Food and Drug Administration, HHS

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) Specifications. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.

(b) Sponsor. See No. 000069 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 6.25 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) Indications for use. Treatment of skin and soft tissue infections, such as wounds, abscesses, cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing Staphylococcus aureus, nonbeta-lactamase producing S. aureus, Staphylococcus spp., Streptococcus spp., E. coli, and Pasteurella spp.

Also, treatment of urinary tract infections (cystitis) due to susceptible strains of E. coli.

(iii) Limitations. Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and reevaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cats—(i) Amount. 62.5 milligrams (1 milliliter) (50 milligrams amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

(ii) Indications for use. Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicillinase) producing S. aureus, nonbeta-lactamase Staphylococcus aureus, Staphylococcus spp., Streptococcus spp., and Escherichia coli. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

(iii) Limitations. Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

§ 520.90 Ampicillin oral dosage forms.

§ 520.90a Ampicillin capsules.

(a) Specifications. Each capsule contains 125 milligrams or 250 milligrams of ampicillin.

(b) Sponsor. See No. 00008 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times