FINDING OF NO SIGNIFICANT IMPACT

Dectomax® (Doramectin) Injectable Solution
for Use in Beef and Non-Lactating Dairy Cattle

NADA 141-061

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) injectable solution for use in beef and non-lactating dairy cattle for the treatment of parasitic infections. The drug is administered by intramuscular or subcutaneous injection at a dose level of 200 mg doramectin per kilogram body weight. In support of the application, Pfizer Inc. has submitted an Environmental Assessment (EA), dated March 3, 1996, for Dectomax injectable solution.

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 injectable 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. 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. Comparisons of predicted environmental concentrations and toxicity values for indicator organisms

provide sufficient safety margins. Conducted experiments indicate that doramectin residues would be expected to remain appreciably bound in soils.

To address the concern that the use of Dectomax injectable 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 *in vitro* upon Immature Dung Beetles and Horn Flies
- Effect of Doramectin on Disintegration of Dung Pats in Pasture
- 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

The Hazard Assessment concludes that sufficient dortamectin-free dung should be available within a locale to maintain beetle populations and that effects on dung degradation rates, if any, would not be significant.

We have reviewed the March 3, 1996, EA and supporting information and find that the manufacture and use of Dectomax injectable solution for use in beef and non-lactating dairy cattle is not expected to have a significant impact on the environment.

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

Attachments: March 3, 1996, Environmental Assessment