§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) Specifications. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) Sponsor. See No. 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.

(iii) Limitations. Forudder instillation in lactating cattle only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

(2) Dry cows—(i) Amount. 10 milliliters in each quarter at time of drying off.

(ii) Indications for use. Treatment of subclinical mastitis caused by susceptible strains of Staphylococcus aureus and Streptococcus agalactiae.

(iii) Limitations. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

§ 526.1810 Pirlimycin hydrochloride aqueous gel.

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

(b) Sponsor. See No. 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 (three milkings) following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 28 days following the last treatment. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 526.50 Amikacin sulfate intrauterine solution.

§ 529.360 Cephalothin discs.

§ 529.400 Chlorhexidine tablets and suspension.

§ 529.469 Competitive exclusion culture.

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS
§ 529.469 Competitive exclusion culture.

(a) Specifications. Each packet of lyophilized culture contains 200 or 500 doses in frozen pellets to be reconstituted for use.


(2) For 500-dose packet, add contents of one 500-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 500-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]

1 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 require bioequivalency and safety information.
§ 529.1003  Flurogestone acetate-imregnated 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 5420, 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)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), 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.
(2) Amount. The drug concentrations required are as follows:

<table>
<thead>
<tr>
<th>Fish</th>
<th>Concentration of formalin (microliters per liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tanks and raceways (for up to 1 hour)</td>
</tr>
<tr>
<td>Salmon and trout:</td>
<td>Up to 170</td>
</tr>
<tr>
<td>Above 50 °F</td>
<td>Up to 250</td>
</tr>
<tr>
<td>Below 50 °F</td>
<td>Up to 250</td>
</tr>
<tr>
<td>Catfish, largemouth bass, and bluegill</td>
<td>Up to 250</td>
</tr>
</tbody>
</table>

* 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)

<table>
<thead>
<tr>
<th>Tanks and raceways (up to 4 hours daily)</th>
<th>Earthen ponds (single treatment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penaeid Shrimp ...</td>
<td>50 to 100</td>
</tr>
<tr>
<td></td>
<td>25</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Aquatic species</th>
<th>administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))</th>
<th>administer in earthen ponds indefinitely (µL/L or ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmon and trout:</td>
<td>Up to 170</td>
<td>15 to 25</td>
</tr>
<tr>
<td>Above 50 if</td>
<td>Up to 250</td>
<td>15 to 25</td>
</tr>
<tr>
<td>Below 50 if</td>
<td>Up to 250</td>
<td>15 to 25</td>
</tr>
<tr>
<td>All other finfish</td>
<td>Up to 250</td>
<td>15 to 25</td>
</tr>
</tbody>
</table>

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.

(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 Ichnophthirius 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.

§ 529.1044 Gentamicin sulfate in certain other dosage forms.

§ 529.1044a Gentamicin sulfate intravascular solution.

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

(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.

§ 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...
§ 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. 000074, 000009, 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.

§ 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 treatment of parasitic infections. Information on possible adverse effects on fish health 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 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.
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.


§ 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.

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


§ 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.


(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 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.


PART 530—EXTRALABEL DRUG USE IN ANIMALS

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.

§ 530.2 Purpose.

The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from