

**FINDING OF NO SIGNIFICANT IMPACT**

**for**

**Flavomycin® (Bambermycins)  
for use in Feedlot Cattle**

**NADA 44-759 R100**

**Hoechst-Roussel Agri-Vet Co.  
Somerville, NJ**

**FOR PUBLIC DISPLAY**

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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. Therefore, an environmental impact statement will not be prepared.

Hoechst-Roussel Agri-Vet Co., has submitted an original New Animal Drug Application (NADA) for Flavomycin®(bambermycins) for use in feedlot cattle at a rate of 10-20 mg bambermycins per head per day. In support of the NADA, the sponsor has submitted an environmental assessment (EA; dated March, 1993) under 21 CFR 25.31a(a) for the manufacture and use of Flavomycin®. Bulk drug product will be manufactured at Hoechst Aktiengesellschaft, Germany, and the premix will be manufactured at Merck & Co., Inc., St. Louis, Missouri. Hoechst-Roussel Agri-Vet Co., will be the distributor of the product and will control the premix manufacture.

The EA and attachments provide adequate environmental and occupational information for the manufacture of the raw and finished drug products. Applicable emission regulations and permits and occupational safety regulations are cited and a statement of compliance with the appropriate regulations is provided. The EA contains an adequate material safety data sheet (MSDS) for Flavomycin®(bambermycins).

Information is provided in the EA on the fate and effects of flavomycin in the environment. The EA demonstrates that the flavomycin enter the environment via cattle manure used as fertilizer on agricultural soils. Hoechst-Roussel has calculated that the maximum possible concentration of flavomycin (assuming no metabolism of the drug in the animal or degradation of the drug in the manure) in soil due to fertilization would be 0.016 ppb<sup>m</sup>. Concentration of flavomycin in the environment would be significantly lower when the excretion of flavomycin in cattle manure (37.4%) along with the degradation of flavomycin in the manure is considered. Biodegradation studies indicate that flavomycin would be expected to biodegrade in soil. Biodegradation studies in four soil types, one of which contained cattle manure, demonstrate that the biodegradation half-life of flavomycin ranging from 13.3 to 28.0 days for four agricultural soil types. This information in the Hoechst-Roussel Agri-Vet Co., EA and appendices is adequate to conclude that the manufacture and use of the product is not expected to have a significant impact on the environment.

8/16/93  
Date

D.N. Jayamath  
Reviewer, Environmental Sciences Staff, HFV-152

8/17/93  
Date

Waine A. Benz  
Primary Action Officer, HFV-126

8/16/93  
Date

Charles E. Eastman  
Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment, dated March, 1993