



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

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JUL 17 2012

Dr. Linda S. Birnbaum
Director
National Institute of Environmental Health Sciences
& National Toxicology Program
Post Office Box 12233
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Dear Dr. Birnbaum:

Thank you for your letter of February 1, 2012, to Secretary Thomas J. Vilsack regarding the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods' (ICCVAM) recommendations for adoption of the LUMI-CELL® Estrogen Receptor (ER) BG1Luc ER Transcriptional Activation (TA) assay.

Our Agency of the Department of Agriculture (USDA) appreciates the opportunity to follow up on our interim response of February 28, 2012. We provided these ICCVAM recommendations to scientists with our Agency's Center for Veterinary Biologics (CVB) and with USDA's Food Safety and Inspection Service (FSIS) for their review. CVB conducts a limited amount of animal testing in accordance with its responsibilities under the Virus-Serum-Toxin Act (VSTA) to ensure that veterinary vaccines and biologics are pure, safe, potent, and effective. FSIS protects public health through food safety and defense, and tests for drug residues and chemical contaminants in meat, poultry, and egg products through the U.S. National Residue Program (NRP) under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act.

Upon review of the information, officials with our Agency and FSIS determined that the recommendations for the use of the LUMI-CELL® ER BG1Luc ER TA assay do not apply to the testing done under the mandates of the VSTA or NRP. Our Agency and FSIS do not employ or require this type of testing or utilize the recommended test endpoint. However, we certainly appreciate the opportunity to review the recommendations and assure you that we will assist in transmitting ICCVAM's recommendations to the regulated animal research community. Our Agency will temporarily post links to the committee's recommendations on the Animal Welfare Information Center's home page at <http://awic.nal.usda.gov/> and will permanently post them at <http://awic.nal.usda.gov/alternatives/> under "Alternatives in Toxicology." This will serve as a resource for investigators considering alternatives to painful or distressful procedures in animals.



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Thank you again for providing this information. USDA continues to encourage the development and use of methods that reduce, refine, or replace animal testing while ensuring the scientifically valid results necessary for regulatory testing.

Sincerely,

/s/

Kevin Shea
Acting Administrator