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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 Med-Pharmex, Inc. The ANADA provides for use of 40- and 80-gram packets and 32-ounce containers of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and broiler chickens for the control of necrotic enteritis.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, has filed ANADA 200-241 that provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and for broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. The ANADA provides for use of 40- and 80-gram packets and 32-ounce containers of product.

The ANADA is approved as a generic copy of Pharmacia & Upjohn's NADA 111-636, Lincomix® Soluble Powder. ANADA 200-241 is approved as of February 4, 1999, and the

regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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.

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 adding a sentence to the end of paragraph (a) and by revising paragraph (b) to read as follows:

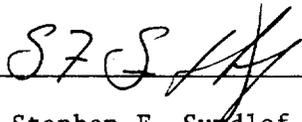
§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* * * * The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) *Sponsors*. Approval for use of 40- and 80-gram packet to Nos. 000009 and 017144 in § 510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in § 510.600(c) of this chapter.

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Dated: 2/26/99
February 26, 1999



Stephen F. Sundlof
Director
Center for Veterinary
Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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