



Department of Energy
Office of Science
Washington, DC 20585



November 30, 2010

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:

This letter is in response to a request from Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences, in a letter dated June 10, 2010. Dr. Birnbaum requested the Department of Energy's review of the test method recommendations for three reports applicable to the murine local lymph node assay alternative test methods. These recommendations are contained in documents entitled: *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: BrdU-ELISA* (NIH Publication No. 10-7552); *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: DA* (NIH Publication No. 10-7551); and *ICCVAM Test Method Evaluation Report on Using the Murine Local Lymph Node Assay for Testing Pesticide Formulations, Metals, Substances in Aqueous Solutions, and Other Products* (NIH Publication No. 10-7512). These documents present the review of two modifications of the LLNA test methods that use non-radioactive approaches to evaluate the hazard potential of test substances to induce allergic contact dermatitis as well as an expansion of the test to include pesticide formulations, metals, substances tested in aqueous solutions, and other products.

These documents were 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 ICCVAM 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 Test Method Evaluation Report and the included Background Review Document have been developed in a thorough, open, and technically defensible manner. These reports and their underlying documentation have 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 does not promulgate regulations or guidelines regarding the assessment of allergic contact dermatitis in regulated products and thus does not have




relevant test methods for which the ICCVAM 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,

/s/

 Michael Kuperberg, Ph.D.
Office of Biological and Environmental Research