

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Lincomycin

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 an abbreviated new animal drug application (ANADA) filed by Alpharma, Inc. The ANADA provides for use of an injectable lincomycin solution for the treatment of infectious arthritis and mycoplasma pneumonia in swine.

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-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed ANADA 200-274 that provides for the use of Lincomycin (lincomycin HCl) Injectable 30% by intramuscular injection for the treatment of infectious arthritis and mycoplasma pneumonia in swine. Alpharma's Lincomycin Injectable 30% is approved as a generic copy of Pharmacia & Upjohn Co.'s LINCOMIX 300, approved under NADA 34-025. The application is approved as of February 1, 2002, 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 amended to reflect a current format.

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DMB
Display Date
Publication Date
Certifier R. LEDESMA

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In accordance with the freedom of information provisions of 21 CFR part 20 and 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 the section heading and paragraphs (a), (b), (e)(1)(i), (e)(1)(iii), (e)(2)(i), and (e)(2)(iii) to read as follows:

§ 522.1260 Lincomycin.

(a) Specifications. Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to 25, 50, 100, or 300 milligrams (mg) of 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 uses as in paragraph (e) of this section.

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

* * * * *

(e) * * *

(1) * * *

(i) Amount. 5 mg per pound (/lb) of body weight twice daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

* * * * *

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

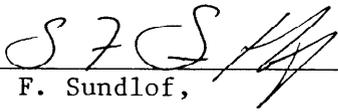
(2) * * *

(i) Amount. 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

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(iii) Limitations. Do not treat within 48 hours of slaughter.

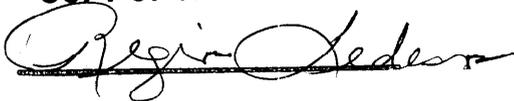
Dated: 4/26/02
April 26, 2002.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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Regina Sedes