U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

Administrator

1200 New Jersey Avenue SE
Washington DC 20590

JUL - 3 2012

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 responds to your February 1, 2012 request that the Department of Transportation review and comment on the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) test method evaluation report entitled "The Lumi-Cell Estrogen Receptor (ER) (BG1Luc ER TA) Test Method: An in Vitro Assay for Identifying Human Estrogen Receptor Agonist and Antagonist Activity of Chemicals." Your letter and the ICCVAM evaluation were referred to the Pipeline and Hazardous Materials Safety Administration (PHMSA), the agency within DOT responsible for regulating the transport of hazardous materials in commerce and participating in the ICCVAM.

We recognize the potential of these recommendations to reduce and refine the use of animals for assessing whether a chemical binds competitively at the ER, blocks the binding of estrogen at the ER, or accelerates degradation of the ER. Though we also recognize the importance of the ability to test for agonist and antagonist activities of chemicals for assessing the risk of their long term effects of cell proliferation such as cancer at woman's target organs containing the ER, the DOT's classification procedures are primarily designed to protect the public from acute and short-term exposure to chemicals during transportation. Consequently, the Federal Hazardous Materials Regulations (HMR 49 CFR 171-180), administered by the DOT, do not include requirements to determine whether a hazardous chemical is an agonist or antagonist for the ER.

Thank you for offering PHMSA the opportunity to serve as a member of ICCVAM and to formally comment on ICCVAM evaluation reports. If we can be of further assistance or answer any additional questions, please do not hesitate to contact Dr. Steve Hwang, our ICCVAM representative from the Office of Hazardous Materials Safety, at 202-366-4476.

Regards,

/s/

Cynthia L. Quarterman

S10-120203-007