§ 524.2338 Terbinafine and betamethasone acetate.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) terbinafine and 1 mg betamethasone acetate.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).

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

[89 FR 42360, May 15, 2024]

§ 524.2350 Tolnaftate cream.

(a) *Specifications.* The drug contains 1 percent tolnaftate in an anhydrous cream base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply a small amount of the cream to the affected areas once or twice a day for 2 to 4 weeks.

(2) *Indications for use.* For the treatment of ringworm lesions due to *Microsporum canis* and *Microsporum gypseum.*

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

[79 FR 10972, Feb. 27, 2014]

§ 524.2482 Triamcinolone spray.

(a) *Specifications.* Each milliliter of solution contains 0.15 milligrams triamcinolone acetonide.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply sufficient pump sprays to uniformly and thoroughly wet the affected areas while avoiding run off of excess product. Administer twice daily for 7 days, then once daily for 7 days, then every other day for an additional 14 days (28 days total).

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis.

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

[68 FR 4916, Jan. 31, 2003, as amended at 78 FR 17868, Mar. 25, 2013]

§ 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

(a) *Specifications.* (1) Each gram of liquid or aerosol contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) Each gram of liquid or aerosol contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) in this section:

(1) No. 069043 for use of product described in paragraph (a)(1).

(2) No. 017135 for use of product described in paragraph (a)(2).

(c) *Conditions of use*—(1) *Amount.* Apply directly to the wound site.

(2) *Indications for use.* As an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate, and organic debris.

[79 FR 10973, Feb. 27, 2014, as amended at 88 FR 14901, Mar. 10, 2023]

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

Sec.

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

§ 526.88 Amoxicillin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains

amoxicillin trihydrate equivalent to 62.5 milligrams (mg) amoxicillin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (equivalent to 62.5 mg amoxicillin) into each infected quarter every 12 hours for a maximum of 3 doses.

(2) *Indications for use*. For the treatment of subclinical infectious bovine mastitis due to *Streptococcus agalactiae* and *Straphylococcus aureus* (penicillin sensitive).

(3) *Limitations*. Milk taken from animals during treatment and for 60 hours (5 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003; 86 FR 13185, Mar. 8, 2021]

§ 526.313 Ceftiofur.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains:

(1) 125 milligrams (mg) ceftiofur equivalents as the hydrochloride salt; or

(2) 500 mg ceftiofur equivalents as the hydrochloride salt.

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

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (125 mg ceftiofur equivalents) into each affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli;* and the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *S. dysgalactiae*.

(3) *Limitations*. Milk taken from cows during treatment (a maximum of 8 daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Federal law prohibits extralabel use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*—(1) *Amount*. Infuse the contents of one syringe (500 mg ceftiofur equivalents) into each affected quarter at the time of dry off.

(2) *Indications for use*. For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. No preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Federal law prohibits extralabel use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

[70 FR 9516, Feb. 28, 2005, as amended at 70 FR 20048, Apr. 18, 2005. Redesignated and amended at 71 FR 39545, July 13, 2006; 79 FR 10973, Feb. 27, 2013; 79 FR 18159, Apr. 1, 2014; 80 FR 34279, June 16, 2015; 86 FR 13185, Mar. 8, 2021]

§ 526.363 Cephapirin benzathine.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains 300 milligrams cephapirin activity (as cephapirin benzathine).

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use in dry cows*—(1) *Amount.* Infuse the contents of one syringe (300 mg cephapirin activity) into each quarter following last milking, but no later than 30 days before calving.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*, including penicillin-resistant strains.

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 37174, Aug. 22, 1978, as amended at 53 FR 27851, July 25, 1988; 73 FR 12262, Mar. 7, 2008; 75 FR 10168, Mar. 5, 2010; 76 FR 17338, Mar. 29, 2011; 86 FR 13186, Mar. 8, 2021; 88 FR 16549, Mar. 20, 2023]

§ 526.365 Cephapirin sodium.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains 200 milligrams (mg) cephapirin sodium activity.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.115 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (200 mg cephapirin activity) into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

(2) *Indications for use.* For the treatment of mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus* including strains resistant to penicillin.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 57455, Dec. 10, 1975, as amended at 53 FR 27852, July 25, 1988. Redesignated at 63 FR 8349, Feb. 19, 1998; 65 FR 20733, Apr. 18, 2000; 73 FR 3181, Jan. 17, 2008; 75 FR 10168, Mar. 5, 2010; 86 FR 13186, Mar. 8, 2021; 88 FR 16549, Mar. 20, 2023]

§ 526.464 Cloxacillin benzathine.

(a) *Specifications.* Each single-dose, 7.5- or 10-milliliter syringe contains cloxacillin benzathine equivalent to 500 milligrams (mg) cloxacillin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use in dry cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 500 mg cloxacillin) into each quarter immediately after last milking, but no later than 30 days before calving.

(2) *Indications for use.* For the treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations.* Animals infused with this product must not be slaughtered for food until 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[86 FR 13186, Mar. 8, 2021]

§ 526.465 Cloxacillin sodium.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains cloxacillin sodium equivalent to 200 milligrams (mg) cloxacillin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 200 mg cloxacillin) into each infected quarter. Treatment should be repeated at 12-hour intervals for a total of 3 doses.

(2) *Indications for use.* For the treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003. Redesignated at 85 FR 18120, Apr. 1, 2020. Redesignated and amended at 86 FR 13186, Mar. 8, 2021]

§ 526.820 Erythromycin.

(a) *Specifications.* (1) Each single-dose, 6-milliliter (mL) syringe contains 300 milligrams (mg) erythromycin (as the base).

(2) Each single-dose, 12-mL syringe contains 600 mg erythromycin (as the base).

(b) *Sponsors.* See Nos. 054771 and 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*—(1) *Amount.* Infuse the contents of one 6-mL syringe (300 mg erythromycin base) into each infected quarter. Repeat infusion at 12-hour intervals for a maximum of 3 infusions.

(2) *Indications for use.* For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating cows.

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

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*—(1) *Amount.* Infuse the contents of one 12-mL syringe (600 mg erythromycin base) into each infected quarter at the time of drying off.

(2) *Indications for use.* For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in dry cows.

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

[86 FR 13186, Mar. 8, 2021, as amended at 88 FR 14901, Mar. 10, 2023]

§ 526.1130 Hetacillin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams (mg) ampicillin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.316 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 62.5 mg ampicillin) into each infected quarter. Repeat at 24-hour intervals for a maximum of 3 treatments.

(2) *Indications for use.* For the treatment of acute, chronic, or subclinical mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus*, and *Escherichia coli*.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 75 FR 10168, Mar. 5, 2010; 84 FR 53311, Oct. 7, 2019; 86 FR 13186, Mar. 8, 2021]

§ 526.1590 Novobiocin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains:

(1) 150 milligrams (mg) of novobiocin equivalents as sodium novobiocin, or

(2) 400 mg of novobiocin equivalents as sodium novobiocin.

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

(c) *Related tolerances.* See § 556.460 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to

150 mg novobiocin) into each infected quarter after milking. Repeat treatment once after 24 hours. Do not milk for at least 6 hours after treatment.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* in lactating cows.

(3) *Limitations.* Milk taken from treated animals within 72 hours (6 milkings) after latest treatment should not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 400 mg novobiocin) into each quarter at the time of drying off.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* For udder installation for the treatment of mastitis in dry cows only. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food for 30 days following udder infusion.

[86 FR 13187, Mar. 8, 2021]

§ 526.1696 Penicillin G procaine.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) See Nos. 042791 and 061133 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than 3 doses, as indicated by clinical response.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberus* in lactating cows.

(3) *Limitations.* For intramammary infusion in lactating cows only. Discard all milk for 60 hours (5 milkings) after the latest treatment. Animals intended for human consumption must not be slaughtered within 3 days of latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use in dry cows*—(1) *Amount.* Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter at time of drying-off.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* For intramammary infusion in dry cows only. Animals intended for human consumption must not be slaughtered within 14 days of last treatment. Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[86 FR 13187, Mar. 8, 2021, as amended at 86 FR 57998, Oct. 20, 2021; 88 FR 27700, May 3, 2023; 88 FR 55567, Aug. 16, 2023]

§ 526.1697 Penicillin G procaine and dihydrostreptomycin.

(a) *Specifications.* Each single-use, 10-milliliter syringe contains a suspension of:

(1) Penicillin G procaine equivalent to 200,000 units penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams dihydrostreptomycin; or

(2) Penicillin G procaine equivalent to 1 million units penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram dihydrostreptomycin.

(b) *Sponsor.* See No. 042791 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in dry cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 200,000 units penicillin G and 300 milligrams dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) *Indications for use.* For the treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae*.

(3) *Limitations.* For use in dry cows only. Not to be used within 6 weeks of calving. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment or within 24 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 1 million units penicillin G and 1 gram dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) *Indications for use.* To reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations.* Not for use in lactating cows. Not to be used within 6 weeks of calving. Milk taken from cows within 96 hours (8 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion or within 96 hours after calving. 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 78 FR 21060, Apr. 9, 2013; 83 FR 14587, Apr. 5, 2018. Redesignated and amended at 86 FR 13187, Mar. 8, 2021; 88 FR 55567, Aug. 16, 2023]

§ 526.1698 Penicillin G procaine and novobiocin.

(a) *Specifications.* Each single-use, 10-milliliter syringe contains a suspension of:

(1) Penicillin G procaine equivalent to 100,000 units penicillin G and 150 milligrams (mg) novobiocin as novobiocin sodium; or

(2) Penicillin G procaine equivalent to 200,000 units penicillin G and 400 mg novobiocin as novobiocin sodium.

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

(c) *Related tolerances.* See §§ 556.460 and 556.510 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 100,000 units penicillin G and 150 mg novobiocin) into each infected quarter after milking. Repeat once after 24 hours.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating cows.

(3) *Limitations.* For udder instillation in lactating cows only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in lactating cows*—(1) *Amount.* Infuse the contents of one syringe (equivalent to 200,000 units penicillin G and 400 mg novobiocin) into each quarter at dry off.

(2) *Indications for use.* For the treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae* in dry cows.

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

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 10973, Feb. 27, 2014; 84 FR 32993, July 11, 2019. Redesignated and amended at 86 FR 13187, Mar. 8, 2021; 88 FR 14901, Mar. 10, 2023]

§ 526.1810 Pirlimycin.

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

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

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

(d) *Conditions of use in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (50 mg pirlimycin) into each infected quarter. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *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 regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 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; 86 FR 13188, Mar. 8, 2021]

PART 528—INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

Sec.

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

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

§ 528.1080 Bc2371 recombinant deoxyribonucleic acid construct.

(a) *Specifications and intended use*. A single copy of Bc2371, a human Factor VII recombinant deoxyribonucleic acid (rDNA) gene construct, located on chromosome 3p1.1–2 in a diploid line (R69) of hemizygous and homozygous New Zealand white rabbits (*Oryctolagus cuniculus*).

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

(c) *Conditions of use*—(1) *Intended use*. The construct directs gene expression of recombinant human Factor VII (hFVII) in the mammary gland such that recombinant hFVII zymogen is present in the rabbit milk, enabling purification and activation of recombinant hFVIIa intended for the treatment of hemophilia A or B in humans with inhibitors to Factors VIII and IX.

(2) *Limitations*. Food or feed from R69 rabbits is not permitted in the food or feed supply.

[84 FR 12494, Apr. 2, 2019]

§ 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]

§ 528.2001 *pPL657* recombinant deoxyribonucleic acid construct.

(a) *Specifications*. *pPL657* in the *glycoprotein galactosyltransferase alpha-1,3* (*GGTA1*) gene in domestic pigs.

(b) *Sponsor*. See No. 086134 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Intended use*. *pPL657* rDNA construct in the *glycoprotein galactosyltransferase alpha-1,3* gene (*GGTA1*) in the lineage of domestic pigs (*Sus scrofa domesticus*) hemizygous and homozygous for the intentional genomic alteration resulting in undetectable endogenous galactose alpha-1,3-galactose sugar residues on biological derivatives of domestic pigs