



CHEMICAL MANUFACTURERS ASSOCIATION

MAR 29 1995

March 23, 1995

Dear Vinyl Chloride Health Committee Members:

A March 22, 1995 letter to William Cibulus of ATSDR is enclosed for your review and files. I will contact Mr. Cibulus next week to schedule a meeting. If you have any questions, please call me at (202) 887-1192.

Sincerely,

Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

Enclosures

SL 107978



CHEMICAL MANUFACTURERS ASSOCIATION

SL 107979

March 22, 1995

William Cibulas, Ph.D.
Chief, Research Implementation Branch
Division of Toxicology
Agency for Toxic Substances & Disease Registry
1600 Clifton Road, N.E.
Mailstop E29
Atlanta, Georgia 30333

Dear Dr. Cibulas:

On January 23, Dr. Christopher DeRosa responded to my letter of November 28, 1994 indicating the intent of the Chemical Manufacturers Association (CMA) Vinyl Chloride Panel to address certain data needs for vinyl chloride identified by the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. DeRosa requested that the Panel take the lead role in developing the protocol for a two-generation reproductive toxicity study of vinyl chloride by the inhalation route.

We have prepared the enclosed protocol of such a study for ATSDR review. Pursuant to your telephone conversation with our counsel, Caffey Norman, we have not attempted to identify dose levels at this time. Dose levels would be determined after a review of existing literature or, if necessary, following a range-finding study, in either event in consultation with ATSDR.

You will note that in a few places information has been redacted from the enclosed protocol. The purpose of these deletions is to remove certain references that would limit the study to a particular laboratory. Such information will be included when a final protocol is submitted for review.

As Mr. Norman discussed with you, selecting dose levels and otherwise providing a completely final protocol for your review would require several additional weeks. We believe that it would be more useful if this time were devoted to considering ways that the enclosed protocol might be enhanced to include measures of

William Cibulas, Ph.D.

March 22, 1995

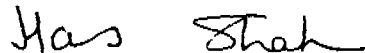
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developmental toxicity. In this regard, Dr. DeRosa's letter requested clarification of the statement in my letter of November 28 that "[i]n light of the existing two-species inhalation developmental toxicity study, and other available data concerning the developmental toxicity of vinyl chloride, we would like to discuss how [the reproductive toxicity] study **and other available data** might be enhanced to include measures of developmental toxicity as an alternative to the two-species developmental toxicity study referred to EPA." This passage was unfortunately garbled during our internal review and the phrase "and other available data" was mistakenly repeated. The italicized words should not appear in the sentence. Our intent is to determine in consultation with ATSDR scientists whether it is possible to include measures of developmental toxicity of interest to ATSDR in the protocol for the two-generation reproductive toxicity study that is enclosed for your review.

To facilitate this discussion, we also have enclosed a review of the available data on the developmental toxicity of vinyl chloride. We look forward to meeting with ATSDR scientists to discuss the strengths and weaknesses of the existing developmental toxicity data and options to obtain any needed additional data that do not require a full two-species developmental toxicity study.

We look forward to a meeting between scientists from the Vinyl Chloride Panel member companies and ATSDR in the near future to discuss the enclosed protocol, the utility of the available developmental toxicity data, and the ways the enclosed protocol might be enhanced.

Sincerely,



Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

Enclosures

cc: W. Caffey Norman, Esq.

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