

FINDING OF NO SIGNIFICANT IMPACT

for

Fenbendazole Swine Premix

NADA 131-675

American Hoechst Corporation

The Bureau of 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.

American Hoechst Corporation of Somerville, New Jersey has filed a new animal drug application (NADA 131-675) providing for the use of fenbendazole premix concentrations of either 4% or 20% as an oral dewormer for swine. The premix is added to the feed of swine at a dose level of 3 mg fenbendazole/kg body weight per day and is used for three consecutive days. Fenbendazole is active against gastrointestinal nematodes, lungworms and kidneyworms. Retreatment with fenbendazole after 4-6 weeks may be necessary if the treated swine continue to be exposed to worms. The treated swine can be slaughtered after treatment without withdrawal time.

The chemical name of fenbendazole is methyl 5-(phenylthio)-2-benzimidazole carbamate. There are a number of widely used compounds which like fenbendazole, contain the benzimidazole nucleus. The use of fenbendazole in swine is expected to displace some of the other benzimidazole compounds already used in this species. Therefore significant additional introductions of benzimidazoles into the environment are not expected to occur.

American Hoechst Corporation has filed the attached environmental impact analysis report (EIAR) in support of the proposed use of fenbendazole in swine. The EIAR submitted indicates that fenbendazole is practically insoluble in water and is strongly adsorbed to topsoil. This EIAR is adequate to conclude that this drug will occur in low concentrations in the aquatic and terrestrial environments and, at these concentrations, is unlikely to result in significant environmental effects.

3-28-83
Date

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3/31/83
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3-28-83
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Attachments

cc: Orig. & dup., NADA 131-675
Reading Board
File (HFV-310)

MGZeeman/cbm/3/28/83