FINDING OF NO SIGNIFICANT IMPACT

for

Melengestrol Acetate MGA® 100/200 Premixes
for Heifers Intended for Breeding

NADA 034-254

Pharmacia & Upjohn Company
Kalamazoo, MI

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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 effect on the quality of the human environment and that, therefore, an environmental impact statement will not be prepared.

On June 25, 1996, the Pharmacia & Upjohn Company submitted an environmental assessment (EA, dated June 13, 1996) for the approval of NADA 034-254. NADA 034-254 provides for the use of melengestrol acetate MGA® 100/200 premixes for the suppression of estrus for heifers intended for breeding.

The EA provides information on manufacturing, emissions, and use of the product. The bulk drug substance and finished drug product will be manufactured at the Pharmacia & Upjohn Company facility in Kalamazoo, MI. 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 MGA are provided.

Pharmacia & Upjohn Company 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 MGA. These studies enable 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.

Predicted environmental concentrations of soil (PEC_{soil}) and water (PEC_{water}) were calculated to address environmental introductions from both feedyard and pasture-fed scenarios. Using these calculations, terrestrial organisms would be exposed to a maximum concentration somewhere between 1.80 ppb (PEC_{soil}) and 73.4 ppb (manure PEC) of MGA. In addition, MGA is not expected to partition into aquatic systems, based on the extent to which it binds to soil.

Nevertheless, the concentration of MGA in water was estimated from a soil sorption/desorption study. Using the lowest K_d measured, the maximum predicted MGA concentration (PEC_{water}) in water would be approximately 9.0 ppt (pg/ml).

The use of MGA to control estrus in heifers intended to breeding is not expected to significantly impact the environment.

The information provided in the June 25, 1996, EA, is adequate to conclude that the manufacture and use of melengestrol acetate MGA® 100/200 Premixes for the suppression of estrus for heifers intended for breeding is not expected to have a significant impact on the environment.

9-19-96 R. C. Livingston

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

Attachment: Environmental Assessment dated June 25, 1996