

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Lincomycin; Technical Amendment

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 an abbreviated new animal drug application (ANADA) filed by Veterinary Laboratories, Inc. The ANADA provides for the use of lincomycin injectable solution in swine for the treatment of infectious arthritis and mycoplasma pneumonia. Additional action is also being taken because we did not specify the concentration of lincomycin solution approved under the ANADA in the final rule that published in the **Federal Register** of May 14, 2002 (67 FR 34387).

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200-315 that provides for use of Lincomycin (lincomycin hydrochloride monohydrate) Injection in swine for the treatment of infectious arthritis and mycoplasma pneumonia. Veterinary Laboratories, Inc.'s Lincomycin Injection is approved as a generic copy of Pharmacia &

Upjohn Co.'s LINCOMIX Injectable, approved under NADA 034-025. The ANADA is approved as of April 2, 3003, and the regulations are amended in 21 CFR 522.1260 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 522.1260 is also being revised to specify the concentration of lincomycin solution approved under ANADA 200-274 (67 FR 34387, May 14, 2002).

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (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)(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 522

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 522 is 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. Section 522.1260 is amended by revising paragraphs (a) and (b) to read as follows:

§ 522.1260 Lincomycin.

(a) *Specifications.* Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

- (1) 25, 50, 100, or 300 milligrams (mg) lincomycin.
- (2) 25, 100, or 300 mg lincomycin.
- (3) 300 mg lincomycin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 000009 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) No. 000857 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 046573 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

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Dated: August 7, 2003.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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