

FINDING OF NO SIGNIFICANT IMPACT

for

Fenbendazole
(10% Suspension, 10% Paste and Type A Medicated Article)
for Use in Dairy Cattle
(Supplements to NADAs 128-620, 132-872 and 137-600)

Hoechst-Roussel Agri-Vet Company
Somerville, NJ

The Center for Veterinary Medicine has considered the potential environmental impact of these actions and has concluded that the actions will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Hoechst-Roussel Agri-Vet Company is requesting approval of supplements to their previously approved NADAs (128-620, 132-872 and 137-600) for the use of fenbendazole in lactating dairy cattle. The proposed use of fenbendazole is as an oral dewormer in dairy cattle of breeding age. The product will be used in suspension, paste, and premixes at relatively the same concentrations. Environmental introductions of fenbendazole resulting from these uses are anticipated to be similar.

Fenbendazole is active against gastrointestinal nematodes and lungworms. Fenbendazole is a member of a class of compounds known as benzimidazoles. It is structurally related to thiabendazole, oxfendazole, and albendazole.

Fenbendazole will be introduced into the environment from dairy facilities, manure application onto agricultural lands, aquatic systems potentially receiving runoff from these sources, and direct introduction of dung deposited on pasture.

In support of each of the NADA supplements, the firm provided the attached environmental assessments (EAs); all dated May 1995. The EAs address the potential environmental and occupational impacts for the final and bulk manufacturing of the product. The EAs also address the environmental introductions from the use of the products.

Although there are uncertainties as to the overall impacts of fenbendazole residues in the environmental, resulting from all uses in cattle, the incremental use proposed in these supplemental applications are not expected to change significantly the nature of the residues or their concentration in the environment.

1-26-96
Date

R.C. Livingston
Director
Office of New Animal Drug Evaluation, HFV-100
Center for Veterinary Medicine

Attachment: 3 Environmental Assessments, dated May 1995