

FINDING OF NO SIGNIFICANT IMPACT

for

Halofuginone Hydrobromide (Stenorol[®] Premix)
for Replacement Cage Laying Chickens and
Replacement Broiler Chickens

NADA 130-951

Hoechst-Roussel Agri-Vet Co.
Somerville, New Jersey

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that it 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 Co., as the United States agent for Roussel-Uclaf of Paris, France, has requested approval of a supplemental new animal drug application (NADA) for the use of halofuginone hydrobromide in replacement cage laying chickens and replacement broiler breeders. The product will be administered to broiler breeders and laying chickens of up to 16 and 20 weeks of age respectively, at the previously approved 2.72 g/ton feed level and for the previously approved indications (21 CFR 558.265). The active ingredient, halofuginone hydrobromide, will be manufactured in the Roussel Uclaf factory, Neuville-sur-Saone, France. The active ingredient will then be coated by DanoChemo A/S, in Ballerup, Denmark. The premix containing halofuginone hydrobromide will be manufactured by Merck & Co., Inc., in St. Louis, Missouri.

Hoechst-Roussel Agri-Vet Co. has filed the attached environmental assessment report, (EA) dated June 1991, which includes the results from the previously approved studies. In addition, the EA indicates that the active ingredient is manufactured in compliance with French government environmental regulations (including occupational) and that the coating facility in Denmark and premix manufacturer in the United States will be in compliance with applicable Federal, State and local requirements. A material safety data sheet (MSDS) for halofuginone hydrobromide included in the EA, contains precautions to be taken during manufacture of the product with instructions for protective gear and first aid measures.

Halofuginone is toxic to aquatic organisms in part per billion concentrations. It has been found to be an ocular and dermal irritant. The premix and final finished feed are labeled to help avoid unintentional and uninformed exposures to humans and aquatic life.

1/8/92
Date

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1/9/92
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Attachment: Environmental Assessment, dated June, 1991.