



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

NOV 29 1995

received
11/29/95

Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, DC 20037

Dear Dr. Shah:

This is in response to your November 28 letter regarding the intent of the Chemical Manufacturers Association (CMA) Vinyl Chloride Panel to address vinyl chloride data needs identified by the Agency for Toxic Substances and Disease Registry (ATSDR). We have discussed your letter with Dr. Auer and his staff at the Environmental Protection Agency (EPA). ATSDR and EPA will continue to coordinate all voluntary research interests concerning chemicals identified in the September 30 notice (59 FR 49934).

We are pleased that CMA is interested in conducting voluntary research to address ATSDR's data needs for vinyl chloride. In your letter, you indicated that a Memorandum of Understanding (MOU) to address these data needs will be executed by May 31, 1995. Also, you suggested that CMA and ATSDR scientists meet to discuss the design of a two-generation reproductive study by the inhalation route, however, we request that CMA take the lead role in developing the study protocol. Consistent with ATSDR's published procedures for conducting voluntary research (57 FR 54160), we ask that CMA submit a study protocol to be reviewed by Agency scientists and a panel of peer reviewers selected by the Associate Administrator for Science, ATSDR. At that time, it would be appropriate for the Agency to discuss the study plan with CMA including study protocol and time schedule. The Agency and CMA may then choose to enter into an MOU after agreeing upon an approved study plan. A copy of the Federal Register notice describing these procedures is enclosed for your information.

With regard to ATSDR's data need for a 2-species developmental toxicity study via inhalation, please clarify the statement in your letter concerning the existing 2-species developmental study and other available developmental toxicity data. Specifically, we would like to know how such studies "might be

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enhanced to include measures of developmental toxicity as an alternative to the two-species developmental toxicity referred to EPA."

We look forward to our continuing dialogue with CMA leading to the signing of an MOU to conduct research to address ATSDR's data needs for vinyl chloride. If you have any questions, please contact me at 404-639-6300.

Sincerely yours,

A handwritten signature in cursive script that reads "Christopher T. DeRosa".

Christopher T. DeRosa, Ph.D.
Director, Division of Toxicology

Enclosure

CC:
Dr. Charles Auer

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