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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 8, 2012

RADM 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 Dr. Stokes:

This letter is in response to Dr. Linda S. Birnbaum's, Director, National Institute of Environmental Health Sciences, February 1, 2012 request that the US Food and Drug Administration review NIH Publication No. 11- 7850, ICCVAM *Test Method Evaluation Report: The LUMI-CELL® ER (BG1Luc ER TA) Test Method, An In Vitro Assay for Identifying HumanEstrogen Receptor Agonist and Antagonist Activity of Chemicals.*

FDA agrees that the accuracy and reliability of the BG1Luc ER TA test method support its use as a screening test to identify substances with *in vitro* ER agonist or antagonist activity. However, FDA notes that with respect to use of the BG1Luc ER TA test method and FDA-regulated products, FDA does not envision a use for this method in its current regulatory framework.

In accordance with Sections 4 (a)-(e) of the ICCVAM Authorization Act, FDA has addressed each of the requirements as follows:

1. Identification of Tests: The use of this assay may not have utility for FDA-regulated products at this time.
2. Alternatives: FDA is committed to promoting and encouraging the use of alternatives when appropriate. FDA's guidance can be found on our website at www.fda.gov. FDA has no specific plans for modifying any guidance as a result of these recommendations.
3. Recommendation Adoption: The FDA concurs with the technical aspects of the recommendations. However, the ICCVAM test recommendations are not acceptable for satisfactorily fulfilling the test needs for FDA regulated products.

The FDA appreciates the opportunity to review these materials, and acknowledges the time and energy ICCVAM devotes to advancing the "three Rs" principles of reduction, refinement and replacement of animal use and looks forward to continuing interactions with ICCVAM as part of the FDA's commitment to applying the 3 R's, where possible, in FDA programs.

Sincerely,

/s/

Jesse Goodman, MD, MPH
FDA Chief Scientist & Deputy Commissioner for
Science & Public Health