JUL 17 2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 10 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Rear Admiral William S. Stokes
Director, NTP Interagency Center for the Evaluation of
Alternative Toxicological Methods
National Institute of Environmental Health Sciences
Post Office Box 12233
Research Triangle Park, North Carolina 27709

Dear Admiral Stokes:

The Administrator of the U.S. Environmental Protection Agency received the February 1, 2012 letter from Dr. Linda S. Birnbaum, Director of the National Institute of Environmental Health Sciences and National Toxicology Program, concerning the BG1Luc Estrogen Receptor Transcriptional Activation assay and its potential use in the EPA's Endocrine Disruptor Screening Program. I am pleased to respond on the Administrator's behalf, and as requested by Dr. Birnbaum I am sending the EPA's response to you.

The EPA regards the BG1Luc assay as an alternative to the OCSPP 890.1300 test guideline for transcriptional activation currently used in the EPA's Endocrine Disruptor Screening Program. The EPA participated in ICCVAM's Interagency Endocrine Disruptor Working Group and the Organisation for Economic Cooperation and Development's Validation Management Group for Non-Animal Testing while these groups were evaluating the BG1Luc assay, and we concur with the opinion of ICCVAM and the VMG-NA that the BG1Luc assay is validated for the purpose of identifying substances with *in vitro* ER activity. The BG1Luc assay has been approved by the OECD's Working Group of National Coordinators of the Test Guidelines Programme (April 2012) and the OECD has requested written approval by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology no later than 12 July 2012 and publication in Fall 2012. When adopted by OECD as an international test guideline for detecting ER agonist and antagonist activity of chemicals, all 34 member countries, including the United States, will accept testing data generated in accordance with the BG1Luc ER TA Test Guideline. Adequately performed studies using the BG1Luc assay will satisfy the Estrogen Receptor Transcriptional Activation requirement of the EDSP.

The EPA thanks ICCVAM for the extensive effort it undertook to validate the BG1Luc assay and to coordinate its adoption internationally.

Sincerely,

/s/
Frank T. Sanders
Director
Office of Science Coordination and Policy