gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of Peru balsam, and 788.0 milligrams of castor oil.

(2) **Sponsor.** See No. 051079 in §510.600(c) of this chapter.

(b)(1) **Specifications.** The drug is a liquid for direct application or an aerosol preparation formulated so that each gram delivered to the wound site contains 0.1 milligram of crystalline trypsin, 72.5 milligrams of Peru balsam, and 800 milligrams of castor oil.

(2) **Sponsor.** See No. 017135 in §510.600(c) of this chapter.

(c) **Conditions of use.** The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.


**PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS**

**Sec.**

526.88 **Amoxicillin trihydrate for intramammary infusion.**

(a) **Specifications.** Each single dose syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams of 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—Lactating cows—(1) Amount.** One syringe (equivalent to 62.5 milligrams amoxicillin) per quarter.

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

(3) **Limitations.** Administer after milking. Clean and disinfect the teat. Use one syringe per infected quarter every 12 hours for a maximum of 3 doses. Do not use milk taken from treated animals for food purposes within 60 hours (5 milkings) after last treatment. Do not slaughter treated animals 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.


526.313 **Ceftiofur.**

(a) **Specifications.** Each single-use, 10-milliliter syringe of ceftiofur hydrochloride suspension contains 125 milligrams (mg) or 500 mg ceftiofur equivalents.

(b) **Sponsor.** See No. 000009 in §510.600(c) of this chapter.

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

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

(e) **Conditions of use in cattle—(1) Lactating cows—(i) Amount.** Infuse 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) **Indications for use.** For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative *staphylococci*, *Streptococcus dysgalactiae*, and *Escherichia coli*.
(iii) **Limitations.** Milk taken from cows during treatment (a maximum of eight 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 pre-slaughter withdrawal period is required.

(2) **Dry cows**—

(i) **Amount.** Infuse 500 mg per affected quarter at the time of dry off.

(ii) **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*.

(iii) **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 pre-slaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption.


§ 526.363 Cephapirin benzathine.

(a) **Specifications.** Each 10 milliliter disposable syringe contains 300 milligrams of cephapirin activity (as cephapirin benzathine) in a peanut-oil gel.

(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**—

(1) **Amount.** Infuse the contents of one syringe into each quarter.

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

(3) **Limitations.** Infuse each quarter following last milking, but no later than 30 days before 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. For use in dry cows only.


§ 526.365 Cephapirin sodium.

(a) **Specifications.** Each 10-milliliter dose contains 200 milligrams of cephapirin sodium activity in a peanut-oil gel.

(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 one dose 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.** If improvement is not noted within 48 hours after treatment, consult your veterinarian. 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.


§ 526.464 Cloxacillin intramammary dosage forms.

§ 526.464a Cloxacillin benzathine.

(a) **Specifications.** Each dose contains cloxacillin benzathine equivalent to 500 milligrams of cloxacillin.

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

(c) **Sponsor.** See No. 000010 in § 510.600(c) of this chapter for use in dairy cows.

(1) **Amount.** Administer aseptically into each quarter immediately after last milking.