

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DDM

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Officer	A. Corbin

**Oral Dosage Form New Animal Drugs; Clindamycin Liquid**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

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**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 [*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 200-291 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.

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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 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*.

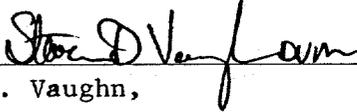
(2) \* \* \*

(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  
June 30, 2006.



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