

NADA 11-315 amj

FINDING OF NO SIGNIFICANT IMPACT

for

NADA 011-315

Neomycin Sulfate (NEOMIX® 325 and NEOMIX® AG 325) Soluble Powder
for Use in Cattle, Swine, Sheep, and Goats

The Upjohn Company
Kalamazoo, MI

The Center for Veterinary Medicine has carefully 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 and that an environmental impact statement therefore will not be prepared.

The Upjohn Company submitted a supplemental new animal drug application for the use of neomycin sulfate soluble powder (NEOMIX® 325 and NEOMIX® AG 325) for the treatment of bacterial enteritis in cattle, swine, sheep, and goats. Environmental assessments (EAs) covering the manufacture and use of neomycin sulfate soluble powder were necessary for this action because of the type of changes in the indications and dosages required to comply with the Drug Efficacy Study Implementation. The Upjohn Company provided an EA covering the manufacture of the product. The Upjohn EA also references an Animal Health Institute (AHI) EA (dated, October 1987 and revised, June 1988) that addresses the environmental aspects associated with the use of the product. Copies of these EAs are attached.

In the AHI EA, the indications for use of the product are incorrect (i.e., they incorrectly include poultry, dogs, cats, mink, and veal calves). They are correctly stated in the Upjohn EA (i.e., only cattle [excluding veal calves], swine, sheep, and goats are included).

Therefore, the EAs provide adequate information to address the potential environmental impacts due to manufacture and use of the product and demonstrate that the action is not expected to have a significant effect on the quality of the human environment.

11/15/91
Date

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Attachments: The Upjohn Company EA, dated May 23, 1991
The AHI EA, dated October 1987 revised June 1988 and references