The redesignation, revisions, and addition read as follows:

§ 522.313c Ceftiofur sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor.* See No. 000009 in § 510.600(c) 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*—(i) *Amount.* 3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis.*

(iii) *Limitations.* Treated pigs must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni* in beef and dairy cattle; and for treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment.

(3) *Sheep*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of sheep respiratory disease (pneumonia) associated with *M. haemolytica* and *P. multocida.*

(4) *Goats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *M. haemolytica* and *P. multocida.*

(5) *Chickens*—(i) *Amount.* 0.08 to 0.20 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *Escherichia coli* organisms susceptible to ceftiofur in day-old chicks.

(6) *Turkeys*—(i) *Amount.* 0.17 to 0.5 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur in day-old poults.

(7) *Horses*—(i) *Amount.* 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site.

(ii) *Indications for use.* For treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus.*

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

(8) *Dogs*—(i) *Amount.* 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared, for 5 to 14 days.

(ii) *Indications for use.* For treatment of canine urinary tract infections associated with *E. coli* and *Proteus mirabilis.*

■ 4. Add new § 522.313 as a heading only to read as follows:

§ 522.313 Ceftiofur injectable dosage forms.

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 5. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 6. Redesignate § 526.314 as § 526.313 and amend as follows:

■ a. Revise paragraph (a);

■ b. Redesignate paragraph (d) as paragraph (e) and add new paragraph (d);

■ c. Revise newly redesignated paragraphs (e)(1)(i) and (e)(2)(i);

■ d. In the second sentence of newly redesignated paragraph (e)(1)(iii), remove ''no preslaughter withdrawal period'' and add in its place ''a 2-day pre-slaughter withdrawal period'';

■ e. In the second sentence of newly redesignated paragraph (e)(2)(iii), remove ''a 3-day preslaughter withdrawal period'' and add in its place ''a 16-day pre-slaughter withdrawal period''; and

■ f. In newly redesignated paragraphs (e)(1)(iii) and (e)(2)(iii), remove ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

The revisions and additions read as follows:

§ 526.313 Ceftiofur.

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

* * * * *

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

(e) * * *

(1) * * *

(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.

* * * * *

(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 eight consecutive days, a 2-day pre-slaughter withdrawal period is required.

(2) * * *

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

* * * * *

(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 treated cows. Following label use, no pre-slaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption.

Dated: June 27, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E6–10973 Filed 7–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for use of ceftiofur crystalline free acid suspension via a new injection site in beef and nonlactating dairy cattle, for use in lactating dairy cattle for the treatment of respiratory disease, and for the establishment of a 13-day pre-slaughter withdrawal period in cattle. FDA is also amending the regulations to revise the tolerance for residues of ceftiofur in bovine kidney to accommodate these new conditions of use.

DATES: This rule is effective July 13, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42nd St., New York, NY 10017, filed a supplement to NADA 141–209 for EXCEDE (ceftiofur crystalline free acid) Sterile Suspension, approved for veterinary prescription use by injection in cattle for respiratory disease. The supplemental application provides for subcutaneous injection in beef and nonlactating dairy cattle in the posterior aspect of the ear where it attaches to the head (base of the ear), for use in lactating dairy cattle by subcutaneous injection in the base of the ear for the treatment of bovine respiratory disease, and for the establishment of a 13-day pre-slaughter withdrawal period in cattle. FDA is also amending the regulations to revise the tolerance for residues of ceftiofur in bovine kidney to accommodate these new conditions of use. The application is approved as of June 2, 2006, and the regulations are amended in 21 CFR 522.315 and 556.113 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of the safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning June 2, 2006. The 3 years of marketing exclusivity applies only to the new administration site and new indication for which this supplement is approved.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Parts 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Amend § 522.315 as follows:

■ a. Redesignate § 522.315 as § 522.313a;

■

■ b. Revise paragraph (a);

■ c. Redesignate paragraph (d) as paragraph (e);

■ d. Add new paragraph (d); and

■ e. Revise newly redesignated paragraphs (e)(1)(iii) and (e)(2).

The redesignations, revisions, and addition read as follows:

§ 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.

* * * * *

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

(e) * * *

(1) * * *

(iii) *Limitations.* Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required.

(2) * * *

(i) *Amount.* 6.6 mg ceftiofur equivalents per kg of body weight as a single injection. For subcutaneous injection in the middle third of the posterior aspect of the ear or in the posterior aspect of the ear where it attaches to the head (base of the ear) in beef and non-lactating dairy cattle. For subcutaneous injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle.

(ii) *Indications for use.* 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*.

(iii) *Limitations.* Following label use as a single treatment, a 13-day pre-slaughter withdrawal period is required. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.113 [Amended]

■ 4. In § 556.113, in paragraph (b)(3)(i) remove ''8'' and add in its place ''0.4''; remove paragraph (b)(3)(iv); and redesignate paragraph (b)(3)(v) as paragraph (b)(3)(iv).

Dated: June 30, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E6–10972 Filed 7–12–06; 8:45 am]

BILLING CODE 4160–01–S