

(b) *Sponsors*. See Nos. 000074, 000209, 010019, 012164, and 059258 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.

(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]

#### § 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]

#### § 529.2150 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]

#### § 529.2090 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.

## § 529.2464

(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]

### § 529.2464 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.

(c) *Conditions of use*—(1) *Amount.* 6 grams per day, intrauterine, for 3 consecutive days during estrus.

(2) *Indications for use. Horses.* Intrauterine treatment of endometritis caused by beta-hemolytic streptococci.

(3) *Limitations.* For intrauterine use in horses only. Infuse aseptically. Not for use in horses raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

### § 529.2503 Tricaine methanesulfonate.

(a) *Chemical name.* Ethyl-*m*-amino-benzoate methanesulfonate.

(b) *Sponsor.* See Nos. 050378 and 051212 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the temporary immobilization of fish, amphibians, and other aquatic cold-blooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(2) It is used as follows:

(i) For fish the drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for

## 21 CFR Ch. I (4–1–01 Edition)

the specific lots of fish under prevailing conditions.

(ii) For amphibians and other aquatic coldblooded animals, the drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(iii) Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature should exceed 10° C. (50° F.). In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use.

[40 FR 13881, Mar. 27, 1975, as amended at 49 FR 5748, Feb. 15, 1984; 51 FR 11439, Apr. 3, 1986; 63 FR 7702, Feb. 17, 1998]

## PART 530—EXTRALABEL DRUG USE IN ANIMALS

### Subpart A—General Provisions

Sec.

- 530.1 Scope.
- 530.2 Purpose.
- 530.3 Definitions.
- 530.4 Advertising and promotion.
- 530.5 Veterinary records.

### Subpart B—Rules and Provisions for Extralabel Uses of Drugs in Animals

- 530.10 Provision permitting extralabel use of animal drugs.
- 530.11 Limitations.
- 530.12 Labeling.
- 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

### Subpart C—Specific Provisions Relating to Extralabel Use of Animal and Human Drugs in Food-Producing Animals

- 530.20 Conditions for permitted extralabel animal and human drug use in food-producing animals.
- 530.21 Prohibitions for food-producing animals.
- 530.22 Safe levels and analytical methods for food-producing animals.
- 530.23 Procedure for setting and announcing safe levels.
- 530.24 Procedure for announcing analytical methods for drug residue quantification.
- 530.25 Orders prohibiting extralabel uses for drugs in food-producing animals.