FINDING OF NO SIGNIFICANT IMPACT

for

EXCENEL® (ceftiofur HCl oil) Sterile Suspension
for Bovine Respiratory Disease
NADA 140-890

The Upjohn Company
Kalamazoo, Michigan

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.

The Upjohn Company is proposing to use an oil suspension of ceftiofur HCl for injection (EXCENEL®) for the treatment of bovine respiratory disease. The drug would be administered by intramuscular injection at a dosage of 1.0 mg per pound of body weight repeated every 24 hours for three to five days, as needed. The dose and indication has been previously approved for ceftiofur sterile powder (21 CFR 522.313). The primary difference between the proposed and the approved product is that the proposed product is for over-the-counter use. However, because of the method of application, injection, and the indication for the treatment of a disease, EXCENEL® is not expected to significantly increase the use and environmental introduction of ceftiofur.

In support of their application, the firm has submitted an Environmental Assessment (EA), dated July 1990, which addresses the potential environmental impact of the manufacture of the bulk and finished drug at Kalamazoo, Michigan and the use of the product. We have reviewed the EA and find the proposed manufacture and use of ceftiofur suspension is not expected to have a significant impact on the environment.

7-25-90
Date

A.H. Kollath DVM
Primary Action Officer, HFV-133

7/25/90
Date

Preparer and Chief,
Environmental Sciences Staff, HFV-162

Attachment: Environmental Assessment w/ Appendices