DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
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RADM William S. Stokes
Rear Admiral, US Public Health Service
Director, National Toxicology Program Interagency Center for
the Evaluation of Alternative Toxicological Methods
National Institute of Environmental Health Sciences
P.O. Box 12233, K2-16
Research Triangle Park, North Carolina 27709

Dear RADM Stokes:

I am responding to Dr. Birnbaum's February 1, 2012, letter to me transmitting the LUMI-CELL® Estrogen Receptor (ER) BG1Luc Estrogen Receptor (ER) Transcription Activation (TA) test method recommendations from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) as required by Section 3(e)(4) of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*-3). As indicated in the ICCVAM report, the test method recommendations relate to test methods and strategies are proposed to further reduce and refine the use of animals when used as a screening test to identify substances with *in vitro* ER agonist or antagonist activity.

We appreciate the Committee's recommendations and note that the ICCVAM Authorization Act (P.L. 106-545, Section 5, Application (a)) states that this Act does not apply to NIH programs. You should know, however, that the Office of Laboratory Animal Welfare within the Office of Extramural Research will provide access to ICCVAM's test recommendations through a Web link.

NIH remains committed to animal welfare efforts and to research efforts that improve human and animal health. Additionally, we promote the development of sound research designs and alternative methods to reduce the use of animals in biomedical research.

My understanding is that other components of the NIH will be responding to your transmittal as well.

Sincerely yours,

/s/

Francis S. Collins, M.D., Ph.D.
Director