



June 5, 2012

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 Admiral Stokes,

I am responding to Dr. Linda Birnbaum's February 1, 2012 letter requesting NLM review of the recommendations for the LUMI-CELL[®] Estrogen Receptor (ER) BG1Luc Estrogen Receptor (ER) Transcriptional Activation (TA) test method (NIH Publication No. 11 -7850). This method underwent an international validation study, followed by extensive evaluation of the results by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and others. This process led to ICCVAM's recommendations that the accuracy and reliability of this test method support its use as a screening test to identify substances with in vitro ER agonist or antagonist activity.

NLM agrees with ICCVAM's recommendations. As you know, we do not have any regulatory or testing authority that would need to be in compliance with these recommendations. We continue to endorse ICCVAM's recommendations and its ongoing work to promote and encourage the development and use of alternative test methods that are found to be effective and applicable. Access to these recommendations will be included in ALTBIB, NLM's Web portal on "Resources on Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing" (<http://toxnet.nlm.nih.gov/altbib.html>). ALTBIB will soon provide enhanced access to ICCVAM-related content, including easy access to validated test methods and methods undergoing validation.

We are pleased to participate in ICCVAM's efforts as it continues its work to facilitate the evaluation and adoption of test methods that provide improved animal welfare while protecting human health and the environment.

Yours truly,



/s/

Donald A.B. Lindberg, M.D.
Director