]

§ 524.981c Fluocinolone acetonide, neomycin sulfate cream.

(a) Specifications. The drug contains 0.025 percent fluocinolone acetonide 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. (1) The drug is used in the relief of pruritus and inflammation associated with superficial acute and chronic dermatoses in dogs. It is used in the treatment of such conditions as allergic and acute moist dermatoses and nonspecific dermatoses in dogs. It is used in the treatment of wound infections in dogs and cats.

(2) A small amount is applied to the infected area two or three times daily.

(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]

§ 524.981d Fluocinolone acetonide, dimethyl sulfoxide solution.

(a) Specifications. Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide with propylene glycol and citric acid.

(b) Sponsor. See No. 000856 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs 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.

(2) It is administered by instillation of 1 to 2 milliliters into each anal sac following expression of anal sac contents. It may be necessary to repeat treatment at 60-day intervals to maintain an odor-free state. The total dosage used should not exceed 2 milliliters per anal sac per treatment.

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

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

§ 524.981e Fluocinolone acetonide, dimethyl sulfoxide otic solution.

(a) Specifications. Each milliliter of solution contains 0.01 percent fluocinolone acetonide in 60 percent dimethyl sulfoxide with propylene glycol and citric acid.

(b) Sponsor. See No. 000033 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs for the relief of pruritus and inflammation associated with acute and chronic otitis.

(2) It is administered at 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters. The ear canal should be cleansed by some appropriate method prior to instillation of the solution and the ear should be massaged gently following instillation.
(3) There should be careful initial evaluation and followup of infected ears. Incomplete response or exacerbation of corticosteroid-responsive lesions may be due to the presence of an infection which requires identification or antibiotic sensitivity testing, and the use of the appropriate antimicrobial agent. As with any corticosteroid, animals with a generalized infection should not be treated with this product without proper supportive antimicrobial therapy. Preparations with dimethyl sulfoxide should not be used in pregnant animals. For use by or on the order of a licensed veterinarian.

§ 524.1005 Furazolidone aerosol powder.

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

(b) Sponsors. (1) See No. 053501 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 pyogenic dermatitis.

(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. Not for use in horses intended for food.


§ 524.1044 Gentamicin sulfate ophthalmic and topical dosage forms.

§ 524.1044a Gentamicin ophthalmic solution.

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

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

(c) Conditions of use. (1) The drug is used in dogs and cats for the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(2) Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

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


§ 524.1044b Gentamicin sulfate, betamethasone valerate 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]

§ 524.1044e Gentamicin sulfate ophthalmic ointment.

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

(b) Sponsors. See Nos. 000061 and 025463 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.

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

[69 FR 47363, Aug. 5, 2004]

§ 524.1044d Gentamicin sulfate, betamethasone valerate 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. (1) The drug is used or indicated for use in dogs in the treatment of acute and chronic canine otitis externa and canine infected superficial lesions caused by bacteria sensitive to gentamicin.

(2)(i) For the treatment of acute and chronic canine otitis externa the drug is administered by instillation of 3 to 8 drops into the ear canal twice daily for 7 days. The external ear and ear canal should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(ii) For the treatment of canine infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Observe patients for signs of adrenocorticoid overdosage. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

(4) For 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]

§ 524.1044e Gentamicin sulfate 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) Conditions of use. (1) The drug is indicated for the treatment of pink eye in cattle (infectious bovine keratoconjunctivitis) caused by Moraxella bovis.

(2) One actuation of the sprayer delivers 0.7 milliliter containing 0.75 milligram gentamicin. The sprayer should be held upright 3 to 6 inches from the affected eye, with the opening directed towards the eye, and pumped once. It is advisable to treat once a day for up to 3 days.

(3) Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by Moraxella bovis may produce similar signs. If conditions persists or increases, discontinue use and consult veterinarian.

§ 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, 054925, 058005, 058829, and 065531 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 spray 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.


§ 524.1044g Gentamicin sulfate, betamethasone valerate, 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, 10-, 12.5-, 15-, 25-, 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. 059130 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.

(1) 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.


§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

(a) Specifications. Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligrams (mg) gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(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 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-g (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 (Pseudomonas spp. [including P. aeruginosa], coagulase-positive staphylococci, Enterococcus faecalis, Proteus mirabilis, and beta-hemolytic streptococci).


§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) Specifications. Each milliliter (mL) of solution contains gentamicin

(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.
Food and Drug Administration, HHS § 524.1146

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 two drops of solution in the conjunctival sac three or four times a day.

(2) Indications for use. For treatment of external bacterial infections of the eye (conjunctiva and cornea).

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

[75 FR 54492, Sept. 8, 2010]

§ 524.1132 Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate otic suspension.

(a) Specifications. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone aceponate, 15.1 mg of miconazole nitrate, and 1,505 micrograms (μg) 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]

§ 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. 000859 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]

§ 524.1146 Imidacloprid and moxidectin.

(a) Specifications—(1) Each milliliter of solution contains 100 milligrams (mg) imidacloprid and 25 mg moxidectin for use as in paragraph (d)(1) of this section.

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraph (d)(2) of this section.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

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

(d) Conditions of use—(1) Dogs—(i) Amount. 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. 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).

(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 catti), and hookworms (Ancylostoma tubaeforme); kills adult fleas and treats flea infestations (Ctenocephalides felis).

[72 FR 10597, Mar. 9, 2007]
§ 524.1193 Ivermectin topical solution.

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

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

(1) Nos. 050604, 055529, 061623 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

(2) Nos. 054925, 059130, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

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

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

(e) Conditions of use 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—(i) It is used for the treatment and control of: Gastrintestinal 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.

(ii) It controls infections and prevents reinfection with O. ostertagi, O. radiatum, H. placei, T. axei, C. punctata, and C. oncophora for 14 days after treatment.

(iii) 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. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

§ 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 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.

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) Specifications. The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. 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. For use only by or on the order of a licensed veterinarian.

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) Specifications. The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10 milligrams of kanamycin activity (as the sulfate) per milliliter of solution.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administration 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. For use only by or on the order of a licensed veterinarian.

§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) Specifications. (1) Calcium amphomycin is the calcium salt of amphomycin. It conforms to the following specifications:

(i) Its potency is not less than 863 micrograms of amphomycin per milligram;

(ii) Its moisture content is not more than 10 percent; and

(iii) Its pH in a 2-percent aqueous suspension is 6.0 to 7.5.

(2) The drug is in a water-miscible ointment or cream base and each gram of ointment or cream contains: 5.0 milligrams of kanamycin activity as the sulfate, 5.0 milligrams of amphomycin activity as the calcium salt, and 10.0 milligrams of hydrocortisone acetate.

(b) Sponsor. See No. 000061 and 053501 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.

§ 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.


§ 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. 012578 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]

§ 524.1446 Milbemycin oxime 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.

(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]
§ 524.1450 Moxidectin.

(a) Specifications. Each milliliter contains 5 milligrams (mg) moxidectin (0.5 percent solution).

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

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

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

(e) Conditions of use—(1) Amount. Administer topically 0.5 mg per kilogram of body weight.

(2) 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), Tr. 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 reinfec-
tion 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.

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


§ 524.1454b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.

(a) Specifications. The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomy-
cin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

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

(c) Conditions of use. (1) It is used in horses, dogs, and cats in the treatment or adjunctive therapy of certain ear and skin conditions when such condi-
tions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indi-
cated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflam-
matory response is deemed desirable. The product may be used as a dusting powder following amputation of tails, claws, and dew-claws and following ear trimming, castrating, and such sur-
gical procedures as ovariohysterectomies. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital der-
matitis in dogs.

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

§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride 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. 000009 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used in treating such conditions as 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.

(2) 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.

(3) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the drug. If such signs are noted, therapy with the drug should be stopped. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984]

§ 524.1484e Neomycin sulfate and polymyxin B sulfate 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. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is recommended for the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivities, and blepharitis in the dog.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(2) The recommended dosage is 1 to 2 drops per eye every 6 hours.

(3) In treating ophthalmological conditions associated with bacterial infections the drug is contraindicated in those cases in which microorganisms are nonsusceptible to the antibiotics incorporated in the drug.

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

§ 524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.

(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. 000009 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) It is useful in treating such conditions as acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. It is indicated as treatment or adjunctive therapy of certain ear conditions in dogs and cats caused by or associated with neomycin-susceptible organisms and/or allergy. In otitis externa, 2 to 6 drops may be placed in the external ear canal two or three times daily.1

(2) Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia. Thus, if improvement is not noted within 2 or 3 days, or if redness, irritation, or swelling persists or increases, the diagnosis should be re-determined and appropriate therapeutic measures initiated. Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy. If such signs are noted, therapy should be stopped.1

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

§ 524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.

(a) Specifications. Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is recommended for use as an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

(2) In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (two to four drops per square inch) twice daily. In treating otitis externa, five to 15 drops of the drug should be instilled in the ear twice daily. The drug is limited to 7 days maximum duration of administration.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 524.1484h Neomycin, penicillin, polymyxin, 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 B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

(b) Sponsor. See 000009 in § 510.600(c) of this chapter.

(c) Special considerations. The labeling shall state: This medication contains penicillin. Allergic reactions in humans are known to occur from topical exposure to penicillin.

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.
§ 524.1484i

(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]

§ 524.1580 Nitrofurazone ophthalmic and topical dosage forms.

§ 524.1580a [Reserved]

§ 524.1580b Nitrofurazone ointment.

(a) Specifications. The drug contains 0.2 percent nitrofurazone in a watersoluble base.

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

(1) See Nos. 000010, 000069, 050749, 054925, 058005, and 061623 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 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 in 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]

EDITORIAL NOTE: For Federal Register citations affecting §524.1580b, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 524.1580c Nitrofurazone soluble powder.

(a) Specifications. The drug contains 0.2 percent nitrofurazone in a watersoluble base.

(b) Sponsors. See Nos. 000010 and 000069 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Apply several times daily to the lesion...
Food and Drug Administration, HHS

§ 524.1580d [Reserved]

§ 524.1580e Nitrofurazone ointment with butacaine sulfate.

(a) Specifications. The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) Sponsor. See No. 054925 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. For prevention or treatment of surface bacterial infections of ears, wounds, burns, and cutaneous ulcers of dogs, cats, and horses.1

(2) Limitations. Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.1


1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.
for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§524.1600b
Nystatin, neomycin, thiostrepton, and triamcinolone acetonide 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) Conditions of use. (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (Candida albicans), and antibacterial agent in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(2) It is to be administered as follows:

(i) For conjunctivitis and keratitis: Apply one drop of ointment to the affected eye(s) two or three times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions the drug may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

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

§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.

§524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

§524.1662a Oxytetracycline hydrochloride 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 propel- lant 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. 000069 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is indicated for relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions. The indications include 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 in dogs and cats.  

(2) 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 after the initial favorable response has been obtained.

(3) 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.

§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate 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. 000069 in §510.600(c) of this chapter.

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

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

(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 1/4 to 1/3 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 the 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 "runoff," 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 1 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 inhibi-
ting 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.

(d) Related tolerances. See 40 CFR 180.261.

§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

§ 524.1881a [Reserved]

§ 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.

(a) Specifications. Prednisolone acetate-neomycin sulfate sterile suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base) in each milliliter of sterile suspension.

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

(c) Conditions of use. (1) The drug is indicated for treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa in dogs and cats.

(2) For beginning treatment of acute ocular inflammations 1 or 2 drops may be placed in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, the dosage may be reduced to 1 drop 2 to 4 times daily. In otitis externa, 2 to 6 drops may be placed in the external ear canal 2 or 3 times daily.

(3) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.

(4) 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]

§ 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.

(a) Specifications. Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

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

(c) Special considerations. The long-term toxicity of proparacaine is unknown. Prolonged use may possibly delay wound healing.

(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 cauteryization 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 such as those associated with allergic reactions or gross irritants.

(2) A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition remains under control. Treatment may require from a few days to several weeks.

(3) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]
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]

§524.2098 Selamectin.

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

(b) Sponsor. See Nos. 000069 in §510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use—(1) Amount. 2.7 milligrams of selamectin, topically, per pound (6 milligrams 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 (Ankylostoma 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.


§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, 017135, and 050604 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.


§524.2350 Tolnaftate cream.

(a) Specifications. The drug contains 1 percent tolnaftate (2-naphthyl-N-methyl-N-(3-tolyl) thionocarbamate) in an anhydrous cream base.

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

(c) Conditions of use. (1) The drug is indicated for treatment of ringworm lesions due to Microsporum canis and Microsporum gypseum in dogs and cats.

(2) A small amount of the cream is applied to the affected areas once or twice a day for 2 to 4 weeks. The areas to be treated are first cleared of exudate and the hair clipped if the areas are not already denuded. The cream is massaged into each lesion and immediate surrounding area until the cream is no longer visible.
(3) If no response is seen after 2 weeks of treatment with the drug the diagnosis should be reviewed.

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


§ 524.2482 Triamcinolone spray.

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

(b) Sponsor. See No. 067292 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.

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


§ 524.2483 Triamcinolone cream.

(a) Specifications. The vanishing cream contains 0.1 percent triamcinolone acetonide.

(b) Sponsor. See Nos. 000010, 015914, and 054925 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Rub into affected areas two to four times daily for 4 to 10 days.

(2) Indications for use. For topical treatment of allergic dermatitis and summer eczema.

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


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

(a) (1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Sponsor. See No. 051079 in §510.600(c) of this chapter.

(b) (1) Specifications. The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) Sponsor. See No. 017135 in §510.600(c) of this chapter.

(3) Conditions of use. The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.


PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec. 526.88 Amoxicillin trihydrate for intramammary infusion.

526.313 Ceftiofur.

526.363 Cephapirin benzathine.

526.365 Cephapirin sodium.

526.464 Cloxacillin intramammary dosage forms.

526.464a Cloxacillin benzathine.

526.464b Cloxacillin benzathine for intramammary infusion, sterile.

526.464c Cloxacillin sodium for intramammary infusion, sterile.

526.464d Cloxacillin sodium for intramammary infusion.

526.820 Erythromycin.

526.1130 Hetacillin potassium for intramammary infusion.

526.1590 Novobiocin oil suspension.

526.1696 Penicillin intramammary dosage forms.

526.1696a Penicillin G procaine.

526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

526.1810 Pirlimycin.