

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations for preslaughter withdrawal time for lincomycin soluble powder products used to make medicated drinking water for swine to correct inadvertent editorial errors. This action is being taken to ensure accuracy and clarity in the agency's regulations.

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

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: ghaibel@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: FDA has found that § 520.1263c (21 CFR 520.1263c) does not reflect the approved preslaughter withdrawal time for three lincomycin soluble powder products used to make medicated drinking water for swine. The 6-day withdrawal time was inadvertently removed for a generic product approved under ANADA 200-189 at the time it was being removed for the pioneer product approved under NADA 111-636 (64 FR 13341, March 18, 1999). The conditions of use for two other products approved February 4, 1999, under ANADA 200-241 (64 FR 13508, March 19, 1999) and

September 22, 1999, under ANADA 200–233 (64 FR 66382, November 26, 1999) were subsequently codified without a withdrawal period. At this time, the regulations are being amended in § 520.1263c to correct these errors.

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 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.

§ 520.1263c [Amended]

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (d)(1)(iii) by adding at the end the sentence “For Nos. 046573 and 051259: Do not slaughter swine for 6 days following last treatment.”

Dated: November 8, 2002.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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