

§ 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 gypsum* 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]

§ 524.2481 Triamcinolone cream.

(a) *Specifications.* The vanishing cream contains 0.1 percent triamcinolone acetonide.

(b) *Sponsor.* See Nos. 053501 and 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Rub into affected areas two to four times daily for 4 to 10 days.

(2) *Indications for use.* As an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

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

[71 FR 13542, Mar. 16, 2006]

§ 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.
526.314	Ceftiofur.		
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.

§ 526.88

21 CFR Ch. I (4-1-06 Edition)

- 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-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).
- 526.1696c Penicillin G procaine-dihydrostreptomycin 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. 000061 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; 68 FR 44878, July 31, 2003]

§ 526.314 Ceftiofur.

(a) *Specifications—*(1) Each 10-milliliter (mL) syringe contains ceftiofur hydrochloride suspension equivalent to 125 milligrams (mg) ceftiofur.

(2) Each 10-mL syringe contains ceftiofur hydrochloride suspension equivalent to 500 mg ceftiofur.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

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

(d) *Conditions of use in cattle—*(1) *Lactating cows—*(i) *Amount.* 125 mg per affected quarter using product described in paragraph (a)(1) of this section. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use.* For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.

(iii) *Limitations.* Milk taken from cows during treatment (a maximum of eight 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, no preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dry cows—*(i) *Amount.* 500 mg per affected quarter at the time of dry off using product described in paragraph (a)(2) of this section.

(ii) *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*.

(iii) *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 3-day preslaughter withdrawal period is required for treated cows. Following label use, 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.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005]

§ 526.363 Cephapirin benzathine.

(a) *Specifications.* Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as

Food and Drug Administration, HHS

§ 526.464b

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 used 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]

§ 526.365 Cephapirin sodium for intramammary infusion.

(a) *Specifications.* Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity 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) The drug is used for the treatment of lactating cows having bovine mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*.

(2) Administer one dose into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours. If improvement is not noted within 48 hours after treatment, consult your veterinarian.

(3) Milk that has been taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988. Redesignated at 63 FR 8349, Feb. 19, 1998; 65 FR 20733, Apr. 18, 2000]

§ 526.464 Cloxacillin intramammary dosage forms.

§ 526.464a Cloxacillin benzathine for intramammary infusion.

(a) *Specifications.* Each dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer aseptically into each infected quarter immediately after last milking or early in dry period.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Animals infused with this product must not be slaughtered for food use for 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter for use in dairy cows.

(1) *Amount.* Administer one dose in each quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in non-lactating cows due to *S. agalactiae* and *S. aureus*.

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

§ 526.464b Cloxacillin benzathine for intramammary infusion, sterile.

(a) *Specifications.* Each 6 milliliter dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

§ 526.464c

(b) *Related tolerances.* See § 556.165 of this chapter.

(c) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(1) *Amount.* 6 milliliters per infected quarter aseptically immediately after last milking at the time of drying-off of the cow.

(2) *Indications for use.* Treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* in dairy cows at the time of drying-off of the cow.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for human food. Animals infused with this product must not be slaughtered for food from the time of infusion until 72 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

(1) *Amount.* One dose per infected quarter immediately after last milking.

(2) *Indications for use.* Treatment and prophylaxis of bovine mastitis in non-lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*.

(3) *Limitations.* For use in dry cows only. Not to be used within 4 weeks (28 days) of calving. Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.464c Cloxacillin sodium for intramammary infusion, sterile.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent to 20.0 milligrams of cloxacillin.

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

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use. Lactating cows—*
(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

21 CFR Ch. I (4–1–06 Edition)

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (four milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

§ 526.464d Cloxacillin sodium for intramammary infusion.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent 20.0 milligrams of cloxacillin.

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

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions for use. Lactating cows—*
(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

§ 526.820 Erythromycin.

(a) *Specifications.* (1) Each 6-milliliter, single-dose, disposable syringe contains 300 milligrams of erythromycin

(as the base), 0.45 milligram of butylated hydroxyanisole, and 0.45 milligram of butylated hydroxytoluene.

(2) Each 12-milliliter, single-dose, disposable syringe contains 600 milligrams of erythromycin (as the base), 0.90 milligram of butylated hydroxyanisole, and 0.90 milligram of butylated hydroxytoluene.

(3) The vehicle is triglyceride of saturated fatty acids from coconut oil.

(4) The drug may or may not be sterile.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. (i) Lactating cows: After milking, cleaning, and disinfecting, infuse contents of a single 6-milliliter syringe into each infected quarter; repeat procedure at 12-hour intervals for a maximum of 3 consecutive infusions.

(ii) Dry cows: After milking, cleaning, and disinfecting, infuse contents of a single 12-milliliter syringe into each infected quarter at the time of drying off.

(2) *Indications for use*. Treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating or dry cows.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

[47 FR 15772, Apr. 13, 1982, as amended at 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 526.1130 Hetacillin potassium for intramammary infusion.

(a) *Specifications*. Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.

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

(c) *Conditions of use*. *Lactating cows*—(1) *Amount*. 10 milliliters of hetacillin potassium equivalent to 62.5 milligrams ampicillin into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

(2) *Indications for use*. Treating acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*,

Streptococcus dysgalactiae, *Staphylococcus aureus*, and *Escherichia coli*.

(3) *Limitations*. If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992]

§ 526.1590 Novobiocin oil suspension.

(a)(1) *Specifications*. Each 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount*. Ten milliliters (equivalent to 400 milligrams of novobiocin) infused in each quarter.

(ii) *Indications for use*. It is used in dry cows for the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food use for 30 days following udder infusion. For udder installation for the treatment of mastitis in dry cows only.

(b)(1) *Specifications*. Each 10 milliliters of oil suspension contains the equivalent of 150 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.460 of this chapter.

(4) *Conditions of use*—(i) *Amount*. Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.

(ii) *Indications for use*. Use in lactating cows for treatment of mastitis

caused by susceptible strains of *Staphylococcus aureus*.

(iii) *Limitations*. Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 10554, Mar. 14, 1978]

§ 526.1696 Penicillin intramammary dosage forms.

§ 526.1696a Penicillin G procaine in oil.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 100,000 units of penicillin G in peanut, sesame, or soybean oils.

(b) *Related tolerances*. See § 556.510 of this chapter.

(c) *Sponsor*. See No. 010515 in § 510.600(c) of this chapter.

(1) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions specified in paragraph (c)(2)(i)(B) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Conditions of use*. Treating bovine mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberis* in lactating cows as follows:

(i) *Three-dose regimen*. Administer by intramammary infusion in each infected quarter as follows:

(A) *6-milliliter dose (peanut oil)*. Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 84 hours (7 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after the latest treatment.

(B) *10-milliliter dose (sesame oil)*. Treatment may be repeated at 12-hour intervals. Milk that has been taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(ii) *Two-dose regimen. 10-milliliter dose (peanut oil)*. Administer by intramammary infusion in each infected quarter. Treatment may be repeated at intervals of 12 hours. Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 4 days after latest treatment.

(d) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(1) *10-milliliter dose (peanut oil)*. Administer by intramammary infusion in each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) *Indications for use*. Treating bovine mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberis* in lactating cows as follows:

(3) *Limitations*. Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) *Sponsor*. See No. 010515 (sesame oil) and No. 050604 (peanut oil) in § 510.600(c) of this chapter.

(1) *NAS/NRC status*. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Single-dose regimen*. One 10-milliliter dose (sesame oil or peanut oil) in each infected quarter at time of drying-off.

(3) *Indications of use*. Treating bovine mastitis caused by *Streptococcus agalactiae* in dry cows.

(4) *Limitations*. Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable

quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[57 FR 37335, Aug. 18, 1992, as amended at 58 FR 500, Jan. 6, 1993]

§ 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows—(1) Amount.* One syringe into each quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae*.

(3) *Limitations.* Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992]

§ 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

(a) *Specifications.* Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.

(b) *Sponsor.* See No. 033392 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use. Dairy cows—(1) Amount.* One syringe per quarter at the last milking prior to drying off.

(2) *Indications for use.* Intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations.* Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) *Specifications.* For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Lactating cows—(i) Amount.* 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use.* Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations.* For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) *Dry cows—(i) Amount.* 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use.* Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations.* For udder instillation in dry cows only. Do not use less

§526.1810

than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§526.1810 Pirlimycin hydrochloride.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams of pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor.* See 000009 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.515 of this chapter.

(d) *Conditions of use.* (1) *Dose.* 50 milligrams in each infected quarter, repeated once after 24 hours.

(2) *Indications for use.* For lactating dairy cattle for the treatment of clinical and subclinical mastitis caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 9 days following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.

529.50 Amikacin sulfate intrauterine solution.

529.400 Chlorhexidine tablets and suspension.

529.469 Competitive exclusion culture.

529.1003 Flurogestone acetate-impregnated vaginal sponge.

529.1030 Formalin.

529.1044 Gentamicin sulfate in certain other dosage forms.

529.1044a Gentamicin sulfate intrauterine solution.

529.1044b Gentamicin sulfate solution.

529.1115 Halothane.

21 CFR Ch. I (4-1-06 Edition)

529.1186 Isoflurane.

529.1660 Oxytetracycline.

529.1940 Progesterone intravaginal inserts.

529.2150 Sevoflurane.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

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

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in §510.600(c) of this chapter for uses as in paragraph (d) of this section.

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

(d) *Conditions of use—(1) Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations.* Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

§529.50 Amikacin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 and 059130 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law