

FINDING OF NO SIGNIFICANT IMPACT

for

Ceftiofur HCl Oil Suspension for Injection  
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 for the treatment of bovine respiratory disease. The drug would be administered by intramuscular injection at a dosage of 0.5 mg per pound of body weight repeated every 24 hours for three to five days, as needed. The product will be used in beef and non-lactating dairy cattle.

In support of their application, the firm has submitted an Environmental Assessment (EA), dated March 1988, which addresses the potential environmental impact of the manufacture of the bulk drug at Kalamazoo, Michigan.

We have reviewed the EA. This action could have been categorically excluded from the requirement for an EA under 21 CFR 25.24(d)(1)(iii) as a new formulation of a previously approved drug. See 21 CFR 522.313. Since the firm prepared an abbreviated EA containing useful information, we have chosen to prepare this finding of no significant impact and to make both available to the public.

7-8-1988  
Date

Gilbert Samuehou acting for CE+1  
Primary Action Officer, HFV-133

7-7-88  
Date

J. C. Matheson  
Preparer and Chief,  
Environmental Sciences Branch, HFV-162

Attachment: Environmental Assessment w/ Appendices