



National Institutes of Health
National Institute of
Environmental Health Sciences
NTP Interagency Center for the Evaluation
of Alternative Toxicological Methods
P. O. Box 12233
Research Triangle Park, NC 27709
<http://iccvam.niehs.nih.gov>

March 5, 2013

Dr. George DeGeorge
Chief Scientific Officer
MB Research Laboratories
1765 Wentz Road
Spinnerstown, PA 18968

Dear Dr. DeGeorge:

Thank you for nominating the In Vitro Sensitization Assay (IVSA) for ICCVAM review. NICEATM and the ICCVAM Interagency Immunotoxicity Working Group have reviewed the data you submitted and completed a preliminary evaluation. Although the method seems promising for the detection of skin sensitizers, ICCVAM has decided not to continue with further evaluation.

ICCVAM is a partner in the International Cooperation on Alternative Test Methods (ICATM) (see <http://iccvam.niehs.nih.gov/about/icatm.htm>). One aim of the ICATM is to achieve greater efficiency and effectiveness by avoiding duplication of effort among the partners. The IVSA is very similar to one of the four 3-D human skin models that are being evaluated by the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) for the purpose of identifying skin sensitizers. This particular model also measures the production of IL-18 in response to exposure to test substances. Thus, the rationale for ICCVAM to suspend the evaluation of the IVSA is to avoid duplicating the effort of another ICATM partner.

EURL ECVAM's evaluation and validation will presumably result in the production of performance standards for mechanistically and functionally similar test methods. NICEATM will inform you about the development of such performance standards so that you can participate in the development as a stakeholder. After performance standards have been established, I suggest that you submit data so that the IVSA can be evaluated using the established performance standards.

We greatly appreciate your involvement in the development of alternative toxicity test methods that replace, reduce, and refine the use of animals and we look forward to working with you in the future.

Sincerely,

/s/

Warren Casey, Ph.D., DABT
Acting Director, NICEATM