(2) Feedlot lambs—(i) Amount. 12 milligrams (1 pellet) per animal.

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

(iii) Limitations. Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter.

(3) Steers—(i) Amount. 72 milligrams (six 12-milligram pellets) per animal.

(ii) Indications for use. For increased rate of weight gain in steers fed in confinement for slaughter.

(iii) Limitations. Implant subcutaneously in ear only.

§ 524.155 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) Sponsor. To firms identified in §510.600(c) of this chapter as follows:
(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.
(2) To 000061 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) Conditions of use. 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. Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

(a) Sponsor. To firms identified in §510.600(c) of this chapter as follows:
(1) To 000009; each gram contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.
(2) To 025463; each gram contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5
milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

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


§ 524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.

(a) Specifications. Each gram of the drug contains 10 milligrams cephalonium, 5,000 units polymyxin B sulfate, 0.25 milligram flumethasone, 30 milligrams iodochlorhydroxyquin, and 40 milligrams piperocaine hydrochloride in a suitable and harmless ointment base.

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

(c) Conditions of use. The drug is recommended for dermal and otic use on dogs and cats for the treatment of the following conditions when complicated by bacteria, yeast, or fungus: Pyodermatitis, allergic dermatitis, dermatophytosis, nonspecific pruritus, and external otitis. For mild inflammations a periodic treatment of applying from once daily to twice weekly may be indicated. In severe conditions apply once or twice daily when continuous treatment may be indicated. Dosage per treatment should not exceed 300 milligrams of the ointment. For otic use treatment should not exceed a total of 12 days. For use only by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]
times a day for the first 72 hours, depending upon the severity of the condition. Intervals between applications may be increased after the first 2 days.

(2) Indications for use. Treatment of bacterial conjunctivitis caused by organisms susceptible to chloramphenicol. Therapy should be continued for 48 hours after the eye appears normal.

(3) Limitations. Therapy for cats should not exceed 7 days. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use, and institute appropriate therapy. Prolonged use in cats may produce blood dyscrasias. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

§ 524.390c Chloramphenicol-prednisolone-tetracaine-squalane topical suspension.

(a) Specification. Each milliliter contains 4.2 milligrams of chloramphenicol, 1.7 milligrams of prednisolone, 4.2 milligrams of tetracaine, and 0.21 milliliter of squalane.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply two or three times daily for not more than 7 days. Severe infections should be supplemented by systemic therapy.

(2) Indications for use. Treatment of acute otitis externa and pyodermas (acute moist dermatitis, vulvar fold dermatitis, lip fold dermatitis, interdigital dermatitis, and juvenile dermatitis) in dogs and cats.

(3) Limitations. The drug must not be used in the eyes. Prolonged use in cats may produce blood dyscrasias. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992]

§ 524.390d Chloramphenicol-prednisolone ophthalmic ointment.

(a) Specifications. Each gram contains 10 milligrams of chloramphenicol and 2.5 milligrams of prednisolone acetate.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. Dogs and cats. (1) Amount. Apply 4 to 6 times daily to the affected eye for the first 72 hours depending upon the severity of the condition. Continue treatment for 48 hours after the eye appears normal.

(2) Indications for use. Treatment of bacterial conjunctivitis and ocular inflammation caused by organisms susceptible to chloramphenicol.

(3) Limitations. Therapy for cats should not exceed 7 days, prolonged use in cats may produce blood dyscrasia. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs or if clinical improvement is not noted within a reasonable period, discontinue use and institute appropriate therapy. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992]

§ 524.402 Chlorhexidine diacetate ointment.

(a) Specifications. The product contains 1 percent of chlorhexidine diacetate in an ointment base.

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

(c) Conditions of use. (1) The drug is used as a topical antiseptic ointment.
§ 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 1/4-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]

§ 524.450 Cuprimyxin 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 1/4-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 solution.

(a) Specifications. The drug contains 37.5 percent copper naphthenate in a suitable solvent.
(b) Sponsor. See Nos. 000856 and 017135 in §510.600(c) of this chapter.
(c) Conditions of use—(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. Remove debris and necrotic material before applying. Avoid contact around eyes. Do not use on animals that are raised for food production. Do not contaminate feed. Do not allow runoff of excess drug into hair because contact with the drug may cause some hair loss.

[40 FR 48128, July 18, 1980]

§ 524.520 Cuprimyxin cream.

(a) Specifications. The drug contains 0.5 percent cuprimyxin (6-methoxy-1-phenazinol 5, 10-dioxide, cupric complex) in an aqueous cream base.
(b) Sponsor. See No. 000004 in §510.600(c) of this chapter.
(c) Conditions of use—(1) Cuprimyxin is a broad spectrum antibacterial and antifungal cream for the topical treatment of superficial infections in horses, dogs, and cats caused by bacteria, dermatophytes (Trichophyton spp., Microsporum spp.) and yeast (Candida albicans) affecting skin, hair, and external mucosae.
(2) The cream is applied twice daily to affected areas by rubbing into lesions. Treatment should be continued for a few days after clinical recovery to avoid possible relapses.
(3) After application to cutaneous areas, a change in color from dark green to pink is due to the liberation of free myxin from its copper complex.
(4) If no response is seen within seven days, diagnosis and therapy should be reevaluated. If any adverse local reaction is observed after topical application, discontinue treatment.
(5) 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 45 FR 56799, Aug. 26, 1980]

§ 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 use.

§ 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 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.

§ 524.660b 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 of solution contains 5 milligrams of doramectin.

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

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

(d) Conditions of use—Cattle—(1) Amount. 5 milligrams per 10 kilograms (5 milligrams per 22 pounds).
   (2) Indications for use. For treatment and control of infections of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfec-
   tion with Cooperia oncophora and Dictyocaulus viviparus for 21 days, and Ostertagia ostertagia, C. punctata, and Oesophagostomum radiatum for 28 days after treatment.

(3) Limitations. Administer as a single dose. 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 524.814 Eprinomectin.

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

(b) Sponsor. See No. 000006 in §510.600(c) of this chapter.

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

(d) Conditions of use—(1) Amount. One milliliter (5 milligrams) per 10 kilograms of body weight (500 micrograms per kilogram).
§ 524.900 Famphur.

(2) Indications for use. The drug used in beef and dairy cattle for the treatment and control of adult and fourth stage larvae (L4) gastrointestinal nematodes (Haemonchus placei, Ostertagia ostertagi (including inhibited L4)), Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. surnabada, Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum, Trichuris spp. (adults); lungworms (adult and L4) (Dictyocaulus viviparus); cattle grubs (all parasitic stages) (Hypoderma lineatum, H. bovis); lice (Damalinia bovis, Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus); mange mites (Choriotes bovis, Sarcopes scabiei), and flies (Haematobia irritans). Controls H. irritans for 7 days and D. vivaparous for 21 days after treatment.

(3) Limitations. Apply topically along backbone from withers to tailhead. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 524.920 Fenthion.

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

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

(c) Sponsor. See Nos. 000061 and 060594 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 40 CFR 180.214.

(f) Conditions of use. (i) The drug is used as a pour-on formulation for the control of grubs and lice in beef and nonlactating cattle.

(ii) It is used at the rate of one-half fluid ounce per 100 pounds of body weight placed 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. 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 freshening.
of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; 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.

(c) Specifications. (1) The drug is in a liquid form containing 20 percent 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 in 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.

(d) Specifications. (1) 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.

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

(3) Special considerations. Fenthion is a cholinesterase inhibitor. Do not use this product on dogs simultaneously with or within 14 days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use with flea or tick collars.

(4) Conditions of use—(i) Amount. Four to 8 milligrams per kilogram of body weight.

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

(iii) Limitations. Apply the contents of the proper size, single-dose tube directly to one spot on the dog's skin. Frequency of repeat treatments depends upon rate of flea reinfections. Do not use more often than once every 2 weeks. Treatment at 2-week intervals is not to exceed 6 months. Do not use on puppies under 10 weeks of age. Do not use on sick, stressed, or convalescing dogs. Safe use in breeding males has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

(a) Specifications. Each milliliter of ophthalmic preparation contains 0.10
§ 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 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 dogs. 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 62 FR 40932, July 31, 1997]

§ 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).
Food and Drug Administration, HHS § 524.1005

(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.

§ 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.

§ 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. 000069 in §510.600(c) of this chapter for use of the 10 percent product as in paragraphs (c)(2)(i) through (iii) of this section.

(2) See No. 000069 for use of the 4 percent product as in paragraph (c)(2)(iv) of this section.

(c) Conditions of use—(i) 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.

(ii) 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).
§ 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 base.

(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 otitis externa caused by bacteria sensitive to gentamicin; the drug is also used or indicated for use in dogs and cats in the treatment of superficial infected lesions caused by bacteria sensitive to gentamicin.

(ii) For the treatment of acute and chronic canine otitis externa caused by bacteria sensitive to gentamicin, the drug is administered by instillation of 3 to 8 drops of solution into the ear canal twice daily for 7 to 14 days. Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced but care should be taken not to discontinue therapy prematurely. 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.

§ 524.1044b Gentamicin sulfate, betamethasone valerate otic solution.

(a) Specifications. Each cubic centimeter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone alcohol.

(b) Sponsor. See Nos. 000061 and 051259 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 otitis externa caused by bacteria sensitive to gentamicin; the drug is also used or indicated for use in dogs and cats in the treatment of superficial infected lesions caused by bacteria sensitive to gentamicin.

(ii) For the treatment of canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin, 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 with other drugs known to induce ototoxicity is not recommended. This preparation should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with this drug. The antibiotic sensitivity of the pathogenic organism should be determined prior to use of this preparation.

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

§ 524.1044c Gentamicin ophthalmic ointment.

(a) Specifications. Each gram of sterile ointment 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 on dogs and cats for topical treatment of conjunctivitis caused by susceptible bacteria.

(2) Apply approximately a ½-inch strip to the affected eye 2 to 4 times a day.

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


§ 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.

(ii) 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, crusty exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(iii) 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.

(ii) 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.
§ 524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

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

(b) Sponsor. See Nos. 000061 and 051259 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used in dogs in the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

(2) For the treatment of infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. One actuation of the sprayer delivers 0.7 milliliter of the spray. The drug should be administered with two spray actuations 2 to 4 times daily for 7 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. 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) 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) Sponsor. See 000061 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the treatment of canine otitis externa associated with yeast (Malassezia pachydermatis, formerly Pityrosporum canis) and/or bacteria susceptible to gentamicin.

(2) For 7.5 or 15 g tube, instill 4 drops of ointment twice daily into the ear canal of dogs weighing less than 30 pounds, instill 8 drops twice daily for dogs weighing 30 pounds or more. For 215 g bottle, instill 2 drops of ointment twice daily into the ear canal of dogs weighing less than 30 pounds, instill 4 drops twice daily for dogs weighing 30 pounds or more. Therapy should continue for 7 consecutive days.

(3) The external ear should be cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable solutions. Excessive hair should be clipped from the treatment area. If hypersensitivity occurs, treatment should be discontinued and alternate therapy instituted.

(4) Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

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

§ 524.1193 Ivermectin pour-on.

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

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.
(c) Related tolerances. See §556.344 of this chapter.

(d) Conditions of use—(1) Amount. One milliliter per 22 pounds of body weight.

(2) Indications for use. It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) Ostertagia ostertagi (including inhibited stage), Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia spp., Oesophagostomum radiatum, O. venulosum (adults), Strongyloides papillosus (adults), Trichuris spp. (adults), lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); cattle grubs (parasitic stages) (Hypoderma bovis, H. lineatum); lice (Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenopotes capillatus); mites (Chorioptes bovis, Sarcoptes scabiei var. bovis); horn flies (Haematobia irritans). It is also used to control infections of gastrointestinal roundworms O. ostertagi, O. radiatum, H. placei, T. axei, Cooperia punctata, and C. oncophora for 14 days after treatment.

(3) Limitations. For use on skin surface only. 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. Drug has been associated with severe adverse reactions in sensitive dogs; therefore drug is not recommended for use in animals other than cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30 of this chapter.

(2) 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, dacyrocystitis, 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.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30 of this chapter.

(2) The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10.0 milligrams of kanamycin activity (as the sulfate) per cubic centimeter 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 treating conditions such as conjunctivitis, blepharitis, dacyrocystitis, 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. 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. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]
§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) Specifications. (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by §444.30(a)(1) of this chapter.

(2) 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.

(3) 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. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is indicated for use in dogs in the following conditions associated with bacterial infections caused by organisms susceptible to one or both antibiotics: Acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcer, superficial wounds, and superficial abscesses.

(2) The ointment should be applied 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. Before application, hair in the affected area should be closely clipped and the area should be thoroughly cleansed of crusts, scales, dirt, or other detritus. When treating infections of the anal gland, the drug should be introduced into the orifice of the gland and not through any fistulous tract. If no response is evident in 7 days, diagnosis and therapy should be reevaluated.

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

§ 524.1240 Levamisole.

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

(b) Sponsor. See 000061 and 010042 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 retreatment 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 011509 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 treating moist dermatitis and hotspots 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 nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.

(a) Specifications. (1) The cream contains 23 milligrams of miconazole nitrate (equivalent to 20 milligrams of miconazole base) per gram.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter for use of miconazole nitrate spray.

(c) Conditions of use. (1) Miconazole nitrate is an antifungal agent for topical treatment of infections in dogs and cats caused by Microsporum canis, Microsporum gypseum, and Trichophyton mentagrophytes.

(2) 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.

(3) Accurate diagnosis of infecting organism is essential. Identify by microscopic examination of a mounting of infected tissue in potassium hydroxide solution or by culture on an appropriate medium.

(4) If no improvement is observed in 2 weeks, reevaluate diagnosis and therapy.

(5) Avoid contact with eyes since irritation may result.

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


§ 524.1451 Moxidectin.

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

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

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

(d) Conditions of use—(1) Amount. 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.

(2) Indications for use. Beef and nonlactating dairy cattle for treatment and control of internal and external parasites; gastrointestinal roundworms (Ostertagia ostertagi (adult and L4, including inhibited larvae), Haemonchus placei (adult), Trichostrongylus axei (adult and L4), T. colubriformis (adult), Cooperia oncophora (adult), C. punctata (adult), Bunostomum phlebotomum (adult), Oesophagostomum radiatum (adult), Nematodirus helvetianus (adult)); 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, Damalinia bovis); and horn flies (Haematobia irritans). To control infections and to protect from reinfestation with O. ostertagi for 28 days after treatment and with D. viviparus for 42 days after treatment.

(3) Limitations. Apply topically along the top of the back from the withers to the tailhead. Because a withdrawal period for milk has not been established, do not use on 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[63 FR 14036, Mar. 24, 1998]

§ 524.1465 Mupirocin ointment.

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

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

(c) Conditions of use—(1) Dogs: (i) Indications for use. Topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of Staphylococcus aureus and Staphylococcus intermedius.

(ii) Limitations. Apply twice daily. Treatment should not exceed 30 days. Because of potential hazard of nephrotoxicity due to polyethylene glycol content, care should be exercised in treating deep lesions. Safety of
§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) Specifications. Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

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

§ 524.1484b 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 neomycin 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 conditions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in dogs.

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

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.
§ 524.1484g  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) Federal law restricts this drug to use by or on order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994]

§ 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.

(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.

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

§ 524.1484i  Neomycin sulfate, hydrocortisone acetate, sterile ointment.

(a) Specifications. The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin.

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

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]
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(base, and 5 milligrams of hydrocortisone acetate in each gram of ointment.1)

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

(c) Conditions of use. (1) Amount. Apply three or four times daily into the conjunctival sac. With improvement, frequency may be reduced to two or three times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal one to three times daily.1

(2) Indications for use. For treating infections, allergic, and traumatic keratitis, conjunctivitis, acute otitis externa, and to a lesser degree, chronic otitis externa in dogs and cats.1

(3) Limitations. 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 infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia. Federal law restricts this drug to use by or on the order of a licensed veterinarian.1

§ 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 water-soluble base.

(b) Sponsor. For use on dogs, cats, or horses, see Nos. 000010, 000857, 000864, 000069, 050749, 023851, and 051259 in § 510.600(c) of this chapter. For use on dogs and horses, see No. 017135 in § 510.600(c) of this chapter. For use on horses, see No. 017153 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or 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 veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.1

§ 524.1580c Nitrofurazone soluble powder.

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

(b) Sponsor. See Nos. 000010, 000069, and 050749 in § 514.600(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.1

(3) Limitations. 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


§ 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. 051259 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).1

[49 FR 9417, Mar. 13, 1984]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide 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) Sponsor. See Nos. 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter.

(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.1

(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.1

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.1

(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.1

(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.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.

2These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may
(3) Limitations. For mild inflammations, use once daily to once a week. For severe conditions, apply initially two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not for ophthalmic use. 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]

§ 524.1662a Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

(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. 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

§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]
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) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline-sensitive organisms. These infections include the following: Ocular infections due to streptococci, staphylococci, Escherichia coli, and Actinobacillus 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.

(2) It is administered topically to the eye two to four times daily.

(3) Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

§ 524.1742 N-(Mercaptomethyl) phthalimide S-(O,0-dimethyl phosphorodithioate) emulsifiable liquid.

(a) Specifications. The emulsifiable liquid contains 11.6 percent N-(mercaptomethyl) phthalimide S-(O,0-dimethyl phosphorodithioate).

(b) Sponsor. See No. 000061 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>Condition</th>
<th>Dilution rate (gal. drug: gal. of water)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grubs</td>
<td>1:60</td>
</tr>
<tr>
<td>Pour-on</td>
<td>1:2</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 ¼ to ½ 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. Do not 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 when 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 190.261.

§524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.

(a) Specifications. Prednisolone-neomycin sulfate ophthalmic ointment contains 2 milligrams prednisolone and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants. A small quantity of the ointment should be expressed into the conjunctival sac four times a day for 7 days. After 7 days, if clinical improvement is not noted, re-evaluation of the diagnosis should be considered. 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
§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

(a) Specifications. Prednisolone acetate ophthalmic and topical dosage forms contain 0.1 percent prednisolone acetate by weight in each milliliter of sterile solution.

(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) 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]

§ 524.1982 Proparacaine hydrochloride 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. 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 cauterization of corneal ulcers, removal of foreign bodies

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.
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.

§ 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) NAS/NRC status. These conditions are NAS/NRC reviewed and found effective. NADA’s for similar products for these conditions of use need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.
(c) Sponsors. See 015563, 017135, 023851, and 050604 in §510.600(c) of this chapter.

(1) Indications for use. For use on dogs as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and non-specific dermatoses.

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

(3) Limitations. Use carefully around scrotum and eyes, covering the 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.

§ 524.2104 Squalane, pyrethrins and piperonyl butoxide.

(a) Specifications. The drug contains 25 percent squalane (hexamethyltetracosane), 0.05 percent pyrethrins and 0.50 percent technical piperonyl butoxide.
(b) Sponsor. See No. 017030 in §510.600(c) of this chapter.
(c) Conditions of use. (1) The drug is used for the treatment of ear mites in dogs and cats.

(2) It is administered as follows: Cats and dogs 5-15 pounds body weight, 4 to 5 drops in each ear daily. Dogs 16-30 pounds body weight, 5 to 10 drops in each ear daily. Dogs 30 pounds body weight and over 10 to 15 drops in each ear daily. The recommended treatment is for 7 to 10 days with repeated treatment in 2 weeks if necessary.

§ 524.2130 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.
§ 524.2481

(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.


§ 524.2481 Triamcinolone acetonide cream.

(a) Specifications. Triamcinolone acetonide cream contains 0.1 percent triamcinolone acetonide in an aqueous vanishing cream base.

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

(c) Conditions of use. (1) The drug is recommended for use on dogs as an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

(2) The drug is applied by rubbing into affected areas two to four times daily for 4 to 10 days.

(3) For use only 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. 000514 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.

(c) 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.


§ 524.2640 Tylosin, neomycin eye powder.

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

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

(c) Conditions of use. (1) It is used in cattle for the treatment of pinkeye (infectious keratoconjunctivitis).

(2) It is administered by holding the eyelids open and dusting powder into both eyes. The treatment is repeated daily for up to 7 days depending on the severity of the infection. Affected animals should be protected from direct sunlight, dust, and flies. In an affected herd, all animals with or without signs of the disease should receive at least one treatment.

(3) If there is severe eye damage or if the condition persists or increases, discontinue administering the drug and consult a veterinarian.