

**§ 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

preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 56307, Dec. 28, 1976; 50 FR 9800, Mar. 12, 1985; 54 FR 25565, June 16, 1989; 56 FR 37474, Aug. 7, 1991; 66 FR 46369, Sept. 5, 2001]

#### PART 526—INTRAMAMMARY DOSAGE FORMS

Sec.			
526.88	Amoxicillin trihydrate	for	
	intramammary infusion.		
526.363	Cephapirin benzathine.		
526.365	Cephapirin sodium	for	
	intramammary infusion.		
526.464	Cloxacillin intramammary	dosage	
	forms.		
526.464a	Cloxacillin benzathine	for	
	intramammary infusion.		
526.464b	Cloxacillin benzathine	for	
	intramammary infusion, sterile.		
526.464c	Cloxacillin sodium	for	
	intramammary infusion, sterile.		
526.464d	Cloxacillin sodium	for	
	intramammary infusion.		
526.820	Erythromycin.		
526.1130	Hetacillin potassium	for	
	intramammary infusion.		
526.1590	Novobiocin oil suspension.		
526.1696	Penicillin intramammary	dosage	
	forms.		
526.1696a	Penicillin G procaine in oil.		
526.1696b	Penicillin G procaine-dihydro-		
	streptomycin in soybean oil for		
	intramammary infusion (dry cows).		
526.1696c	Penicillin G procaine-dihydro-		
	streptomycin sulfate for intramammary		
	infusion (dry cows).		
526.1696d	Penicillin G procaine-novobiocin		
	for intramammary infusion.		
526.1810	Pirlimycin hydrochloride.		

AUTHORITY: 21 U.S.C. 360b.

#### § 526.88 Amoxicillin trihydrate for intramammary infusion.

(a) *Specifications*. Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use—Lactating cows—*  
(1) *Amount*. One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

(2) *Indications for use*. For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Staphylococcus aureus* (penicillin sensitive).

(3) *Limitations*. Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

#### § 526.363 Cephapirin benzathine.

(a) *Specifications*. Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.115 of this chapter.

(d) *Conditions of use—*(1) *Amount*. Infuse contents of one syringe into each infected quarter.

(2) *Indications for use*. Use in dry cows for treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*.

(3) *Limitations*. Infuse each infected quarter following last milking or early in the dry period, but no later than 30 days before calving. Milk from treated cows must not be use for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. For use in dry cows only.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988]