

FINDING OF NO SIGNIFICANT IMPACT

for

Pirlimycin Hydrochloride (PIRSUE™ Aqueous Gel)  
for Use in Lactating Dairy Cattle

NADA 141-036 A0000

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

The Upjohn Company has submitted an original New Animal Drug Application (NADA) for Pirlimycin Hydrochloride (PIRSUE™ Aqueous Gel) for intramammary treatment of clinical mastitis in lactating dairy cattle. In support of the NADA, the sponsor has submitted an environmental assessment (EA; dated March 16, 1993) under 21 CFR 25.31a(a) for the manufacture and use of PIRSUE™. All manufacturing (bulk and finished drug) and final packaging of the drug product will be conducted at The Upjohn Company's main pharmaceutical manufacturing complex in Kalamazoo (Portage), MI.

The EA and attachments provide adequate environmental and occupational information for the manufacture of the raw and finished drug product. Information is provided in the EA on the introduction of substances into the environment, fate of emitted substances in the environment and environmental effects of released substances. 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 adequate material safety data sheets (MSDS) for pirlimycin hydrochloride and the main raw materials used in the formulation of PIRSUE™ Aqueous Gel.

The information provided in The Upjohn Company 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.

7/26/93  
Date

Paul A. Bloo  
Reviewer, Environmental Sciences Staff, HFV-152

7/26/93  
Date

Shoba K. Das  
Primary Action Officer, HFV-133

7/26/93  
Date

Charles E. Gibson, III  
Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment, dated March 16, 1993