

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 520
Oral Dosage Form New Animal Drugs; Lincomycin and Spectinomycin 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 Agri Laboratories, Ltd. The ANADA provides for the oral use of lincomycin and spectinomycin soluble powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis.

DATES: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200-407 that provides for use of Lincomycin-Spectinomycin (lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate) Water Soluble Powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Agri Laboratories, Ltd.'s Lincomycin-Spectinomycin Water Soluble Powder is approved as a generic copy of L-S 50 Water Soluble Powder, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 046-109. The ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1265 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 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.

■ 2. In § 520.1265, revise the section heading and paragraph (b)(2) to read as follows:

§ 520.1265 Lincomycin and spectinomycin powder.

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(b) * * *

(2) Nos. 057561, 059130, and 061623 for use of product described in paragraph (a)(2) of this section.

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Dated: November 28, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6-20929 Filed 12-7-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 520
Oral Dosage Form New Animal Drugs; Oxytetracycline 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 a supplemental abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The supplemental ANADA revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of fowlbrood of honeybees.

DATES: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200-247 that provides for the use of Oxytetracycline HCl Soluble Powder-343 in several species. The supplement revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of fowlbrood of honeybees. The supplemental ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1660d to reflect the approval and a current format.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 the congressional review requirements in 5 U.S.C. 801-808.

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