(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 (mg), or 1 gram (g) of phenylbutazone. Each bolus contains 1, 2, or 4 gram g of phenylbutazone.

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

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

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

(3) Nos. 000856 and 061623 for use of 100-mg or 1-g tablets in dogs and horses.

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

(5) No. 000143 for use of 1-g tablets in horses.

(6) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 20 mg per pound of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

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

(2) *Horses*—(i) *Amount.* 1 to 2 g per 500 pounds of body weight daily.

(ii) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the use of this drug in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 8192, Feb. 13, 2008, as amended at 74 FR 1146, Jan. 12, 2009; 76 FR 11331, Mar. 2, 2011]

EFFECTIVE DATE NOTE: At 76 FR 17777, Mar. 31, 2011, § 520.1720a was amended by removing and reserving paragraph (b)(4), effective April 11, 2011.

§ 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