

§ 529.1044b

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

(4) Not for use in horses intended for food.

[40 FR 13881, Mar. 27, 1975, as amended at 40 FR 48676, Oct. 17, 1975; 48 FR 31386, July 8, 1983; 52 FR 7833, Mar. 13, 1987; 58 FR 14314, Mar. 17, 1993; 59 FR 31140, June 17, 1994; 60 FR 45042, Aug. 30, 1995; 60 FR 48894, Sept. 21, 1995; 61 FR 17830, Apr. 23, 1996; 62 FR 611, Jan. 6, 1997; 62 FR 35077, June 30, 1997; 63 FR 6644, Feb. 10, 1998]

§ 529.1044b Gentamicin sulfate solution.

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

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

(c) *Conditions of use.* (1) The drug is recommended as an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

(2) The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the gentamicin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100 °F. then immediately submerging them in gentamicin solution maintained at about 40 °F., keeping the eggs submerged for 10 to 15 minutes.

(3) For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

[40 FR 13881, Mar. 27, 1975, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 22889, Apr. 28, 1997]

§ 529.1115 Halothane.

(a) *Specifications.* The drug is a colorless, odorless, nonflammable, nonexplosive, heavy liquid containing 0.01 percent thymol as a preservative.

(b) *Sponsor.* See 000856 and 012164 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Two to 5 percent of inhaled atmosphere for induction of anesthesia; 0.5 to 2 percent for maintenance of anesthesia.¹

(2) *Indications for use.* For nonfood animals for the induction and maintenance of anesthesia.¹

(3) *Limitations.* Administered by inhalation. May be administered with either oxygen or a mixture of oxygen and nitrous oxide. Place drug vaporizer between the gas supply and breathing bag to prevent overdosage. Not recommended for obstetrical anesthesia except when uterine relaxation is required. Do not use in pregnant animals; information on possible adverse effects on fetal development is not available. Operating rooms should have adequate ventilation to prevent accumulation of anesthetic gases. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[46 FR 27915, May 22, 1981, as amended at 62 FR 29014, May 29, 1997]

§ 529.1186 Isoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers. It is nonflammable and nonexplosive.

(b) *Sponsors.* See Nos. 000074, 000209, 010019, 012164, 059258, and 060307 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* For induction of surgical anesthesia: 3 to 5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(ii) *Dogs:* For induction of surgical anesthesia: 2 to 2.5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(2) *Indications for use.* For induction and maintenance of general anesthesia in horses and dogs.

¹These conditions have been reviewed by FDA and found effective. NADA's for similar products for these conditions of use need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(3) *Limitations.* Administer by inhalation; not for use in horses or dogs sensitive to halogenated agents; increasing depth of anesthesia may increase hypotension and respiratory depression; use less than usual amounts of nondepolarizing relaxants; use with vaporizers producing predictable percentage concentrations; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 594, Jan. 7, 1986, as amended at 54 FR 23472, June 1, 1989; 58 FR 17346, Apr. 2, 1993; 59 FR 44315, Aug. 29, 1994; 60 FR 40456, Aug. 9, 1995; 63 FR 8122, Feb. 18, 1998; 63 FR 24106, May 1, 1998; 66 FR 17510, Apr. 2, 2001]

§ 529.1526 Nifurpirinol capsules.

(a) *Specifications.* Each capsule contains 3.8 or 7.6 milligrams of nifurpirinol.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in treating aquarium fish for the control of columnaris disease caused by *Chondrococcus columnaris* susceptible to nifurpirinol.

(2) Use one 3.8 milligram nifurpirinol capsule for each 10 gallons of aquarium water. Empty the contents of the capsule directly into the water and stir briefly. Treat for at least 1 hour. If activated charcoal or carbon filtration is being used, disconnect during treatment, but maintain adequate aeration. Resume water filtration after 1 hour treatment. Usually a single treatment is sufficient. For aquariums with charcoal filters, nifurpirinol can be used once each 24 hours up to 3 consecutive days, discontinuing filtration during treatment. If aquarium does not have charcoal filter, do not retreat within 5 days.

(3) Do not use in salt water aquariums.

(4) Do not use while egg bearers or live bearers are reproducing.

[40 FR 60052, Dec. 31, 1975, as amended at 47 FR 20758, May 14, 1982; 56 FR 43699, Sept. 4, 1991]

§ 529.2090 Salicylic acid.

(a) *Specifications.* (1) Each dose contains 0.55 grain of salicylic acid in a gum arabic and dextrin vehicle.

(2) Each dose is incorporated upon a device (teat dilator) suitable for insertion into and subsequent removal from the teat canal.

(b) *Sponsor.* See No. 045087 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the removal of scar tissue in the teat canal of milk-producing cows.

(2) The labeling bears directions to the user to:

(i) Treat lactating cows initially by inserting dosage and removal of the device;

(ii) Insert second dose and permit device to remain in canal until the next milking; and

(iii) Insert one dose following each milking for not more than 2 days.

(3) Milk that has been drawn from animals within 48 hours of such treatment may not be used for food.

[41 FR 10984, Mar. 15, 1976, as amended at 43 FR 29290, July 7, 1978; 55 FR 29842, July 23, 1990; 55 FR 31481, Aug. 2, 1990; 62 FR 8372, Feb. 25, 1997]

§ 529.2150 Sevoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For induction of surgical anesthesia: 5 to 7 percent sevoflurane with oxygen. For maintenance of surgical anesthesia: 3.7 to 4 percent sevoflurane with oxygen in the absence of premedication and 3.3 to 3.6 percent in the presence of premedication.

(2) *Indications for use.* For induction and maintenance of general anesthesia in dogs.

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

[64 FR 71640, Dec. 22, 1999]

§ 529.2464 Ticarcillin powder.

(a) *Specifications.* Each vial contains ticarcillin disodium equivalent to 6 grams of ticarcillin to be reconstituted with 25 milliliters of sterile water for injection or sterile physiological saline.

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