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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 10 1986

MEMORANDUM

SUBJECT: Atrazine Chronic Feeding/Oncogenicity Study
Preliminary Incidence Table of Tumors Regarding
Possible Section 6(a)(2) Effect

Caswell No. 63

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Background:

The registrant, Ciba-Geigy Corporation, notified the Agency that an increase in mammary tumors had occurred in the 1-year interim sacrifice data (see memorandum of H. Spencer, dated May 17, 1985). The present submission further addresses those earlier findings.

Comments and Recommendations:

Ciba-Geigy Corporation submitted preliminary summary incidence information on histopathological findings of the 2-year oncogenicity study of atrazine in Fisher 344 rats. In the summary tables submitted there were indications of increased numbers of tumors in the mammary glands of the female rats. These data were submitted to the statistical section of the Toxicology Branch for evaluation. Included as an attachment is the result of that statistical evaluation (memorandum of H. Lacayo, March 28, 1986).

It was found in the statistical evaluation of the preliminary data that a concern of a dose-related response does exist for the mammary tumor increases seen.

Unfortunately, the data are of a preliminary nature; are being reevaluated; and are not able to be evaluated without the submission of further information.

The Toxicology Branch will require historical control information on the Fisher 344 rat encompassing the last 5 years from the contract laboratory performing this study. This information is to include, but not be limited to, the onset and control incidence of tumors and tumor types by sex of the mammary glands of the Fisher 344 rat.

In addition, the evaluation of the preliminary data will require the individual incidence data and the remainder of the 2-year study data.

Toxicology Branch again points out the need to postpone further actions on the chemical, atrazine, until this evaluation has been finalized.

Attachment