



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

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

negotiating for a settlement with IBT shortly.

Sincerely,

Hasmukh Shah

Hasmukh C. Shah
Director Special Projects

HCS:md
Enclosures

CMA 004585



BY MESSENGER

CHEMICAL MANUFACTURERS ASSOCIATION

March 19, 1980

Mr. Frank D. Kover - TS 792
Chief
Chemical Hazards Identification
Branch
Assessment Division
Environmental Protection Agency
401 M Street, S.W.
611 East Tower
Washington, D.C. 20460

Dear Mr. Kover:

On January 14, 1977, Mr. Albert Clark forwarded to Mr. Robert McGaughy of EPA, on behalf of the Manufacturing Chemists Association (now the Chemical Manufacturers Association), a copy of the protocol and the 23-month status summary for the Association-sponsored research on vinyl chloride at Industrial Bio-Test Laboratories (IBT). Mr. Clark stated in that letter that the final report was expected to be submitted soon, and when available, would be forwarded to the Agency.

As you know, all testing undertaken at IBT has come under a cloud. In particular, serious flaws were discovered in the vinyl chloride study, and no final report of the IBT study was ever issued. The Association undertook to determine whether the vinyl chloride study could be validated through an audit of the pathology by Experimental Pathology Laboratories (conducted by Dr. William Busey). Dr. Busey subsequently submitted a report of his audit to the Association on January 9, 1979. It was reviewed by an Association task force and, because it was part of a larger audit (including a review of compliance of IBT with good laboratory practices), was not further distributed at that time. Unfortunately, because of the interim change in the management of the Association and the extraordinary increase in the scientific work of the Association caused by the Toxic Substances Control Act and related environmental legislation, we failed to send it to the Agency as a follow-up to Mr. Clark's letter of January 14, 1977.

Formerly Manufacturing Chemists Association—Serving the Chemical Industry Since 1872.

CMA 004586

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Mr. Kover
March 19, 1980
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Recently, the Association has established a task force to oversee and coordinate all scientific testing projects. In the course of reviewing existing projects, this group discovered that we had not made Dr. Busey's audit report on the vinyl chloride study available to the Agency. Accordingly, I am enclosing a copy of the audit report as a follow-up to Mr. Clark's letter of January 14, 1977.

As shown in the interim report sent to the Agency in January, 1977, three suspect brain tumors were noted in male rats at the high dose level. These brain tumors, plus one at the lower dose level, were confirmed by pathology subsequently conducted by IBT and then by Dr. Busey. Unfortunately, not all of the brain specimens were retained by IBT and not all retained specimens were examined. The Association has therefore concluded to determine whether additional information can be obtained from whatever brain specimens remain at IBT from this highly-flawed study by conducting histopathological examination of all remaining brain tissues. We have not identified any other findings that would appear to warrant further attempts to salvage other information from this study.

We apologize for failing to follow-up on Mr. Clark's earlier letter, and wish to assure you that we will, in the future, keep you apprised of any additional relevant information as it becomes available to us.

While CMA does not itself have a Section 8(e) reporting obligation, and while it appears that this information would not be reportable under Section 8(e) in any event, pursuant to our earlier commitment we are submitting it to the Agency.

Sincerely yours,

Hasmukh Shah

Hasmukh C. Shah, Ph.D.
Director, Special Projects

cc: (with enclosure)
Mr. Robert McGaughy
Office of Research &
Development
Environmental Protection Agency

CMA 004587