

**Food and Drug Administration, HHS**

**§ 529.400**

slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

**§ 526.1810 Pirlimycin hydrochloride.**

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams of pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor.* See 000009 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.515 of this chapter.

(d) *Conditions of use.* (1) *Dose.* 50 milligrams in each infected quarter, repeated once after 24 hours.

(2) *Indications for use.* For lactating dairy cattle for the treatment of clinical and subclinical mastitis caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 9 days following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000]

**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

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AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

**§ 529.50 Amikacin sulfate intrauterine solution.**

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 and 059130 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.

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

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988; 62 FR 15110, Mar. 31, 1997; 62 FR 23358, Apr. 30, 1997]

**§ 529.360 Cephalothin discs.**

(a) *Specifications.* Cephalothin discs have a uniform potency of 30 micrograms cephalothin per disc.

(b) *Sponsor.* See No. 000986 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The discs are used for determining the in vitro susceptibility of bacteria to cephaloridine and cephalonium.

(2) For veterinary laboratory diagnosis only.

[40 FR 13881, Mar. 27, 1975, as amended at 64 FR 404, Jan. 5, 1999]

**§ 529.400 Chlorhexidine tablets and suspension.**

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.<sup>1</sup>

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may

*Continued*

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.<sup>1</sup>

(2) *Indications for use*. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.<sup>1</sup>

(3) *Limitations*. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.<sup>1</sup>

[43 FR 10705, Feb. 23, 1979]

**§ 529.469 Competitive exclusion culture.**

(a) *Specifications*. Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.

(1) For 2,000-dose packet, add contents of one 2,000-dose packet of reconstitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.

(2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.

(b) *Sponsor*. See No. 032761 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*. *Chickens*—(1) *Amount*. Apply 25 milliliters of reconstituted culture as a topical spray on each tray of 100 chicks (0.25 milliliter per chick).

(2) *Indications for use*. For early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization.

<sup>1</sup> require bioequivalency and safety information.

(3) *Limitations*. Administer as soon as possible after hatch, preferably at less than 1 day of age. Expose chicks to light for at least 5 minutes after spray treatment to encourage preening for oral uptake of the organisms. Provide access to feed and water as soon as possible after treatment. Do not administer antibiotics to treated chickens.

[63 FR 25164, May 7, 1998]

**§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.**

(a) *Specifications*. Each vaginal sponge contains 20 milligrams of flurogestone acetate.

(b) *Sponsor*. See No. 000014 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use*. For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.

(2) *Limitations*. Using applicator provided, insert sponge into ewe's vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not had lambs. Use plastic or rubber gloves when handling large numbers of sponges to minimize exposure to drug. Do not leave sponge in the vagina for more than 21 days. Ewes must not be slaughtered for food within 30 days of sponge removal.

[49 FR 45420, Nov. 16, 1984]

**§ 529.1030 Formalin solution.**

(a) *Specifications*. Formalin solution is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

(b) *Sponsor*. Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) No. 050378 for use as in paragraphs (d)(1)(iii), (d)(1)(iv), (d)(1)(v), (d)(2)(iii), (d)(2)(iv), (d)(2)(v), and (d)(3).

(2) Nos. 049968 and 051212 for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3).

(c) [Reserved]

(d) *Conditions of use*. It is added to environmental water as follows:

(1) *Indications for use*. (i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Costia* spp., *Scyphidia* spp., *Epistylis* spp., and *Trichodina* spp., and

monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp., on salmon, trout, catfish, largemouth bass, and bluegill.

(ii) Select finfish eggs. For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

(iii) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(iv) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Costia* spp., *Scyphidia* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

(v) All finfish eggs: For control of fungi of the family Saprolegniaceae.

(2) *Amount.* The drug concentrations required are as follows:

(i) For control of external parasites on select finfish:

Fish	Concentration of formalin (microliters per liter)	
	Tanks and raceways (for up to 1 hour)	Earthen ponds (indefinitely)
Salmon and trout:		
Above 50 ° F .....	Up to 170 .....	15–25
Below 50 ° F .....	Up to 250 .....	15–25
Catfish, largemouth bass, and bluegill.	Up to 250 .....	<sup>1</sup> 15–25

<sup>1</sup> Use the lower concentrations when pond is heavily loaded with fish or phytoplankton.

(ii) For control of fungi of the Saprolegniaceae on salmon, trout, and esocid eggs: Apply in constant flow water supply of incubating facilities for 15 minutes. Concentration of formalin used is 1,000 to 2,000 microliters per liter.

(iii) For control of external protozoan parasites on shrimp:

Shrimp	Concentration of formalin (microliters per liter)	
	Tanks and raceways (up to 4 hours daily)	Earthen ponds (single treatment)
Penaeid Shrimp ...	50 to 100 <sup>1</sup> .....	25 <sup>2</sup>

<sup>1</sup>Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when the tanks and raceways are heavily loaded.

<sup>2</sup>Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(iv) For control of external parasites on all finfish:

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))	Administer in earthen ponds indefinitely (µL/L or ppm)
Salmon and trout:		
Above 50 °F	Up to 170	15 to 25 <sup>1, 2</sup>
Below 50 °F	Up to 250	15 to 25 <sup>1, 2</sup>
All other finfish	Up to 250	15 to 25 <sup>1, 2</sup>

<sup>1</sup> Use the lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

<sup>2</sup> Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

(v) For control of fungi of the family Saprolegniaceae on all finfish eggs: Eggs of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 µL/L (ppm) for 15 minutes.

(3) *Limitations.* Fish tanks and raceways may be treated daily until parasite control is achieved. Pond treatment may be repeated in 5 to 10 days if needed. However, pond treatments for *Ichthyophthirius* should be made at 2-day intervals until control is achieved. Egg tanks may be treated as often as necessary to prevent growth of fungi. Do not use formalin which has been subjected to temperatures below 40 °F, or allowed to freeze. Do not treat ponds containing striped bass. Treatments in tanks should never exceed 1 hour even if fish show no signs of stress. Do not apply formalin to ponds with water warmer than 27 °C (80 °F), when a heavy bloom of phytoplankton is present, or when the concentration of 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]

**§ 529.1044 Gentamicin sulfate in certain other dosage forms.**

**§ 529.1044a Gentamicin sulfate intraveterine solution.**

(a) *Specifications.* Each milliliter of the drug contains 50 or 100 milligrams of gentamicin (as the sulfate) in sterile aqueous solution.

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(b) *Sponsor*. See Nos. 000010, 000061, 000856, 000864, 057561, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated for use for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(2) It is administered at a dosage level of 2 to 2.5 grams per day for 3 to 5 days during estrus, each dose being diluted with 200 to 500 milliliters of sterile physiological saline before aseptic infusion into the uterus.

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

(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

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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.<sup>1</sup>

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

(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.<sup>1</sup>

[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.

<sup>1</sup>These 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.

(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

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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

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