DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Capsules and Tablets

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 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 tablets in dogs for the treatment of certain bacterial diseases.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

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 200–316 for CLINITABS (clindamycin hydrochloride) tablets for the treatment of certain bacterial diseases in dogs. The supplemental ANADA provides for an expanded dose range and revised wording of indications. The supplemental ANADA is approved as of June 2, 2006, and the regulations are amended in 21 CFR 520.446 to reflect the approval and a current format.

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 the 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 § 520.446, revise paragraphs (b)(1) and (b)(2); remove paragraph (c); redesignate paragraph (d) as paragraph (c); and revise newly redesignated paragraph (c) to read as follows:

§ 520.446 Clindamycin capsules and tablets.

* * * * *

(b) * * *

(1) Nos. 000009 and 059130 for use of capsules described in paragraph (a)(1) of this section.

(2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.

(c) *Conditions of use in dogs*—(1) 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.

(2) *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 melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*, dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*, and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

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

Dated: June 27, 2006.

Steven D. Vaughn,

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

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