

FINDING OF NO SIGNIFICANT IMPACT

for

**Neomix® 325/ Neomix® AG 325 (Neomycin sulfate)
for Growing Turkeys**

NADA 011-315

**The Upjohn Company
Kalamazoo, Michigan**

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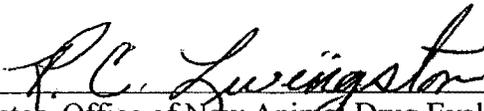
The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be required.

The Upjohn Company, submitted a supplemental new animal drug application for the use of neomycin sulfate (Neomix® 325/ Neomix® AG 325) soluble) for the treatment and control of colibacillosis associated with *Escherichia coli* organisms sensitive to neomycin 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 Upjohn Company has provided the attached environmental assessment (EA, dated February 29, 1996).

The February 29, 1996, EA adequately addresses the potential environmental impact from the manufacture of the product at the Upjohn Company, Kalamazoo, Michigan. The EA also contains as attachment, an October 13, 1987, EA and revised as of June 1988, from 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.

9-5-96
Date



Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: Environmental Assessment dated May 6, 1996, and Attachments