

Food and Drug Administration, HHS

§ 520.970b

for assistance in the diagnosis, treatment, and control of parasitism.

[51 FR 41783, Nov. 19, 1986, as amended at 54 FR 20787, May 15, 1989; 66 FR 47960, Sept. 17, 2001]

§ 520.955 Florfenicol.

(a) *Specifications.* Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.283 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis* Type 2.

(3) *Limitations.* Do not slaughter within 16 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 78357, Dec. 24, 2002]

§ 520.960 Flumethasone tablets.

(a) *Specifications.* Each tablet contains 0.0625 milligram of flumethasone.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) *Dogs:* Administer orally from 0.0625 to 0.25 milligram daily in divided doses.

(ii) *Cats:* Administer orally from 0.03125 to 0.125 milligram daily in divided doses.

(2) *Indications for use.* (i) *Dogs:* It is used for musculoskeletal conditions due to inflammation of muscles or joints and accessory structures, where permanent structural changes do not exist, such as arthritis, the disc syndrome, and myositis.

(ii) *Dogs and cats:* It is used in certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations.* Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infection. Do not use in animals with tu-

berculosis, chronic nephritis, cushingoid syndrome, or where peptic ulcers occur, except for emergency therapy. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 7131, Feb. 6, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

§ 520.970 Flunixin oral dosage forms.

§ 520.970a Flunixin meglumine granules.

(a) *Specifications.* Each 10-gram packet contains flunixin meglumine equivalent to 250 milligrams of flunixin.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 0.5 milligram of flunixin per pound of body weight (one packet per 500 pounds) per day.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

(3) *Limitations.* Administer daily dose for up to 5 days by sprinkling on small amount of feed. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 36381, June 22, 1979. Redesignated at 50 FR 38114, Sept. 20, 1985, and amended at 52 FR 7832, Mar. 13, 1987]

§ 520.970b Flunixin meglumine paste.

(a) *Specifications.* Each 30-gram syringe contains flunixin meglumine equivalent to 1,500 milligrams of flunixin.

(b) *Sponsor.* No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* *Horses*—(1) *Amount.* 0.5 milligram of flunixin per pound of body weight daily.

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(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders.

(3) *Limitations.* For oral use only. Treatment should not exceed 5 consecutive days. The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 38114, Sept. 20, 1985, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.1010 Furosemide.

(a) *Specifications.* (1) Each tablet contains 12.5 or 50 milligrams (mg) furosemide.

(2) Each bolus contains 2 grams (g) furosemide.

(3) Each packet of powder contains 2 g furosemide.

(4) Each milliliter of syrup contains 10 mg furosemide.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use of dosage forms and strengths listed in paragraph (a) of this section for uses as in paragraph (d) of this section.

(1) No. 000010 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section.

(2) No. 000093 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(B) of this section.

(3) No. 057926 for tablets in paragraph (a)(1) of this section for conditions of use in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(3) of this section; for boluses in paragraph (a)(2) of this section and powder in paragraph (a)(3) of this section for conditions of use in paragraph (d)(1) of this section; and for syrup in paragraph (a)(4) of this section for conditions of use in paragraphs (d)(2)(i) and (d)(2)(ii)(A).

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

(d) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount.* 1 to 2 mg per pound (lb) body weight using powder, or one 2-g bolus per animal, per day.

(ii) *Indications for use.* For treatment of physiological parturient edema of

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the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

(2) *Dogs*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use*—(A) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(B) For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency.

(3) *Cats*—(i) *Amount.* 1 to 2 mg/lb body weight, once or twice daily.

(ii) *Indications for use.* For treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

[66 FR 47960, Sept. 17, 2001]

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications.* Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in