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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Addendum to the 6/3/91 Memorandum of Brian Dementi to Joanne Edwards on "Malathion Chronic/Oncogenicity and Ocular Effects Testing Requirements"

Tox Chem. No.: 535
Project No.: 1-1412

FROM: Brian Dementi, Ph.D., D.A.B.T. Brian Dementi 6/24/91
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Upon receipt of the Agency's official copy of the May 2, 1991 letter of American Cyanamid's Michele Bassler to Ms. Lois Rossi, referencing the joint meeting of the Malathion Reregistration Task Force with EPA on March 21, 1991, Toxicology Branch has now had the opportunity to examine the four attachments which were not included with the faxed copy we commented upon earlier.

Attachment 1 is a study protocol (#971-90-186) for a "Chronic Dietary Toxicity and Carcinogenicity Study With AC6,601 in Mice", that would revise an earlier protocol (#971-90-161) submitted by American Cyanamid, by increasing the duration of the study from 18 to 24 months. However, TOX Branch has indicated in the June 3, 1991 memorandum of Dementi to Edwards that the study should preferably be conducted for an 18-month period to better emulate the original NCI study.

Attachments 2 and 3 concern, respectively, a protocol for a "13-week Dietary Toxicity Study in Albino rats with AC6,601," primarily intended to assess effects of malathion upon cholinesterase activity and a procedure for the actual measurement of cholinesterase activity. Inasmuch as TOX Branch affirmed in the June 3, 1991 memo the requirement for a new full 2-year chronic/oncogenicity study of malathion in the rat, the 13-week study is not considered necessary.

Attachment 4 is a protocol (#971-90-163) for a chronic/oncogenicity study of malaoxon in the rat. This particular protocol revises the time points for assaying cholinesterase activity from 6, 12 and 18 months and termination as presented in an earlier version, to 3, 6 and 12 months and termination. TOX Branch considers this revision to be satisfactory.

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