Food and Drug Administration, HHS

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

[43 FR 40456, Sept. 12, 1978]

§524.1484j [Reserved]

§ 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.

- (a) Specifications. Each milliliter of suspension contains 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base), 2 milligrams prednisolone, 5 milligrams tetracaine, and 0.25 milliliter squalane.
- (b) Sponsor. See 017030 in 510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. 2 to 3 applications daily or as needed.
- (2) Indications for use. Indicated for use in dogs and cats for treating acute otitis externa and as adjunctive therapy in management of chronic otitis externa. The product may also be used for treating moist dermatitis in dogs.
- (3) Limitations. Tetracaine and neomycin have the potential to sensitize. If signs of irritation or sensitivity develop, discontinue use. Prolonged use of this product may result in overgrowth of nonsusceptible organisms. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 5265, Feb. 4, 1983; 48 FR 8055, Feb. 25, 1983]

§ 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) Sponsors. See sponsors in §510.600(c) of this chapter.
- (1) See Nos. 000010, 000069, 050749, 054925, 058005, and 061623 for use on dogs, cats, or horses.
- (2) See No. 017135 for use on dogs and horses.
- (3) See Nos. 017153 and 058829 for use on horses.
 - (c) [Reserved]
- (d) Conditions of use—(1) Amount. Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain on the lesion for at least 24 hours. Use of a bandage is optional.
- (2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.
- (3) Limitations. For use only on dogs, cats, and horses. Do not use in horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[46 FR 43402, June 27, 1980]

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

§ 524.1580c Nitrofurazone soluble powder.

- (a) Specifications. The drug contains 0.2 percent nitrofurazone in a water-soluble base.
- (b) *Sponsor*. See Nos. 000010, 000069, and 050749 in §510.600(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 veterinarian.