



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

We are pleased to inform you, as required by the ICCVAM Authorization Act, that the U.S. Consumer Product Safety Commission (Commission) voted unanimously on March 9, 2010 to approve the recommendations of ICCVAM regarding the murine Local Lymph Node Assay (LLNA) including: (1) updates to the test method protocol; (2) establishment of performance standards; and (3) a modified form of the assay, the reduced Local Lymph Node Assay (rLLNA). The revised LLNA test method protocol and the LLNA performance standards encourage the reduction, refinement, or replacement of animals in testing. In a tiered-testing strategy, a test substance is tested *in vivo* if the appropriate hazard determination cannot be made from physicochemical characteristics, expert opinion, prior human experience or animal testing. The rLLNA has an applicability that is very specific; the rLLNA provides the option of significant animal savings benefit where dose-response information is not needed, especially where substances are expected to produce negative results. Under the Federal Hazardous Substances Act "FHSA" 15 U.S.C. §1261-1278, the determination of whether a substance is a "strong sensitizer" or not is based upon a weight-of-evidence approach. Therefore, the LLNA and the rLLNA would fit into a weight-of-evidence evaluation under the FHSA for the purpose of classification for labeling. 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/foia10/brief/iccvam.pdf>.

Sincerely,


Todd Stevenson