DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
and Prevention (CDC)
395 E Street, SW
Washington, DC 20201

February 7, 2011

RADM William S. Stokes, D.V.M., DACLAM
Director, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)
National Institute of Environmental Health Sciences (NIEHS)
P.O. Box 12233, Mail Code K2-16
Research Triangle Park, North Carolina 27709

Dear Dr. Stokes:

As requested by Dr. Linda Birnbaum, Director of NIEHS, in her letter of June 10, 2010, the National Institute for Occupational Safety and Health (NIOSH) is herein responding to you regarding test method recommendations for the Local Lymph Node Assay (LLNA), a test method for potential allergic contact dermatitis (ACD). These methods were recommended by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

NIOSH agrees that the recommended alternative methods are valid for performing the LLNA, as described in the ICCVAM evaluation report and the performance standards report. NIOSH acknowledges the requirement that each agency review these recommended test methods and notify the ICCVAM regarding test methods for which these alternative methods may be substituted. NIOSH is a research agency and has no regulatory testing requirements; however, NIOSH does perform some testing using the LLNA. These methods are applicable to NIOSH use of the LLNA, and NIOSH scientists participated in the evaluation of the new recommendations. NIOSH agrees that the LLNA can be applied to a wider domain of chemical formulations, mixtures, and vehicles than in earlier validations and recommendations; we have used and will continue to use it in screening or characterizing substances in such non-traditional mixtures or formulations. The recommended non-radioactive methods will be considered for use in studies involving screening for identification of potential ACD hazards. However, NIOSH use of the LLNA in assessing potential hazards has no problem with current methods using radioactive markers, and use of non-radioactive markers would require the development and standardization of new methods in our laboratories without reducing the number of animals used; therefore there would be no apparent benefit to the use of the recommended non-radioactive methods. NIOSH has informed scientists of these new recommendations and will continue to inform them via its Animal Care and Use Committee and training of laboratorians in use of the LLNA. The agency will continue to encourage use or consideration of alternative methods including these, in any animal-using tests that the agency may conduct. NIOSH will attempt to identify

and support research programs which may contribute to future development of other alternative test methods.

NIOSH commends the efforts and accomplishments of ICCVAM in reviewing and evaluating these alternative methods and other methods. We are proud of our participation on ICCVAM during its activity as an interagency committee.

Thank you for the opportunity to respond for NIOSH about this ICCVAM achievement.

Sincerely,

John Howard, M.D.
Director

cc:
Paul Nicolaysen, V.M.D.