FILE

FINDING OF NO SIGNIFICANT IMPACT

for

Paratect Bolus (Morantel tartrate)
for Weanling Calves and Yearlings

NADA 134-779
Pfizer, Inc.

The Bureau of Veterinary Medicine has carefully 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 an environmental impact statement therefore will not be prepared.

Pfizer, Inc. has requested approval for the use of Paratect bolus (Morantel tartrate) to control parasitic gastro-enteritis in grazing cattle. The action provides for the oral administration of a single sustained-release Paratect bolus, containing 13.5 g of the active ingredient morantel base (equivalent to 22.7 g of morantel tartrate), to each weaned calf and yearling cattle weighing not less than 200 pounds at the start of the summer grazing season.

The active ingredient of Paratect bolus is the same as for the FDA-approved morantel tartrate for use in a feed premix (21 CFR 558.360) or as a single dose oral bolus (21 CFR 520.1450). The animals receiving Paratect bolus are expected to introduce into the environment morantel and morantel metabolites in concentrations similar to those expected from the currently marketed oral bolus or feed premix formulations. The proposed use of Paratect bolus in cattle is expected to displace other morantel tartrate formulations already approved for use in this species. Therefore, additional introductions of morantel tartrate into the environment are not expected to occur.

Pfizer, Inc. has submitted the attached environmental impact analysis report (EIAR) in support of the proposed use of Paratect bolus in cattle. The EIAR submitted and the previously submitted EIAR's and other environmental information (attached) are adequate to conclude that the proposed use of this drug is unlikely to result in significant environmental effects.

8/29/83
Date

Preparer, HFV-310

8/29/83
Date

Adriano R. Gabuten
Primary Action Officer, HFV-135

8/29/83
Date

Chief, Environmental Impact Staff, HFV-310

Attachment

cc: Orig. & Dup., NADA 134-779
Office File, HFV-310
Reading Board, HFV-310

MWassef:cbm:8/25/83