§ 524.981d Fluocinolone acetonide, di-

methyl 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]

§ 524.1005 Furazolidone aerosol pow-
deter.

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

(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 per-
cent product as in paragraph (c)(2)(iv) of this section.

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

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

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

(iii) [Reserved]

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

(3) Limitations. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug 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 anti-

microbial agent. As with any corticosteroid, animals with a generalized infection should not be treated with this product without proper sup-

portive antimicrobial therapy. Prepara-
rations with dimethyl sulfoxide should not be used in pregnant ani-
mals. For use by or on the order of a li-
censed veterinarian.
Food and Drug Administration, HHS

§ 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 ophthalmic ointment.
(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 canine 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.

§ 524.1044d Gentamicin sulfate, betamethasone valerate 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.

§ 524.1044c 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.