



CHEMICAL MANUFACTURERS ASSOCIATION

cc: DeRosa

June 9, 1995

Christopher T. DeRosa, Ph.D.
Director, Division of Toxicology
Agency for Toxic Substances and Disease Registry
1600 Clifton Road, N.E., Mailstop E29
Atlanta, Georgia 30333

Re: Vinyl Chloride

Dear Dr. DeRosa:

By letter dated May 4, you indicated that the Agency for Toxic Substances and Disease Registry (ATSDR) would be receptive to a proposal for a combined reproductive toxicity and developmental toxicity study to meet the identified data needs for vinyl chloride. In our conference call on May 16, Dr. William L. Breslin of the Dow Toxicology Research Laboratory described how we would propose to expand the protocol submitted by the Vinyl Chloride Panel on March 22 for a two-generation reproductive toxicity study by including an additional group of 30 female rats that would be mated and evaluated (including fetal evaluation) for the developmental parameters specified in the EPA guideline for inhalation developmental toxicity studies, 40 C.F.R. § 798.4350.

During the conference call, we indicated that the Panel would submit by June 9 a revised protocol to address the priority data needs identified by ATSDR for reproductive and developmental toxicity studies for vinyl chloride. The final protocol is enclosed.

My letter of November 28, 1994 indicated the Panel's intent to work with ATSDR toward the execution by May 31, 1995 of a memorandum of understanding (MOU) to address the data needs identified for vinyl chloride, consistent with the policy statement issued by ATSDR and EPA on November 18, 1994. Obviously, we will not be able to have an MOU in place by that deadline, but I believe that we are making significant progress. I understand that you will coordinate with EPA to extend, as appropriate, the time within which ATSDR will

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BFG 01862

Christopher T. DeRosa, Ph.D.
June 9, 1995
Page 2

notify EPA of the vinyl chloride testing to be conducted under a voluntary research agreement between the Panel and ATSDR, which in turn will extend the time for EPA to decide whether such agreement adequately addresses the testing needs identified by EPA in its September 30, 1994 solicitation notice.

In this regard, we understand that ATSDR will shortly be meeting with EPA and that you will discuss with EPA staff the rationale for their interest in the neurotoxicity of vinyl chloride, as well as the possibility of satisfying EPA's identified testing need by expanding the enclosed protocol to address additional neurotoxicity endpoints. We also would be interested in any comments EPA staff might have on the enclosed protocol.

We will wait to hear from you as to ATSDR's and EPA's responses. In particular, we will need to know whether the enclosed protocol should be revised and resubmitted to ATSDR prior to its submission to the panel of peer reviewers that we understand ATSDR will be selecting.

Sincerely,



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

Enclosure

cc: W. Caffey Norman, Esq.

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