

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.

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