

FINDING OF NO SIGNIFICANT IMPACT

for

**Dectomax® (Doramectin) Pour-On Solution
for Beef and Non-Lactating Dairy Cattle**

**Pfizer Inc.
Groton, CT**

FOR PUBLIC DISPLAY

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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.

Pfizer Inc. has submitted a new animal drug application for Dectomax® (doramectin) pour-on solution for the treatment and control of parasitic infections in beef and non-lactating dairy cattle. The drug is applied topically along the dorsal midline of the back between the withers and tail head at the recommended dosage level of 500 ug doramectin per kilogram body weight. In support of the application, Pfizer Inc. has submitted an Environmental Assessment (EA), dated 8/2/96.

The EA provides information on manufacturing, emissions, and use of the product. The bulk drug substance (doramectin) will be produced at Pfizer's manufacturing plant in Nagoya, Japan. Dectomax pour-on solution will be manufactured at Pfizer's Lee Summit, Missouri, plant. 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 doramectin and Dectomax are provided.

Pfizer has submitted a data package to address potential environmental effects from the use of this product. The package contains environmental fate and effects studies for doramectin. Estimates of terrestrial (including dung pat) and aquatic concentrations are provided. An exposure assessment, based on physical/chemical and fate data; and an effects assessment, based on a series of indicator organism toxicity tests are provided. Comparisons of predicted environmental concentrations and toxicity values for indicator organisms, including avian toxicity, provide sufficient safety margins. Conducted experiments indicate that doramectin residues would be expected to remain appreciably bound in soils.

To address concerns that the use of Dectomax pour-on solution in pastured cattle in the U.S. may adversely impact dung dependent arthropods and dung degradation processes, Pfizer has provided the following studies and analyses:

- Effect of Doramectin on Immature Dung Beetles and Horn Flies
- Effects of Doramectin Pour-On on Three Species of Dung Inhabiting Insects
- Effect of Doramectin on Invertebrate Colonization and Disintegration of Dung Pats in Pasture
- Patterns of Drug Use information
- Ecology of Dung Beetles in the U.S.
- Potential Effects of Doramectin Treatment on Dung Degradation
- Hazard Assessment: exotic dung beetles

The EA supports the conclusion that sufficient doramectin-free dung would be available within a locale to maintain beetle populations and that effects on beetle populations or dung degradation rates, if any, would not be significant.

We have reviewed the EA and supporting information and find that the manufacture and use of Dectomax pour-on solution for use in beef and non-lactating dairy cattle is not expected to have a significant impact on the environment.

10/1/96 *A. C. Livingston*
Date Director, Office of New Animal Drug Evaluation, HFV-100

Attachment: Environmental Assessment: Dectomax® (Doramectin) Pour-On Solution for Beef and Non-Lactating Dairy Cattle