

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
April 24, 1980

DATE: April 24, 1980  
SUBJECT: CIBA-GEIGY Proposal to Abort a 24-Month Mouse Study (initiated 9/6/79)  
due to Suspected Viral Infection.  
FROM: Laurence D. Chitlik, Toxicologist  
Toxicology Branch/HED (TS-769) *LD 4/24/80*  
TO: James Stone, Acting Product Manager #23  
Registration Division (TS-767) *B. 4/24/80*  
THRU: William L. Burnam, Acting Chief  
Toxicology Branch/HED (TS-769) *WLB*

CIBA-GEIGY believes that this metolachlor 24-month feeding study in mice has been compromised by viral infection and therefore, they want to abort the study. Raltech, on the other hand, believes that Sendai virus is responsible for the infection and that there is no need to terminate the study.

Toxicology Branch recommends that this study should not be aborted at this time. We find that the reasons cited by CIBA-GEIGY are too speculative. The stresses which they related to a viral infection, may also be compound related. We would have to have evidence that the animals demonstrated massive infection due to the virus before agreement can be reached that the study should be aborted. In order to document the viral infection, we propose the following:

1. Isolation of the virus, if possible.
2. Identification of the virus by standard serologic methods, i.e.-the serum neutralization test.
3. Measurement of specific antibody titer in the serum of exposed animals and variation of the titer through the course of the disease. Comparisons of specific antibody content should be made with other animals at Raltech.
4. Histopathologic examination for the specific lesions indicative, for example, of parainfluenza. (eosinophilic intra-cytoplasmic inclusions in lung tissue).

If any of the suggested work has already been completed, please have this information made available to us.