

June 14, 2007

Dr. William S. Stokes  
Director, NICEATM and  
Executive Director, ICCVAM  
National Institute of Environmental Health Sciences  
PO Box 12233, MD EC-17  
Research Triangle Park, NC 27709

Re: FR notice dated May 17, 2007 (CPSC nomination of Local Lymph Node Assay) -  
response to call for nominations for potential Expert Panel [72 FR 23832].

Dear Dr. Stokes,

This letter is in response to the request for comments on the US CPSC proposal to ICCVAM-NICEATM for an updated evaluation of the validation status of the murine local lymph node assay. I am pleased to submit the nomination of Dr. G. Frank Gerberick to serve on the proposed expert panel to review an updated LLNA Background Review Document and (a.) the validity of proposed modifications to the LLNA (eg. non-radioactive protocols), (b.) as a stand-alone assay for potency determination for classification purposes, and (c.) to explore applicability domains to address Regulatory concerns over the LLNA's validity for testing mixtures, aqueous solutions, and metals. It is expected that this Expert Panel would also review any proposed ICCVAM recommendations for: (e.) current uses and/or limitations for above methods, (f.) test method protocols and/or decision criteria, (g.) performance standards, and (h.) future/additional studies.

Dr. Gerberick is an esteemed colleague at the Procter & Gamble Company in our corporate research division overseeing the global Skin Irritation/Contact Sensitization program. His extensive work over the past two decades in the field of dermal irritation/contact sensitization has made him one of the world's foremost authorities on contact allergy and dermal sensitization. This work has included his pioneering work with the LLNA assay and *in vitro* and *in silico* test methodologies for better scientific understanding of the risk factors for dermal sensitization. It is my opinion that he would be a substantial asset to ICCVAM/NICEATM in the evaluation of new information and proposed applications for the assay he helped pioneer.

Thank you for your thoughtful consideration,

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