

least \$200,000,000 and the issuer of such municipal security has outstanding securities that are notes, bonds, debentures, or evidences of indebtedness having a total remaining principal amount of at least \$1 billion; and

(viii) Paragraphs (a)(1)(vi) and (a)(1)(vii) of this section will not apply to securities of an issuer included in the index if:

(A) All securities of such issuer included in the index represent less than 5 percent of the index's weighting; and

(B) Securities comprising at least 80 percent of the index's weighting satisfy the provisions of paragraphs (a)(1)(vi) and (a)(1)(vii) of this section; or

(2)(i) The index includes exempted securities, other than municipal securities, as defined in section 3(a)(29) of the Act and the rules promulgated thereunder, that are:

(A) Notes, bonds, debentures, or evidences of indebtedness; and

(B) Not equity securities, as defined in section 3(a)(11) of the Act (15 U.S.C. 78c(a)(11)) and the rules promulgated thereunder; and

(ii) Without taking into account any portion of the index composed of such exempted securities, other than municipal securities, the remaining portion of the index would not be a narrow-based security index: meeting all the conditions under paragraph (a)(1) of this section.

(b) For purposes of this section:

(1) An issuer is affiliated with another issuer if it controls, is controlled by, or is under common control with, that issuer.

(2) For purposes of this section, *control* means ownership of 20 percent or more of an issuer's equity, or the ability to direct the voting of 20 percent or more of the issuer's voting equity.

(3) The term *issuer* includes a single issuer or group of affiliated issuers.

■ 3. Section 240.6h-2 is added to read as follows:

§ 240.6h-2 Security future based on note, bond, debenture, or evidence of indebtedness.

A security future may be based upon a security that is a note, bond, debenture, or evidence of indebtedness or a narrow-based security index composed of such securities.

By the Commodity Futures Trading Commission.

Eileen A. Donovan,
Acting Secretary.

By the Securities and Exchange Commission.

Dated: July 6, 2006.

J. Lynn Taylor,

Assistant Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Liquid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Virbac AH, Inc. The supplemental ANADA provides for an expanded dose range and revised wording of indications for the oral use of clindamycin hydrochloride liquid in dogs and cats for the treatment of certain bacterial diseases.

DATES: This rule is effective July 13, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed a supplement to ANADA 200-291 for CLINSOL (clindamycin hydrochloride) Liquid. The supplement provides for an expanded dose range and revised wording of indications for the oral use of clindamycin hydrochloride liquid in dogs and cats for the treatment of certain bacterial diseases. The supplemental ANADA is approved as of June 12, 2006, and the regulations are amended in § 520.447 (21 CFR 520.447) to reflect the approval and a current format.

In addition, FDA has found that a 2003 change of sponsorship for CLINSOL Liquid (68 FR 55823, September 29, 2003) is not reflected in the Code of Federal Regulations. Accordingly, § 520.447 is being revised to reflect the correct sponsor drug labeler code. This action is being taken to improve the accuracy of the regulations.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA has determined under 21 CFR 25.33(a)(1) 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 congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.447, revise the section heading and paragraphs (b), (d)(1)(i), (d)(1)(ii), (d)(2)(i), and (d)(2)(ii) to read as follows:

§ 520.447 Clindamycin solution.

* * * * *

(b) *Sponsors.* See Nos. 000009, 051311, and 059130 in § 510.600(c) of this chapter.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days.

Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum*, and *Clostridium perfringens*; dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F.*

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.
[FR Doc. E6-10971 Filed 7-12-06; 8:45 am]

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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).