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Department of Energy
Office of Science
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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 Admiral Stokes:

This letter is in response to a February 1, 2012, request from Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences.

Dr. Birnbaum requested the Department of Energy's review of toxicological test method recommendations for an *in vitro* test method that seeks to detect substances with potential endocrine-disrupting activity. These recommendations are contained in a document entitled: *LUMI-CELL®Estrogen Receptor (ER) BG1Luc Estrogen Receptor (ER) Transcriptional Activation (TA) test method* (NIH Publication No. 11-7850). This document presents a review of, and makes recommendations concerning the use of a specific test method (BG1Luc ER TA that was developed by Xenobiotic Detection Systems, Inc.). The test method measures the induction or inhibition of transcriptional activation activity via estrogen receptor mediated pathways in recombinant cells.

These documents were reviewed by staff in the Department of Energy's Office of Science. Based on this review, the Department of Energy finds that the recommendations are consistent with the ICCVAM efforts to identify test protocols that "more accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use." The Test Method Evaluation Report and the included Background Review Document have been developed in a thorough, open, and technically defensible manner. These reports and their underlying documentation have been reviewed vigorously and made available for general public comment. Both reviewer and public comments were considered and responded to carefully.

The Department of Energy does not promulgate regulations or guidelines regarding the assessment of endocrine-active compounds in regulated products and thus does not have relevant test methods for which the ICCVAM test method recommendations may be added or substituted.

Thank you for the opportunity to review these documents and please accept our appreciation for the time, effort, and expertise that were taken to develop these recommendations and their supporting background review documents.

Sincerely,

/s/

J. Michael Kuperberg, Ph.D.
Office of Biological and Environmental Research