

days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. 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; 73 FR 811, Jan. 4, 2008; 79 FR 10973, Feb. 27, 2014]

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

Sec.

528.1070 Bc6 recombinant deoxyribonucleic acid construct.

528.1092 opAFP-GHc2 recombinant deoxyribonucleic acid construct.

528.2010 Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.

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

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

§ 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use.* Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor.* See No. 086047 in § 510.600 of this chapter.

(c) *Limitations.* Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

[74 FR 6823, Feb. 11, 2009, as amended at 80 FR 34279, June 16, 2015]

§ 528.1092 opAFP-GHc2 recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of the α -form of the opAFP-GHc2 recombinant deoxyribonucleic acid (rDNA) construct at the α -locus in the EO-1 α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*).

(b) *Sponsor.* See No. 086053 in § 510.600 of this chapter.

(c) *Indications for use.* Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) *Limitations.* These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

[80 FR 73104, Nov. 24, 2015]

§ 528.2010 Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of a human lysosomal acid lipase (hLAL) recombinant deoxyribonucleic acid (rDNA) gene construct located at the SYN LAL-C site in chromosome 6 in a specific, diploid line (SBC LAL-C) of hemizygous and homozygous domestic chickens (*Gallus gallus*), derived from the lineage progenitor XLL 109.

(b) *Sponsor.* See No. 069334 in § 510.600 of this chapter.

(c) *Conditions of use—(1) Intended use.* The gene construct directs the expression of that encoding gene such that recombinant, human lysosomal acid lipase (rhLAL) protein intended for the treatment of human disease is present in SBC LAL-C chicken egg whites.

(2) *Limitations.* Food or feed from XLL 109 chickens is not permitted in the food or feed supply.

[81 FR 17608, Mar. 30, 2016]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.

529.56 Amikacin.

529.382 Chloramine-T.

529.400 Chlorhexidine tablets and suspension.

529.536 Detomidine.

529.539 Dexmedetomidine.

529.778 Doxycycline.

529.1030 Formalin.

529.1044 Gentamicin in certain other dosage forms.

529.1044a Gentamicin solution for infusion.

529.1044b Gentamicin solution for dipping eggs.

529.1115 Halothane.

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- 529.1350 Meloxicam.
- 529.1660 Oxytetracycline.
- 529.1940 Progesterone intravaginal inserts.
- 529.2150 Sevoflurane.
- 529.2464 Ticarcillin.
- 529.2503 Tricaine methanesulfonate.
- 529.2620 Triptorelin.

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

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

§ 529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Conditions of use—(1) Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 7072, Feb. 15, 2002, as amended at 79 FR 10973, Feb. 27, 2014]

§ 529.56 Amikacin.

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

(b) *Sponsors.* See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

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

(3) *Limitations.* Do not use in horses intended for human consumption. Fed-

eral law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 10973, Feb. 27, 2014]

§ 529.382 Chloramine-T.

(a) *Specifications.* Chloramine-T trihydrate powder for solution.

(b) *Sponsor.* See No. 086009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.118 of this chapter.

(d) *Conditions of use—(1) Freshwater-reared salmonids—(i) Amount.* 12 to 20 milligrams per liter (mg/L) water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.

(2) *Walleye—(i) Amount.* 10 to 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare*.

(3) *Freshwater-reared warmwater finfish—(i) Amount.* 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared warmwater finfish due to external columnaris disease associated with *F. columnare*.

[79 FR 37621, July 2, 2014]

§ 529.400 Chlorhexidine tablets and suspension.

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

¹These 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

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(b) *Sponsor.* See No. 054771 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.

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

(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.

[43 FR 10705, Feb. 23, 1979, as amended at 79 FR 10973, Feb. 27, 2014]

EDITORIAL NOTE: At 79 FR 10973, Feb. 27, 2014, § 529.400 was amended by revising the section heading, however, the section heading was not provided, therefore, the amendment could not be incorporated because of an inaccurate amendatory instruction.

§ 529.536 Detomidine.

(a) *Specifications.* Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use.* For sedation and restraint.

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

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

§ 529.539 Dexmedetomidine.

(a) *Specifications.* Each milliliter of gel contains 0.09 milligrams (mg) dexmedetomidine (equivalent to 0.1 mg dexmedetomidine hydrochloride).

require bioequivalency and safety information.

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(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer onto the oral mucosa between the dog's cheek and gum at a dose of 125 micrograms per square meter.

(2) *Indications for use.* For the treatment of noise aversion in dogs.

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

[81 FR 17608, Mar. 30, 2016]

§ 529.778 Doxycycline.

(a) *Specifications.* Doxycycline hyclate solution contains 8.5 percent doxycycline activity. A syringe of N-methyl-2-pyrrolidone and poly (DL-lactide) mixed with a syringe of doxycycline produces 0.5 milliliter of solution.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply subgingivally to periodontal pocket(s) of affected teeth.

(2) *Indications for use.* For treatment and control of periodontal disease.

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

[79 FR 10973, Feb. 27, 2014]

§ 529.1030 Formalin.

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

(b) *Sponsors.* See Nos. 049968, 050378, and 067188 in § 510.600(c) of this chapter.

(c) [Reserved]

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

(1) *Indications for use.* (i) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(ii) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

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

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

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(i) 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 ¹	25 ²

¹ 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.

² Single treatment. Treatment may be repeated in 5 to 10 days if needed.

(ii) For control of external parasites on 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 ^{1 2}
Below 50 °F	Up to 250	15 to 25 ^{1 2}
All other finfish	Up to 250	15 to 25 ^{1 2}

¹ 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.

² 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.

(iii) For control of fungi of the family Saprolegniaceae on 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; 68 FR 5563; Feb. 4, 2003; 72 FR 45158, Aug. 13, 2007; 76 FR 17339, Mar. 29, 2011; 79 FR 2786, Jan. 16, 2014]

§ 529.1044 Gentamicin in certain other dosage forms.

§ 529.1044a Gentamicin solution for infusion.

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

(b) *Sponsors.* See Nos. 000061, 000859, 054628, 054771, 057561, 058005, 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, as amended at 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 10973, Feb. 27, 2014]

§ 529.1044b Gentamicin solution for dipping eggs.

(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 in turkeys—(1) Amount.* 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

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100 °F then immediately submerging them in gentamicin solution maintained at about 40 °F, keeping the eggs submerged for 10 to 15 minutes.

(2) *Indications for use.* As an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (*paracolon*), *Salmonella* Saintpaul, and *Mycoplasma meleagridis*.

(3) *Limitations.* 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; 79 FR 10973, Feb. 27, 2014]

§ 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 Nos. 012164 and 054771 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.

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

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 27915, May 22, 1981, as amended at 62 FR 29014, May 29, 1997; 79 FR 10973, Feb. 27, 2014]

§ 529.1150 Hydrogen peroxide.

(a) *Specifications.* Each milliliter of solution contains 396.1 milligrams (mg) hydrogen peroxide (a 35% w/w solution).

(b) *Sponsor.* See No. 050378 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 treatment or using an alternate therapeutic 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, as amended at 78 FR 73698, Dec. 9, 2013]

§ 529.1186 Isoflurane.

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

(b) *Sponsors.* See Nos. 010019, 012164, 054771, 065085, and 066794 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; 76 FR 16533, Mar. 24, 2011; 78 FR 14669, Mar. 7, 2013; 78 FR 17868, Mar. 25, 2013; 80 FR 18776, Apr. 8, 2015]

§ 529.1350 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.1 mg per kilogram of body weight once daily using the metered dose pump.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis in dogs.

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

[77 FR 76863, Dec. 31, 2012, as amended at 80 FR 18776, Apr. 8, 2015]

§ 529.1660 Oxytetracycline.

(a) *Specifications*—(1) Each gram of powder contains 366 milligrams (mg) oxytetracycline hydrochloride.

(2) Each gram of powder contains 753 mg oxytetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of

this section as in paragraph (d) of this section.

(1) Nos. 054771 and 061623 for use of product in paragraph (a)(1) of this section.

(2) Nos. 048164, 054771, and 061623 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in finfish*—(1) *Amount.* Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.

(2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.

[69 FR 6557, Feb. 11, 2004, as amended at 69 FR 61999, Oct. 22, 2004; 70 FR 41140, July 18, 2005; 72 FR 26289, May 9, 2007; 76 FR 17026, Mar. 28, 2011; 79 FR 10973, Feb. 27, 2014]

§ 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains:

(1) 1.38 grams (g) progesterone in molded silicone over a nylon spine.

(2) 0.3 g progesterone in molded silicone over a flexible nylon spine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and the product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.540 of this chapter.

(d) *Special considerations.* Product labeling shall bear the following warning: “Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations.”

(e) *Conditions of use*—(1) *Cows*—(i) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 mg dinoprost as a single intramuscular injection 1 day prior to insert removal (Day 6). When used for indications listed in paragraph (e)(1)(ii)(B) of this section, administer 25 mg dinoprost as a single

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intramuscular injection on the day of insert removal (Day 7).

(ii) *Indications for use*—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers; for advancement of first postpartum estrus in suckled beef cows; and for advancement of first pubertal estrus in replacement beef heifers.

(B) For synchronization of estrus in lactating dairy cows.

(C) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

(D) For induction of estrous cycles in anestrus lactating dairy cows.

(iii) *Limitations*. Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in beef cows that are fewer than 20 days postpartum. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, provided by No. 054771 in § 510.600(c) of this chapter.

(2) *Ewes*—(i) *Amount*. Administer one intravaginal insert per animal for 5 days.

(ii) *Indications for use*. For induction of estrus in ewes (sheep) during seasonal anestrus.

(iii) *Limitations*. Do not use in animals with abnormal, immature, or infected genital tracts; or in ewes that have never lambed. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use.

[74 FR 59074, Nov. 17, 2009, as amended at 75 FR 63085, Oct. 14, 2010; 79 FR 10965, 10974, Feb. 27, 2014; 79 FR 44278, July 31, 2014]

§ 529.2150 Sevoflurane.

(a) *Specifications*. Sevoflurane liquid.

(b) *Sponsors*. See Nos. 012164, 054771, and 066794 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. For induction of surgical anesthesia: up to 7 percent sevoflurane. 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, as amended at 73 FR 25508, May 7, 2008; 74 FR 10484, Mar. 11, 2009, 75 FR 1021, Jan. 8, 2010; 76 FR 16533, Mar. 24, 2011; 78 FR 17868, Mar. 25, 2013; 80 FR 18776, Apr. 8, 2015]

§ 529.2464 Ticarcillin.

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

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 6 grams daily by intrauterine infusion for 3 consecutive days during estrus.

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

(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.

[79 FR 10974, Feb. 27, 2014]

§ 529.2503 Tricaine methanesulfonate.

(a) *Specifications*. The drug is ethyl-*m*-amino-benzoate methanesulfonate.

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

(c) *Conditions of use*—(1) *Amount*. It is used as follows:

(i) *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 the specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic cold-blooded 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.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* 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 exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

[79 FR 10974, Feb. 27, 2014]

§ 529.2620 Triptorelin.

(a) *Specifications.* Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) *Sponsor.* See No. 051233 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) *Indications for use.* For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) *Limitations.* Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

[77 FR 64717, Oct. 23, 2012]

PART 530—EXTRALABEL DRUG USE IN ANIMALS

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AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

SOURCE: 61 FR 57743, Nov. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 530.1 Scope.

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.