§ 522.313 Ceftiofur injectable dosage forms.

§ 522.313a Ceftiofur crystalline free acid.

(a) Specifications. The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 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—(1) Swine. The formulation described in paragraph (a)(1) of this section is used as follows:

(A) Amount. 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(B) Indications for use—(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with M. haemolytica, P. multocida, and H. somni. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with Fusobacterium necrophorum and Porphyromonas levii in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(ii) Limitations. Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

(3) Cattle. The formulation described in paragraph (a)(2) of this section is used as follows:

(A) Amount. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(B) Indications for use. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of Streptococcus equi ssp. zooepidemicus.

(iii) Limitations. Do not use in horses intended for human consumption.

§ 522.313b Ceftiofur hydrochloride.

(a) Specifications. Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

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