Dear Admiral Stokes,

This letter is in response to a request from Linda S. Birnbaum, Director, National Institute of Environmental Health Sciences, in a letter dated September 18, 2009. Dr. Birnbaum requested the Department of Energy’s review of the test method evaluation for the Reduced Murine Local Lymph Node Assay. These recommendations are contained in a document entitled: ICVAM Test Method Evaluation Report: The Reduced Murine Local Lymph Node Assay: An alternative Test Method Using Fewer Animals to Assess the Allergic Contact Dermatitis Potential for Chemicals and Products (NIH Publication No. 09-6349). This document presents an evaluation of the validation status of the reduced murine local lymph node assay (rLLNA) as a test method for assessing the potential of substances to cause allergic contact dermatitis.

This document was reviewed by staff in the Department of Energy’s Office of Science. Based on this review, the Department of Energy finds that the recommendations are consistent with the ICVAM efforts to identify test protocols that “more accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use.” The Background Review Document and the Test Method Evaluation Report have been developed in a thorough, open, and technically defensible manner. This report and its underlying documentation has been reviewed vigorously and made available for general public comment. Both reviewer and public comments were considered and responded to carefully.

The Department of Energy is not one of the Federal agencies that promulgates regulations or guidelines regarding the assessment of allergic contact dermatitis in regulated products and thus does not have relevant test methods for which the ICVAM test recommendations may be added or substituted.
Thank you for the opportunity to review these documents and please accept our appreciation for the time, effort, and expertise that were taken to develop these recommendations and their supporting background review documents.

Sincerely,

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Anna Palmisano, Ph.D.
Associate Director of Science
for Biological and Environmental Research