necrophorum, and *C. perfringens*; and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens.*

(2) * * *

(i) *Amount.* 5.0 to 15.0 mg/lb body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *Staphylococcus aureus*, *S. intermedius*, *Streptococcus spp.*; deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*; and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus spp.*, *C. perfringens*, and *B. fragilis.*

Dated: June 30, 2006.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 526

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 four supplemental new animal drug applications (NADAs) filed by Pharmacia & Upjohn Co. The supplemental NADAs establish or revise preslaughter withdrawal periods in cattle injected with a solution made from ceftiofur sodium powder or with a suspension of ceftiofur hydrochloride, or receiving an intramammary infusion of ceftiofur hydrochloride.

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 42d St., New York, NY 10017, filed supplements to NADA 140–338 for NAXCEL (ceftiofur sodium) Sterile Powder for Injection and to NADA 140–890 for EXCENEL RTU (ceftiofur hydrochloride) Sterile Suspension. These products are approved for veterinary prescription use in livestock by injection for the treatment or control of various bacterial diseases. Pharmacia & Upjohn Co. also filed supplements to NADA 141–238 for SPECTRAMAST LC (ceftiofur hydrochloride) Sterile Suspension and to NADA 141–239 for SPECTRAMAST DC (ceftiofur hydrochloride) Sterile Suspension. These products are approved for veterinary prescription use by intramammary infusion in dairy cows for the treatment of bacterial mastitis. The supplemental NADAs establish or revise preslaughter withdrawal periods in cattle consistent with the tolerance for residues of ceftiofur in bovine kidney which was revised elsewhere in this issue of the **Federal Register**. The applications are approved as of June 2, 2006, and the regulations are amended in 21 CFR 522.313 and 526.314 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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.

The agency has determined under 21 CFR 25.33(a) that these actions are of a type that do 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 in 21 CFR Parts 522 and 526

Animal drugs.

■ 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 526 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. Redesignate § 522.314 as § 522.313b and amend as follows:

■ a. Revise paragraph (a);

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

■ c. Add new paragraph (d); and

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

The redesignation, revisions, and addition read as follows:

§ 522.313b Ceftiofur hydrochloride.

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

* * * * *

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

(e) * * *

(1) * * *

(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 swine must not be slaughtered for 4 days following the last treatment.

(2) * * *

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations.* Treated cattle must not be slaughtered for 3 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

■ 3. Redesignate § 522.313 as § 522.313c and amend as follows:

■ a. Revise the section heading and paragraphs (a) and (b);

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

■ c. Add new paragraph (d); and

■ d. Revise newly redesignated paragraph (e).

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.

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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.