

National Toxicology Program P.O. Box 12233 Research Triangle Park, NC 27709

January 18, 2005

Courtney M. Price Vice President, CHEMSTAR American Chemistry Council 1300 Wilson Boulevard Arlington, VA 22209

Dear Ms. Price:

I am writing in response to your Information Quality Act Request for Correction ("Request") dated July 1, 2004 and filed under the National Institutes of Health "Guidelines for Ensuring the Quality of Information Disseminated to the Public" on behalf of the Vinyl Chloride Health Committee (VCHC) of the American Chemistry Council. The VCHC requests that the entry for vinyl chloride contained in the 10th and previous editions of the Report on Carcinogens (RoC) be changed in the 11th, 12th and future editions based on concerns expressed in your letter. I have reviewed your request and appreciate you bringing these concerns to our attention.

As noted above, we read the Request as a complaint about the 10th RoC, and have considered your comments. We believe that the issues you have raised will be addressed in the 11th RoC.

At the time we received your Request, the NTP was already in the process of preparing a revision of the summary profile for the 11th RoC based on the current, publicly available scientific literature. Based on this review, including the publicly identified literature identified in the Request, the NTP believes that strong evidence supports an association between vinyl chloride exposure and the appearance of angiosarcoma of the liver in humans. We believe that the evidence for an association of vinyl chloride with brain cancer is somewhat weaker than that for angiosarcoma. Further, newer studies suggest that lung cancer, lymphoma, and leukemia may not be associated with vinyl chloride exposure. We will send you a copy of the revised summary profile for vinyl chloride upon final approval of the 11th RoC by the Secretary.

I would like to let you know that you may appeal the agency's decision either in writing or electronically within 30 days of receiving this response. Because we will be revising the vinyl

¹ These guidelines were issued pursuant to: (1) the Department of Health and Human Services "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public" (HHS Guidelines); (2) the Office of Management and Budget "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (OMB Guidelines); and (3) section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001.

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chloride profile in the 11th RoC, we will consider your appeal if filed within 30 days of its issuance. Your request should state the reasons for your appeal. It does not need to reference a tracking number. The request may be sent electronically to InfoQuality@od.nih.gov or in hard copy to the Associate Director for Communications, Office of the Director, National Institutes of Health, Building 1, Room 344, 1 Center Drive, Bethesda, Maryland 20892. If the appeal is sent in hard copy, please clearly mark the appeal and outside envelope with the phrase "Information Quality Appeal."

Sincerely,

hristopher J. Portier, Ph.D.

Associate Director