

§ 520.1696b

21 CFR Ch. I (4–1–02 Edition)

(i) *Indications for use.* Prevention of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) *Limitations.* As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

[57 FR 37326, Aug. 18, 1992]

§ 520.1696b Penicillin G potassium in drinking water.

(a) *Specifications.* When reconstituted, each milliliter contains penicillin G potassium equivalent to 20,000, 25,000, 40,000, 50,000, 80,000, or 100,000 units of penicillin G.

(b) *Sponsors.* See Nos. 046573, 053501, and 061133 in § 510.600(c) of this chapter.

(c) *Conditions of use. Turkeys—(1) Amount.* 1,500,000 units per gallon drinking water for 5 days.

(2) *Indications for use.* Treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

(3) *Limitations.* Prepare concentrated stock solution for use with medication proportioners fresh every 24 hours. Prepare recommended use levels for gravity flow watering system fresh every 12 hours. For best results, treatment should be started at the first sign of infection. Discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption.

[57 FR 37326, Aug. 18, 1992, as amended at 59 FR 42493, Aug. 18, 1994; 60 FR 26359, May 17, 1995; 62 FR 55160, Oct. 23, 1997; 65 FR 10705, Feb. 29, 2000; 66 FR 14073, Mar. 9, 2001]

§ 520.1696c Penicillin V potassium for oral solution.

(a) *Specifications.* When reconstituted, each milliliter contains 25 milligrams (40,000 units) of penicillin V.

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

(c) *National Academy of Sciences/National Research Council (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.

(d) *Conditions of use. Dogs and cats—(1) Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin, and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.1696d Penicillin V potassium tablets.

(a) *Specifications.* Each tablet contains penicillin V potassium equivalent to 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V.

(b) *Sponsors.* See Nos. 017144, 050604, and 053501 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* These 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.

(d) *Conditions of use. Dogs and Cats—(1) Amount.* 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(2) *Indications for use.* Treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to penicillin V potassium.

(3) *Limitations.* Administer orally 1 to 2 hours prior to feeding for maximum absorption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 58775, Nov. 15, 1994]

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams, or 1

gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) *Sponsor*. See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 000061 for use of 100- or 400-milligram or 1-gram tablets, or 2- or 4-gram boluses, in dogs and horses.

(2) Nos. 000010 and 059130 for use of 100- or 200- milligrams or 1-gram tablets in dogs and horses.

(3) Nos. 000031, 000856, 000864, 058829 and 061133 for use of 100-milligram or 1-gram tablets in dogs and horses.

(4) No. 055246 for use of 100-milligram tablets in dogs.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Twenty milligrams per pound of body weight daily.¹

(ii) *Indications for use*. The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.¹

(iii) *Limitations*. Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(2) *Horses*—(i) *Amount*. One to two grams per 500 pounds weight daily.¹

(ii) *Indications for use*. This drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.¹

(iii) *Limitations*. Do not exceed a daily dosage of 4 grams per day. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Not for use in animals intended for food purposes. Federal law restricts this drug to use

by or on the order of a licensed veterinarian.¹

[42 FR 44227, Sept. 2, 1977, as amended at 45 FR 10333, Feb. 15, 1980; 45 FR 14023, Mar. 4, 1980; 46 FR 48642, Oct. 2, 1981; 47 FR 30968, July 16, 1982; 50 FR 49372, Dec. 2, 1985; 52 FR 36023, Sept. 25, 1987; 54 FR 22885, May 30, 1989; 55 FR 8462, Mar. 8, 1990; 59 FR 53585, Oct. 25, 1994; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 63 FR 36178, July 2, 1998; 66 FR 14073, Mar. 9, 2001; 66 FR 14316, Mar. 12, 2001; 66 FR 15349, Mar. 19, 2001]

§ 520.1720b Phenylbutazone granules.

(a) *Specifications*. The drug is in granular form. It is packaged to contain either 8 grams of phenylbutazone per package or 1 gram of phenylbutazone per package.

(b) *Sponsor*. See 000061 in § 510.600(c) for 8-gram package, see 059320 for 1-gram package.

(c) *NAS/NRC status*. The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications*. For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

¹See footnote 1 to § 520.1660b.