

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

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 Cross Vetpharm Group Ltd. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

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: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-377 for LINCOMED (lincomycin hydrochloride) Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Cross Vetpharm Group Ltd.'s LINCOMED Soluble Powder is approved as a generic copy of Pharmacia &

Upjohn Co.'s LINCOMIX Soluble Powder, approved under NADA 111-636. ANADA 200-377 is approved as of December 6, 2004, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 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.

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. Section 520.1263c is amended by revising paragraph (b) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

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(b) *Sponsors.* See Nos. 000009, 046573, 054925, 059130, and 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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Dated: December 29, 2004 .

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S