

JUL 3 2000

FINDING OF NO SIGNIFICANT IMPACT

for

Fenbendazole

(Type A Medicated Article) for Use in Turkeys

(Supplements to NADA 131-675)

Hoechst-Roussel-Vet Company

Warren, 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-Vet Company is requesting approval of supplements to their previously approved NADAs (131-675) for the use of Fenbendazole in turkeys. The proposed use of Fenbendazole is as an oral dewormer. The product will be used in premixes at relatively the same concentrations. Environmental introductions of Fenbendazole resulting from this use is expected to be similar or less than previous approved uses in swine and beef and dairy cattle.

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 turkey facilities, litter application onto agricultural lands, and aquatic systems potentially receiving runoff from these sources.

In support of each of the NADA supplements, the firm provided the attached environmental assessment (EA); dated March 31, 1998. The EA addresses the potential environmental impacts from the environmental introductions from the use of the products.

Although there is some uncertainty about the environmental residues and possible effects of fenbendazole, the use of Fenbendazole in turkeys will result in lower environmental introductions and potential residues than occur from the approved uses of the product in cattle (beef and dairy) and swine. Therefore, it is expected that the new use will result in no changes from previous uses of these products. In order to deal with the uncertainty, a study to determine environmental residues is under consideration by CVM.

5/31/00

Date



Director

Office of New Animal Drug Evaluation, HFV-100
Center for Veterinary Medicine

Attachment: Amended Environmental Assessments dated March 31, 2000

NADA-131-675

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