

**§ 520.1263c**

**21 CFR Ch. I (4-1-02 Edition)**

up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 1891, Jan. 13, 1976; 64 FR 403, Jan. 5, 1999]

**§ 520.1263c Lincomycin hydrochloride soluble powder.**

(a) *Specifications.* Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin. The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) *Sponsors.* Approval for use of 40- and 80-gram packet to Nos. 000009 and 046573 in § 510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in § 510.600(c) of this chapter. Approval for use of 40-gram packet to No. 046573 § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.360 of this chapter.

(d) *Conditions of use*—(1) It is used in drinking water for swine as follows:

(i) *Amount.* 250 milligrams per gallon.

(A) *Dosage.* 3.8 milligrams per pound of body weight per day.

(B) *Indications for use.* Treatment of swine dysentery (bloody scours).

(C) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. Not for use in swine weighing more than 250 pounds.

(ii) [Reserved]

(2) It is used in drinking water for broiler chickens as follows:

(i) *Amount.* 64 milligrams per gallon.

(A) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

(B) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

(ii) [Reserved]

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000]

**§ 520.1284 Sodium liothyronine tablets.**

(a) *Specifications.* Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

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

(c) *Conditions of use.* (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8µg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(3) 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 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

**§ 520.1288 Lufenuron tablets.**

(a) *Specifications*—(1) *Dogs.* Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron.

(2) *Cats.* Each tablet contains either 90, 135, 204.9 or 270 mg of lufenuron.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Minimum of 10 mg of lufenuron per kilogram (4.5 mg per pound (lb)) of body weight.

(2) *Indications for use*. For use in dogs and puppies, 6 weeks of age and older, for the prevention and control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

(d) *Conditions of use in cats*—(1) *Amount*. Minimum of 30 mg of lufenuron per kilogram (13.6 mg/lb) of body weight.

(2) *Indications for use*. For use in cats and kittens, 6 weeks of age and older, for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

[63 FR 52968, Oct. 2, 1998]

#### § 520.1289 Lufenuron suspension.

(a) *Specifications*. Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use*. For control of flea populations.

(3) *Limitations*. For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no effect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

[60 FR 20402, Apr. 26, 1995, as amended at 62 FR 8371, Feb. 25, 1997]

#### § 520.1310 Marbofloxacin tablets.

(a) *Specifications*. Each tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. 1.25 mg per pound (lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use*. For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[64 FR 39919, July 23, 1999, as amended at 66 FR 46369, Sept. 5, 2001]

#### § 520.1320 Mebendazole oral.

(a) *Chemical name*. Methyl 5-benzoyl-benzimidazole-2-carbamate.

(b) *Specifications*. As oral powder: Each gram contains either 40 or 166.7 milligrams of mebendazole. As oral paste: Each gram contains 200 milligrams of mebendazole. As oral suspension: Each milliliter contains 33.3 milligrams of mebendazole.

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

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 gram of mebendazole per 250 pounds of body weight per dose, as an oral powder, paste or suspension.

(ii) *Indications for use*. It is used in horses for treatment of infections caused by large roundworms (*Parascaris equorum*); large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*); small