

FINDING OF NO SIGNIFICANT IMPACT

f o r

**Safe-Guard® (Fenbendazole Premix)
For Use as an Anthelmintic in
Zoo and Wildlife Animals**

NADA 131-675

**Hoechst-Roussel Agri-Vet Company
New Jersey**

FOR PUBLIC DISPLAY

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for

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New Jersey

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.

Hoechst-Roussel Agri-Vet Co. has requested approval of their application for the manufacture and sale of Safe-Guard® (Fenbendazole Premix) for use as an anthelmintic in zoo and wildlife animals. Fenbendazole granules are approved for use in horses and dogs as specified under 21 CFR §520.905. In support of the NADA, Hoechst-Roussel has provided the attached environmental assessment (EA; dated September 1993). Bulk fenbendazole is manufactured at Hoechst AG, Frankfurt, Germany. The Type A Medicated Article is manufactured at Feed Specialties, Des Moines, Iowa and Purina Mills, Inc., Bridgeton, Missouri.

Hoechst-Roussel Agri-Vet Company's September 1993, EA contains as attachments, an EA for the Hoechst facility in Germany, a Material Safety Data Sheet (MSDS) for fenbendazole, and EAs for the two premix facilities, Feed Specialties, Des Moines, Iowa and Purina Mills, Inc., Bridgeton, Missouri.

The Hoechst AG EA contains a statement of compliance with the environmental regulations of Germany countersigned by an official of the State Government of Hesse (City of Darmstadt, Germany). The September 9, 1993, EA for Feed Specialties Company, Inc., lists the substances expected to be emitted, describes controls exercised to modify emissions, and permit numbers for air pollution control and disposal of solid waste. Additionally, the EA contains a statement of compliance with emissions requirements set by Federal, State, and local agencies. The March 12, 1993, EA for Purina Mills, Inc., lists the substances expected to be emitted, controls exercised to modify the emissions, and provides permit numbers for emissions regulations, liquid and solid waste discharge, and a certificate of compliance with the emissions requirements set by Federal, State, and local agencies.

We have reviewed the Hoechst-Roussel Agri-Vet Company's September 1993, EA along with the attached EAs for the Hoechst facility in Germany and for the two premix facilities, Feed Specialties, and Purina Mills, Inc., and the Material Safety Data Sheet (MSDS) for fenbendazole. Together, these provide adequate environmental and occupational safety information to determine that the manufacture of the product is not expected to have a significant impact on the human environment.

2/1/94
Date

- 2 -
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Attachments: Environmental Assessment dated September 1993