FINDING OF NO SIGNIFICANT IMPACT

for

Albendazole Suspension for Cattle

NADA 110-048
SmithKline Animal Health Products

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.

SmithKline Animal Health Products is requesting approval for the use of albendazole suspension as an anthelmintic for cattle. A one time dose of 10 mg/kg body weight eliminates a number of internal parasites in cattle, including liver flukes.

In support of their new animal drug application, the firm has conducted a number of environmental studies and prepared an environmental assessment (attached) which evaluates the potential environmental impacts of the manufacture and use of the product. We have concluded that the product can be manufactured and used without any expected adverse environmental effects. Precautions taken at the sites of manufacture of the bulk product and its final formulation are expected to minimize occupational exposures and environmental release. Any residues of albendazole or its major metabolites entering the environment as a result of administering the drug to cattle are expected to initially bind to soil and, when exposed to sunlight, rapidly degrade.

3/24/89
Date

John L. Olsen
Primary Action Officer, HFV-135

3/23/89
Date

Jack C Matheson
Preparer and Chief,
Environmental Sciences Staff, HFV-162

Attachment: SmithKline's March 7, 1989 Environmental Assessment

110-048-1989