FINDING OF NO SIGNIFICANT IMPACT

and

Enviromental Assessment

Dectomax® (Doramectin) Injectable Solution for Use in Swine

NADA 141-061 C0013

Pfizer Inc.
Groton, CT

FOR PUBLIC DISPLAY

FINDING OF NO SIGNIFICANT IMPACT

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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 supplement to the approved new animal drug application for Dectomax® (doramectin) injectable solution. The supplement provides for the use of the product in swine for the treatment of parasitic infections. The drug is administered by intramuscular injection. In support of the application, Pfizer Inc. has submitted an Environmental Assessment (EA) dated March 11,1996. A copy of the EA is attached.

The EA provides information on manufacturing and use of the product.

Pfizer Inc. has submitted a data package to address potential environmental effects from use of this product. The package contains environmental fate and effects studies for doramectin. These studies enable the development of an estimate of environmental concentrations, an exposure assessment, and an effects assessment.

Doramectin residues enter the environment through animal wastes. Information is provided in the EA that demonstrates that doramectin is sorbed tightly in soils and that sorption minimizes aquatic concentrations. A soil column leaching study confirms the experimentally derived Kd and Koc values. Comparison of predicted environmental concentrations and toxicity values for indicator organisms provides sufficient safety margins.

The EA provides adequate information to determine that the manufacture and use of doramectin injectable for swine would not be expected to cause a significant impact on the environment.

9-9-97
Date

R. C. Livingston
Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: March 11, 1996, Environmental Assessment