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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Neomycin Sulfate

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 new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for the use of neomycin sulfate Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats in a broader range of concentrations.

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

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, has filed a supplemental application to NADA 140-976 that provides for use of Neomix® (neomycin sulfate) Type A medicated articles to make Type B and Type C medicated feeds for cattle, swine, sheep, and goats used for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin. The supplemental NADA requested that the approved range of concentrations for neomycin Type C medicated feeds of 400 to 1,600 grams per ton (g/ton) be broadened to 250 to 2,250 g/ton. The approved daily dose of 10 milligrams per pound of body weight remains unchanged. The supplemental NADA is approved as of June 28, 2000, and the regulations are amended in 21 CFR 558.364 to reflect the approval.

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Approval of this supplemental NADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary is not required.

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

List of Subjects in 21 CFR Part 558

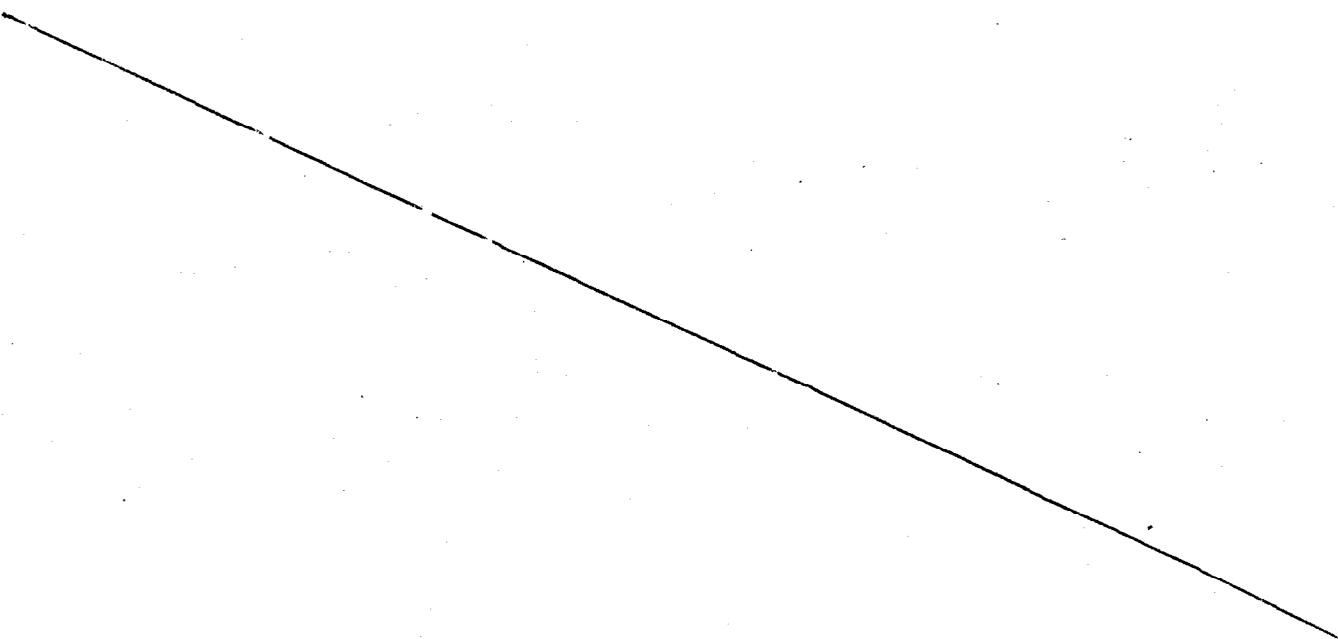
Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.



§ 558.364 [Amended]

2. Section 558.364 *Neomycin sulfate* is amended in the table in paragraph (d) in entry "(1)" under "Neomycin sulfate" by removing "400 to 1,600" and by adding in its place "250 to 2,250".

Dated:

July 18, 2000
July 18, 2000

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug
Evaluation
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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