

§ 529.1044

dissolved oxygen is less than 5 milligrams per liter.

[51 FR 11441, Apr. 3, 1986, as amended at 58 FR 59169, Nov. 8, 1993; 59 FR 60076, Nov. 22, 1994; 63 FR 38304, July 16, 1998; 68 FR 5563; Feb. 4, 2003; 72 FR 45158, Aug. 13, 2007]

§ 529.1044 Gentamicin sulfate in certain other dosage forms.

§ 529.1044a Gentamicin sulfate intruterine solution.

(a) *Specifications.* Each milliliter of solution contains 50 or 100 milligrams gentamicin sulfate.

(b) *Sponsors.* See Nos. 000010, 000061, 000856, 057561, 058005, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Infuse 2 to 2.5 grams per day for 3 to 5 days during estrus.

(2) *Indications for use.* For control of bacterial infections of the uterus (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 51727, Aug. 31, 2006]

§ 529.1044b Gentamicin sulfate solution.

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

(b) *Sponsors.* See Nos. 000061 and 054925 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

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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; 71 FR 13543, Mar. 16, 2006]

§ 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]

§ 529.1150 Hydrogen peroxide.

(a) *Specifications.* Each milliliter of solution contains 396.1 milligrams (mg)

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.

hydrogen peroxide (a 35% w/w solution).

(b) *Sponsor*. See No. 061088 in § 510.600(c) of this chapter.

(c) *Conditions of use in finfish*—(1) *Amount*—(i) Freshwater-reared finfish eggs: 500 to 1,000 mg per liter (L) of culture water for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs or 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all warmwater species of freshwater-reared finfish eggs.

(ii) Freshwater-reared salmonids: 100 mg/L for 30 minutes or 50 to 100 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

(iii) Coolwater species of freshwater-reared finfish fingerlings and adults (except northern pike & paddlefish) and channel catfish fingerlings and adults: 50 to 75 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath. Coolwater species of freshwater-reared finfish fry (except northern pike, pallid sturgeon & paddlefish) and channel catfish fry: 50 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath.

(2) *Indications for use*. For control of mortality in freshwater-reared finfish eggs due to saprolegniasis; for control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*; and for control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*).

(3) *Limitations*. Initial bioassay on a small number is recommended before treating the entire group. Eggs: Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider withholding treat-

ment or using an alternate therapeutant during that sensitive time to reduce egg mortalities due to drug toxicity. Finfish: Use with caution on walleye. Preharvest withdrawal time: zero days.

[72 FR 5330, Feb. 6, 2007]

§ 529.1186 Isoflurane.

(a) *Specifications*. The drug is a clear, colorless, stable liquid.

(b) *Sponsors*. See Nos. 000074, 000209, 010019, 012164, 060307, and 065085 in § 510.600(c) of this chapter.

(c) *Conditions of use*. Administer by inhalation:

(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.

(3) *Limitations*. Do not use in horses intended for human consumption. 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; 71 FR 43967, Aug. 3, 2006; 74 FR 68530, Dec. 28, 2009]

§ 529.1455 Methoxyflurane.

(a) *Specifications*. Methoxyflurane liquid.

(b) *Sponsor*. See No. 025245 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Amount*. The amount of methoxyflurane used depends on the weight of the patient, the depth of anesthesia, and the type of equipment used. Anesthesia may be induced with methoxyflurane alone, or by the intravenous administration of a short-acting general anesthetic or by inhalation of another anesthetic agent.

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