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RCB
5-11-82
Hummel
File petition
PP#8G2068

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 11 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Henry Jacoby (21)
Registration Division (TS-767)

SUBJECT: Vinclozolin; (RONILAN). Further Assessment of Mouse Oncogenicity Data. PP#8G2068
CASWELL#323C BAS 353F Fungicide.

We suggest that the registrant, BASF Wyandotte Corporation, be informed that upon further appraisal of the data from the mouse oncogenicity study of vinclozolin, it would appear vinclozolin at 4374 ppm may cause leukemia type tumors in male mice. In the treated mice we also noted 3 cases of adenoma in the liver; none were seen in the controls.

We recognize that such tumors are not rare in the mouse. We also acknowledge that, when comparing total numbers of tumors of all types in treated mice with total numbers of tumors in controls, oncogenicity is not evident. Therefore, in order to further elucidate the oncogenic potential of vinclozolin in the mouse, we request that tissues from the mid and low dose mice also be subjected to histological evaluation and that a report of the evaluation be submitted. In the report particular attention should be made to the leukemia and related diseases and to liver adenomas by animals and by organs in tabulating the results. An attempt also should be made at grading the lesions according to severity or deviation from average. Further, in order that risk assessments may be made, we request that applicator exposure assessments be provided for the various label uses of the pesticide.

A reevaluation of the study will be forwarded to you within one week.

Roland A. Gessert
LDC 5/10/82
RG 5/11/82

Roland A. Gessert, D.V.M.
Toxicology Branch
Hazard Evaluation Division (TS-769)

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