

(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 reinfestations. 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.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 16656, Apr. 21, 1976; 42 FR 58741, Nov. 11, 1977; 45 FR 62425, Sept. 19, 1980; 50 FR 19169, May 7, 1985]

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

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

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

[44 FR 16012, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996]

§ 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

§ 524.981c

21 CFR Ch. I (4-1-04 Edition)

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 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).

(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 of 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.