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CHEMICAL MANUFACTURERS ASSOCIATION

May 29, 1980

Mr. Frank D. Kover
Chief
Chemical Hazards Identification
Branch
Assessment Division
Environmental Protection Agency
401 M Street, S. W.
611 East Tower
Washington, D. C. 20460

R&S 113709

Dear Mr. Kover:

Reference is made to our letter of March 19, 1980 in which we mentioned that the Chemical Manufacturers Association (CMA) planned to conduct a histopathological examination of all remaining brain tissues in the flawed vinyl chloride inhalation study conducted at Industrial Bio-Test Laboratories (IBT). This investigation has now been completed by Dr. William Busey of Experimental Pathology Laboratories, Inc. and his pathology report is enclosed.

Dr. Busey's findings revealed the existence of seven olfactory neuroblastomas in rats exposed to vinyl chloride in the highest dose group. These tumors are of the same type as those reported by Maltoni in animals exposed to a similar concentration, and are thus supportive of his findings.

In addition, CMA also contracted with Dr. Bob West of Bob West Associates to conduct a review and audit of chamber concentration monitoring, body weight data, animal acquisition, and mortality logs. His report is also enclosed. Dr. West found numerous inconsistencies in the conduct of the study and concluded that results could be interpreted in a qualitative manner only.

After reviewing the reports, CMA considers that the IBT data do not warrant further study and CMA will be

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negotiating for a settlement with IBT shortly.

Sincerely,

Hasmukh Shah

Hasmukh C. Shah
Director Special Projects

HCS:md
Enclosures

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