



U.S. CONSUMER PRODUCT SAFETY COMMISSION
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JUL 23 2012

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Executive Director
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Rear Admiral William S. Stokes
Director
National Toxicology Program Interagency Center for the
Evaluation of Alternative Toxicological Methods (NICEATM)
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709



Dear Rear Admiral Stokes:

On behalf of the U.S. Consumer Product Safety Commission, I am pleased to inform you that I have approved the recommendations of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) regarding the LUMI-CELL[®] Estrogen Receptor (BG1LucERTA) Screening Assay. Specifically, these recommendations are:

1. That the assay is accurate and reliable enough to “support its use to screen substances for *in vitro* estrogen receptor (ER) agonist and/or antagonist activity” and that the accuracy of the assay is “at least equivalent to that of the current ER TA test method included in regulatory testing guidance (EPA OPPTS 890.1300)”;
2. That the protocols provided in the ICCVAM NICEATM report are to be performed when using the LUMI-CELL[®] assay to screen substances, characterize the assay, or describe the assay limitations;
3. That a variety of future studies potentially could improve the usefulness and applicability of the test method;
4. That all data generated from assay refinement and comparative validation studies is to be provided to ICCVAM so that ICCVAM can further “characterize the usefulness and limitations of the BG1LucER TA test method as a screening test to identify substances with ER agonist or antagonist activity”; and

5. That performance standards developed by NICEATM and the Endocrine Disruptor Work Group (EDWG) are to be used by laboratories with no experience in order to demonstrate their technical proficiency at performing the LUMI-CELL[®] assay.

Cautionary labeling of a consumer product, regarding the hazards associated with that product, is required by the Federal Hazardous Substances Act (FHSA). In order to determine the appropriate labeling to use, product-associated substances first must be investigated toxicologically. Data from *in vivo* or non-animal test models (*i.e., in vitro* testing) may be used during this process to determine the substance's "toxicity" or status as a "chronic hazard" under the FHSA. The CPSC encourages the development and use of non-animal test models because they minimize the number of animals used and reduce the pain or suffering associated with animal testing.

Information from the LUMI-CELL[®] assay may be invaluable when determining whether a compound is a chronic hazard in a weight-of-evidence approach. The assay may also provide supporting information that reduces the need to use a full complement of test animals to determine whether a chemical or substance is a chronic hazard. The LUMI-CELL[®] assay, therefore, encourages the reduction, refinement, or replacement of animals in testing.

The LUMI-CELL[®] assay briefing memo sent to the Executive Director can be found on the CPSC website (www.cpsc.gov) in the Library (FOIA) section at <http://www.cpsc.gov/LIBRARY/FOIA/FOIA11/brief/Lumicell.pdf>.

Sincerely,

/s/

Kenneth R. Hinson
Executive Director