

FINDING OF NO SIGNIFICANT IMPACT

for

BANAMINE® Injectable
for Cattle

Schering-Plough Animal Health, Inc.
Kenilworth, NJ

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

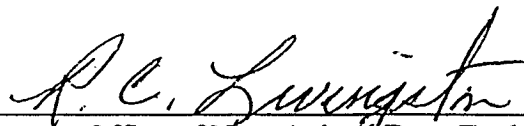
Schering-Plough Animal Health, Inc., has submitted a new animal drug application for BANAMINE® (flunixin meglumine) injectable for cattle. The product is for therapeutic use on a prescription basis. In support of the application, the drug sponsor has correctly submitted an environmental assessment (EA), dated June 5, 1996, for the manufacture of BANAMINE® as required under 21 CFR 25.31a(b)(4).

The EA provides information on manufacturing, emissions, control exercised on emitted substances, fate of emitted substances and the firm's compliance with applicable environmental and occupational requirements at the sites of product manufacture.

We have reviewed the EA and available study report data and find that they collectively demonstrate that significant environmental impacts are not expected from the manufacture of the product. Additionally, there is no information available to indicate that significant environmental effects are expected from the use and disposal of the product.

1-27-97

Date



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

Attachment: Environmental Assessment, dated June 5, 1996