CASWELL FILE

Atrazine / Review # 57 / 7.21.86 / 4 pages

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

Releasable

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 21 1986

MEMORANDUM

SUBJECT: Confirmation Letter from Registrant, Ciba-Geigy
Re: Length of Continuation of Mouse Oncogenicity Study on Atrazine

Caswell No.: 63

FROM: Henry Spencer, Ph.D. 7/18/86
Review Section VII
Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

THRU: Albin Kocialski, Ph.D., Supervisory Pharmacologist
Review Section VII
Toxicology Branch
Hazard Evaluation Division (TS-769C)
ABK 7/18/86

and

Theodore Farber, Ph.D., Chief
Toxicology Branch
Hazard Evaluation Division (TS-769C)
for UVS 7/15/86

Comment:

The registrant's representative, T. Parshley, telephoned the Agency on May 16, 1986 concerning an apparent problem of when to terminate the ongoing oncogenicity study on atrazine.

Toxicologist, H. Spencer, indicated that the Guidelines called for a minimum of 78 weeks on study and that at least a 25 percent survival rate must be maintained. Both requirements

had been met. Therefore, it was at the discretion of the registrant to terminate the study as long as the 25 percent survival was maintained.

The letter of Mr. T. Parshley dated June 3, 1986 is an accurate description of the conversation transpiring on May 16, 1986.

ATTACHMENT.

Agricultural Division
CIBA-GEIGY Corporation
P.O. Box 18300
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Telephone 919 292 7100

CIBA-GEIGY

June 3, 1986

Mr. Robert J. Taylor
Product Manager (25)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2 - Room 245
Arlington, VA 22202

Dear Mr. Taylor:

SUBJECT: CONFIRMATION OF TELEPHONE CONVERSATION REGARDING SURVIVAL/STUDY TERMINATION FOR ATRAZINE MOUSE CHRONIC TOXICITY STUDY

As you may recall, on May 16, 1986, CIBA-GEIGY contacted the Agency to request an opinion from the Toxicology Branch regarding the survival in an ongoing mouse chronic toxicity/ oncogenicity study being conducted with atrazine. The purpose of this letter is to document the ensuing conversation CIBA-GEIGY had with the Toxicology Branch.

CIBA-GEIGY spoke with Hank Spencer of the Toxicology Branch and provided the following information on survival in the ongoing subject study as of week 79.

- 21/60 high dose females were remaining (35%).
- The next lowest survival is 63% in the control females.
- Male survival in all doses ranges from 75-85%.

Several options regarding study termination were subsequently discussed. The initial recommendation from Dr. Spencer was to terminate the high dose females only when survival reached 25% and continue the study in the other dose groups. However, after consultation with the Toxicology Branch management, Dr. Spencer made the following comments:

- Since the Guidelines for a mouse chronic toxicity study call for a duration of 78 weeks minimum, the study requirement for duration has been met.
- Since the Guidelines also state that the study can be terminated when survival in any dose group reaches 25%, CIBA-GEIGY has the discretion to terminate the study when this occurs.

While no decision has yet been made in regard to study termination, CIBA-GEIGY does nonetheless concur with the Agency's determination that the study has met the minimum time requirements and study termination when survival reaches 25% in any dose group is at our discretion.

CIBA-GEIGY appreciates the open discussions on the part of the Agency regarding this matter. Notification will be made to the Agency if and when the study is terminated. It is obvious that because of the findings of mammary tumors in the atrazine rat study recently submitted to EPA, the results of this study can be of significance for the Agency's deliberations. Therefore, CIBA-GEIGY will attempt to allow the study to continue as long as sufficient survival allows for collection of meaningful results.

If there are any questions concerning matters contained in this letter, please do not hesitate to contact us.

Sincerely,

Thomas J. Parshley
Regulatory Specialist

TJP/cg/0211