



December 13, 2011

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Rear Admiral William S. Stokes
Director, National Toxicology Program Interagency Center
for the Evaluation of Alternative Toxicological Methods
National Institute of Environmental Health Sciences
P.O. Box 12233 Mail Code K2-16
Research Triangle Park, NC 27709

Dear Admiral Stokes:

I am responding to Dr. Linda Birnbaum's June 30, 2011 letter requesting NLM review of the test method recommendations contained in the "ICCVAM Test Method Evaluation Report: Usefulness and Limitations of the Murine Local Lymph Node Assay for Potency Categorization of Chemicals Causing Allergic Contact Dermatitis in Humans" (NIH Publication No. 11-7709). These recommendations cover a specific criterion for the murine local lymph node assay (LLNA) when this assay is being used to categorize the potency of chemicals that may cause allergic contact dermatitis (ACD) in humans.

ICCVAM recommends that the specific potency criterion for positive results using the LLNA can help categorize some chemicals and products as strong skin sensitizers. However, a failure to meet this criterion cannot be the basis for demonstrating that a substance is not a strong skin sensitizer. ICCVAM recommends that additional testing or information would be needed to determine whether or not a substance is a strong human skin sensitizer. These recommendations are noted by ICCVAM as potential updates to the 2009 United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) currently being considered for adoption by Federal agencies.

NLM agrees with ICCVAM's recommendations. The ICCVAM evaluation process includes scientific peer review by an international independent panel or experts, review by the federally chartered Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), and several public commenting opportunities. ICCVAM considered the peer review report, and the SACATM and public comments in preparing the final recommendations.

As you know, NLM does not have any regulatory or testing authority that would need to be in compliance with these recommendations. NLM endorses ICCVAM's recommendations and ongoing work to promote and encourage the development and use of alternative test methods that are found to be effective and applicable. Access to these recommendations will be included in ALTBIB, NLM's Web portal on "Resources on Alternatives to the Use of Live Vertebrates in

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Biomedical Research and Testing” (<http://toxnet.nlm.nih.gov/altbib.html>). Noteworthy is that ALTBIB is being enhanced by NLM to provide even more access to ICCVAM-related content, including validated test methods and methods undergoing validation.

We are pleased to participate in the efforts of the ICCVAM, and look forward to continuing to serve on this committee as it works to facilitate the evaluation and adoption of test methods that provide improve animal welfare while protecting human health and the environment.

Yours truly,

Dr. Donald A.B. Lindberg