FINDING OF NO SIGNIFICANT IMPACT

for

IVOMEC® EPRINEX™ (eprinomectin) Pour-On
for Beef and Dairy Cattle

Merck & Co.
Rahway, NJ

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

Merck & Co. has submitted a new animal drug application for IVOMEC® EPRINEX™ (eprinomectin) Pour-On for Beef and Dairy Cattle. In support of the application, the drug sponsor has submitted an Environmental Assessment (EA), dated November 4, 1996, for the manufacture and use of EPRINEX™ as required under 21 CFR 25.31a(a) for new animal drug applications.

The EA provides information on manufacturing, emissions, and use of the product. The bulk drug substance will be produced at Merck facilities in Elkton, VA, and Danville, PA. Formulation and packaging of EPRINEX™ will take place at the Merck facilities in Barceloneta, Puerto Rico, and Haarlem, Holland. Citations of applicable laws and regulations and certifications that the sites are in compliance with applicable environmental and occupational safety requirements are provided. Material Safety Data Sheets (MSDS) for eprinomectin and EPRINEX™ pour-on are provided.

Merck has submitted a data package to address potential environmental effects from use of this product. The package contains environmental fate and effects studies for eprinomectin. These studies enabled the sponsor to develop an estimate of environmental concentrations; an exposure assessment, based on physical/chemical and fate data; and an effects assessment, based on a series of indicator organism toxicity tests.

Eprinomectin residues enter the environment through animal wastes. Information is provided in the EA to demonstrate that eprinomectin is sorbed tightly in soils and sediment. Comparison of predicted environmental concentrations and toxicity values for a variety of indicator organisms provides sufficient safety margins for tested aquatic and terrestrial organisms.

The EA addresses specific concerns about the potential for adverse impacts on dung dependent arthropods and dung degradation processes from the use of EPRINEX™ in pastured cattle (including dairy cattle) in the U.S. Previous assessments (e.g., IVOMEC® SR Bolus; NADA 140-988) have considered the additive effects from injectable, pour-on, and sustained release formulations. The present EA broadens these assessments to include lactating dairy cattle, a class of animals not previously incorporated into an assessment of anthelmintic use patterns.

The information provided in the EPRINEX™ EA supports the conclusion that the addition of dairy cattle as an eligible class for treatment would not significantly increase the percentage of total pastured cattle treated with anthelmintics and ectoparasiticides. Based on drug use patterns and beetle ecology

information, it is concluded that beetle populations and dung degradation processes would not be significantly impacted by the approval for use of this product.

Information in the EA also addresses potential impacts to avian species from exposures to this pour-on dosage form. The information indicates that significant impacts on avian species are not anticipated from the use of the product.

We have reviewed the EA and conclude that the EA provides adequate information to determine that the manufacture and use of EPRINEX™, as described in the EA, would not be expected to cause a significant impact on the environment.

12-20-96
Date

Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: November 4, 1996, Environmental Assessment