

FINDING OF NO SIGNIFICANT IMPACT

for

Morantel Tartrate
Feed Premix (NADA 92-444 C045)
and Bolus (NADA 93-903 C045)
for Use in Dairy Cattle

Pfizer Inc., Groton, CT

The Center for 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. is requesting approval of supplemental new animal drug applications for morantel tartrate feed premix (NADA 92-444 C045) and bolus (NADA 93-903 C045). The supplements provide for the deletion of the statement "not for use in dairy animals of breeding age" with subsequent directions providing for dairy animals of breeding age. The NADA's are currently approved for the use of the products in cattle with a warning against use in dairy cattle of breeding age. The dosage and indications for the products will remain the same as currently approved.

The action represents an increase in the use pattern of the drug and requires an environmental assessment (EA) under 21 CFR 25.31a(a) of FDA's new NEPA-implementing regulations. The firm has provided an EA (copy attached), signed November 7, 1986, in accord with these regulations. The EA submitted by the firm provides an assessment of the expected increase in the use of morantel tartrate resulting from its use in dairy cattle of breeding age. The EA points out that morantel tartrate is metabolized by dairy cattle essentially the same as for other cattle, and that the increase in annual use of morantel tartrate, resulting from its use in dairy cattle of breeding age, will not exceed the amount originally projected for its use. An EA for the original use of morantel tartrate in cattle, which resulted in a finding of no significant impact, is attached to the current EA. Additionally, it is expected that morantel tartrate will rapidly degrade in the environment as a result of photo-, chemical, and biological degradation. The Center has reviewed the EA addressing the current actions, in conjunction with the EA from the previous action, and concludes that the use of morantel tartrate in dairy cattle of breeding age will not have a significant impact on the quality of the human environment.

2/5/86
Date

Charles E. Guba
Preparer, HPV-152

Date

Adrian R. Gabuten
Primary Action Officer, HPV-135

2/5/86
Date

J. H. [Signature]
Chief, Environmental Staff, HPV-152

Attachment

cc: Orig. & Dup., (NADA 92-444 C-045 & (NADA 93-903 C-045)
Office File, HPV-152
Reading Board, HPV-152

CEEirkson:cbm:2/4/86(1.20)