

§ 520.1720

21 CFR Ch. I (4–1–03 Edition)

§ 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. 000856, 000864, 058829 and 061623 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; 67 FR 67521, Nov. 6, 2002; 68 FR 4914, Jan. 31, 2003]

§ 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.

¹ See footnote 1 to § 520.1660b.