

per 10 pounds of body weight (approximately 2.5 to 5 milligrams per kilogram), once or twice daily, with a 6- to 8-hour interval between successive daily doses.

(2) *Indications for use.* It is used in dogs for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(3) *Limitations.* The dosage should be adjusted to the animal's response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema or, when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. If given in excessive amounts or over extended periods of time, the drug may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 11177, Mar. 17, 1978, as amended at 47 FR 15327, Apr. 9, 1982]

§ 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 rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 3 days following treatment.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997]

§ 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications.* Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 059130 in § 510.600(c) of this chapter.

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

(d) *Conditions of use—(1) Amount.* Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use.* In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations.* For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997]

§ 520.1044c Gentamicin sulfate soluble powder.

(a) *Specifications.* Each gram of gentamicin sulfate soluble powder contains gentamicin sulfate equivalent to 16.7, 66.7, or 333.3 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600(c) of this chapter.

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

(d) *Conditions of use—(1) Amount.* Colibacillosis: gentamicin sulfate equivalent to 25 milligrams of

gentamicin per gallon of drinking water for 3 consecutive days, to provide 0.5 milligram per pound of body weight per day; swine dysentery: gentamicin sulfate equivalent to 50 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 1 milligram per pound of body weight per 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 rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 10 days following treatment.

[49 FR 29778, July 24, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 48675, Dec. 24, 1987; 62 FR 29013, May 29, 1997]

§ 520.1100 Griseofulvin.

(a) *Chemical name.* 7-Chloro-2',4,6-trimethoxy-6'-methylspiro [benzofuran-2(3H), 1'-[2]-cyclohexene]-3,4'-dione.

(b) *Specifications.* Complies with U.S.P. for griseofulvin microsize.

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

(d) *Conditions of use.* (1) As a soluble powder for horses, it is administered as a drench or as a top dressing on feed. It is used for equine ringworm infection caused by *Trichophyton equinum* or *Microsporium gypseum*. Administer for not less than 10 days a daily dose as follows: Adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

(2)(i) Boluses containing 2.5 grams of griseofulvin are used in horses for treating ringworm infection caused by *Trichophyton equinum*. It is administered to adult horses at a level of one bolus per day, to yearlings at one-half to one bolus per day, and to foals at

one-half bolus per day. All three dosage levels should be administered for a period of not less than 10 days. In responsive cases, treatment should be continued until all infected areas are proven negative by appropriate culture. Not for use in horses intended for food.

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

(3) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(a) Daily (single or divided) dose:

Body weight (pounds)	Dosage (milligrams)
Up to 6	62.5
6 to 18	125
18 to 36	250
36 to 48	375
48 to 75	500

(b) *Weekly (single) dose:* If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight x body weight x number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes*, *T. rubrum*, *T. schoenleini*, *T. sulphurem*, *T. verrucosum*, *T. interdigitale*, *Epidermophyton floccosum*, *Microsporium gypseum*, *M. canis*, *M. audouini*.

(iii) *Limitations.* For satisfactory diagnosis, a microscopic tissue examination or culture is recommended prior to treatment. Treatment should be continued for 3 to 4 weeks in skin and hair infections, and up to 4 months for infections involving nails or claws. Clipping of hair, nails, and claws to help remove any remaining viable fungi is indicated. Safety for use of griseofulvin for pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989]