

require from a few days to several weeks.¹

(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.¹

(4) For use only by or on the order of a licensed veterinarian.¹

[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 longterm 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 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.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 524.2098 Selamectin.

(a) *Specifications.* Each milliliter contains 60 or 120 milligrams of selamectin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 2.7 milligrams of selamectin, topically, per pound (6 milligrams per kilogram) of body weight.

(2) *Indications for use.* Kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and control of tick (*Dermacentor variabilis*) infestations in dogs. Treatment and control of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. For dogs and cats 6 weeks of age and older.

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

[64 FR 37401, July 12, 1999, as amended at 64 FR 48707, Sept. 8, 1999; 65 FR 45282, July 21, 2000]

§ 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)).

§ 524.2350

(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 000061, 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 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.

[47 FR 53351, Nov. 26, 1982, as amended at 48 FR 32762, July 19, 1983; 54 FR 36962, Sept. 6, 1989; 56 FR 9623, Mar. 7, 1991; 58 FR 41025, Aug. 2, 1993; 63 FR 26981, May 15, 1998]

§ 524.2350 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.

(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.

[43 FR 29289, July 7, 1978, as amended at 52 FR 7833, Mar. 13, 1987]

21 CFR Ch. I (4-1-03 Edition)

§ 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. 051259 and 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.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985; 65 FR 16817, Mar. 30, 2000]

§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 067292 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1) *Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

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

[68 FR 4916, Jan. 31, 2003]

§ 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. 062794 in § 510.600(c) of this chapter.

(b)(1) *Specifications.* The drug is a liquid for direct application or an aerosol