

IMS

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

**New Animal Drugs; Neomycin Sulfate Soluble Powder**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

Display Date 12-26-02  
Publication Date 12-27-02  
Certifier G. Penley

11170210326

**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 Alpharma, Inc. The supplemental ANADA provides for use of neomycin sulfate soluble powder in the drinking water of growing turkeys for the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin.

**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: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to ANADA 200-130 that provides for use of NEO-SOL 50 (neomycin sulfate) soluble powder for making medicated drinking water for administration to cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin. The supplemental ANADA provides for use of neomycin in the drinking water of growing turkeys for the control of mortality associated with *E. coli* organisms susceptible to neomycin.

The supplemental application is approved as of October 25, 2002, and the regulations are amended in 21 CFR 520.1484 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 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 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**

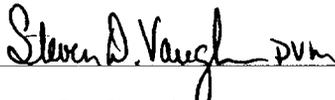
1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

§ 520.1484 [Amended]

2. Section 520.1484 *Neomycin sulfate soluble powder* is amended in paragraph (b)(1) by removing “046573” and in paragraph (b)(2) by adding in numerical sequence “046573”.

Dated: 12-17-02  
December 17, 2002.



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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

**BILLING CODE 4160-01-S**

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

