FINDING OF NO SIGNIFICANT IMPACT

for

Halofuginone Hydrobromide (Stenoral®) for Turkeys

NADA 140-824

Roussel-UCLAF

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.

Roussel-UCLAF has prepared and submitted through its U.S. agent (Hoechst-Roussel Agri-Vet Company) a new animal drug application (NADA) that would provide for the use of halofuginone hydrobromide at 1.5 - 3 ppm continuously in the feed of turkeys for the prevention of coccidiosis.

In support of their application, the firm has submitted an environmental assessment (attached) addressing the new use of the drug. Mitigations against occuptional exposures and potential damage to aquatic life are adequately provided for in the labeling for the new use of the drug. We have reviewed the environmental assessment and find that it is adequate.

This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the FEDERAL REGISTER of April 26, 1985 (50 FR 16636, effective July 25, 1985).

10/16/86
Date

Adriana R. Gabuten
Primary Action Officer, HFV-135

10-15-86
Date

John C. Matheson DR
Preparer and Chief
Environmental Staff, HFV-152

Attachment

HFA-305