

MAY 5 1999

FINDING OF NO SIGNIFICANT IMPACT

for

**NEOMIX[®] 325/NEOMIX[®] AG 325 (Neomycin Sulfate)
For Growing Turkeys**

NADA 011-315

**Pharmacia & Upjohn Company
Kalamazoo, Michigan**

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The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be required.

The Pharmacia & Upjohn Company submitted a supplemental new animal drug application for the use of neomycin sulfate (Neomix® 325/ Neomix® AG 325 soluble powder) for the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys. The maximum dosage will be 7.0 mg of neomycin base (10 mg neomycin sulfate) per pound of body weight per day supplied in the drinking water. Neomycin sulfate is approved for use in cattle (excluding veal calves), swine, sheep and goats under 21 CFR 520.1484. In support of the supplement, the firm has provided the attached environmental assessment (EA, dated February 29, 1996).

The EA, dated February 29, 1996, adequately addresses the potential environmental impact from the manufacture of the product by the Pharmacia & Upjohn Company, Kalamazoo, Michigan. The EA also contains an attached EA dated October 13, 1987, and revised June 1988, by the Animal Health Institute (AHI) which provides for the potential environmental impact which could result from the use of neomycin products, including its use in turkeys. A material safety data sheet for neomycin sulfate is included as an attachment to the EA.

The submitted EAs contain adequate information to determine that the manufacture and use of the product is not expected to have a significant impact on the human environment.

5/4/99
Date

Maya Ann Miller
Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: Environmental Assessment dated February 29, 1996, and Attachments