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U.S. CONSUMER PRODUCT SAFETY COMMISSION
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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 Rear Admiral Stokes:

As required by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Authorization Act of 2000, we are pleased to inform you that the U.S. Consumer Product Safety Commission (Commission) voted unanimously on December 28, 2011, to approve the recommendation of ICCVAM regarding the Murine Local Lymph Node Assay (LLNA). The recommendation is that the LLNA should not be considered a standalone assay for skin sensitization potency classification. However, based on the strength of the analysis provided and the currently available database of LLNA data, this assay can be a valuable tool in a weight-of-evidence evaluation for determining the skin sensitization potency of a substance.

The Commission supports reducing the number of animals used and the pain or suffering associated with animal testing. The Commission also encourages the development and use of alternatives to animal test models. Labeling a consumer product regarding the hazards associated with that product is required by the Federal Hazardous Substances Act (FHSA). In order to determine the appropriate cautionary labeling for "strong sensitizers," animal testing may be necessary. In a tiered-testing strategy, a test substance is tested *in vivo* only if the appropriate hazard determination cannot be made from its physicochemical characteristics, expert opinion, prior human experience data, or existing animal testing data. Under the FHSA 15 U.S.C. §1261-1278, the determination of whether a substance is a "strong sensitizer" is based upon a weight-of-evidence approach. Therefore, the LLNA would fit into a weight-of-evidence evaluation under the FHSA for the purpose of classifying substances for labeling.

Although the ICCVAM proposal for using the LLNA test method for potency determinations does not impact the LLNA's requirement for using animals or the number of animals that will be required (based on the updated protocol), the application of this test method for potency determination could broaden the use of the LLNA protocol in place of guinea pig tests, and

therefore, could reduce the number of guinea pigs that are being used to assess skin sensitization potency. The agency encourages ICCVAM to continue to accrue data. Although the existing National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) database of LLNA test data is large (more than 600 substances), most of the available data consists of substances that are moderate, weak, or nonsensitizers, classes of substances that fall outside the CPSC's jurisdiction.

The briefing package sent to the Commission can be found on the Commission website (www.cpsc.gov) in the Library (FOIA) section at http://www.cpsc.gov/LIBRARY/FOIA/FOIA12/brief/iccvam.pdf.

Sincerely,

Todd A. Stevenson
Secretary