§ 524.2338 Terbinafine and betamethasone acetate.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) terbinafine and 1 mg betamethasone acetate.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).

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

[89 FR 42360, May 15, 2024]

§ 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate in an anhydrous cream base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a small amount of the cream to the affected areas once or twice a day for 2 to 4 weeks.

(2) *Indications for use.* For the treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypseum.*

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

[79 FR 10972, Feb. 27, 2014]

§ 524.2482 Triamcinolone spray.

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

(b) *Sponsor.* See No. 051311 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, as amended at 78 FR 17868, Mar. 25, 2013]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a) *Specifications.* (1) Each gram of liquid or aerosol contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Each gram of liquid or aerosol contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) in this section:

(1) No. 069043 for use of product described in paragraph (a)(1).

(2) No. 017135 for use of product described in paragraph (a)(2).

(c) *Conditions of use*—(1) *Amount.* Apply directly to the wound site.

(2) *Indications for use.* As an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate, and organic debris.

[79 FR 10973, Feb. 27, 2014, as amended at 88 FR 14901, Mar. 10, 2023]

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

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

§ 526.88 Amoxicillin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains

amoxicillin trihydrate equivalent to 62.5 milligrams (mg) amoxicillin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

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

(d) *Conditions of use in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (equivalent to 62.5 mg amoxicillin) into each infected quarter every 12 hours for a maximum of 3 doses.

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

(3) *Limitations*. Milk taken from animals during treatment and for 60 hours (5 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered 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; 68 FR 44878, July 31, 2003; 86 FR 13185, Mar. 8, 2021]

§ 526.313 Ceftiofur.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains:

(1) 125 milligrams (mg) ceftiofur equivalents as the hydrochloride salt; or

(2) 500 mg ceftiofur equivalents as the hydrochloride salt.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (125 mg ceftiofur equivalents) into each affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli;* and the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *S. dysgalactiae*.

(3) *Limitations*. Milk taken from cows during treatment (a maximum of 8 daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Federal law prohibits extralabel use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*—(1) *Amount*. Infuse the contents of one syringe (500 mg ceftiofur equivalents) into each affected quarter at the time of dry off.

(2) *Indications for use*. For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. No preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Federal law prohibits extralabel use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005. Redesignated and amended at 71 FR 39545, July 13, 2006; 79 FR 10973, Feb. 27, 2013; 79 FR 18159, Apr. 1, 2014; 80 FR 34279, June 16, 2015; 86 FR 13185, Mar. 8, 2021]