

(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.