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

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

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

(iii) [Reserved]

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

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

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

§ 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.

[41 FR 14189, Apr. 2, 1976, as amended at 52 FR 7832, Mar. 13, 1987]

§ 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.

(2)(i) 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.

(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 with this