



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Washington, DC
20250

Samuel H. Wilson
Acting Director
National Institute of Health
P.O. Box 12233
Research Triangle Park, NC 27709

APR 16 2009

Dear Mr. Wilson:

Thank you for your letter of October 23, 2008, to the Department of Agriculture (USDA) concerning *in vitro* test methods forwarded by the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

We appreciate the opportunity to review ICCVAM's test recommendations on the use of five *in vitro* methods proposed for assessing potential pyrogenicity of pharmaceuticals and other products, as potential replacements for the *in vivo* rabbit pyrogen test. As you know, USDA's Center for Veterinary Biologics (CVB) is the only regulatory unit within USDA that requires animal testing. In accordance with its responsibilities under the Virus-Serum-Toxin Act (VSTA), CVB conducts a limited amount of animal testing to ensure that veterinary vaccines and biologics are pure, safe, potent, and effective. However, CVB does not utilize the rabbit pyrogen test to fulfill its responsibilities under the VSTA.

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 requirements. Accordingly, we will post links to these methods on the Web site of the Animal Welfare Information Center at <http://awic.nal.usda.gov/alternatives/> as a resource for investigators considering alternatives to painful or distressful procedures in animals. Thank you again for providing this information.

Sincerely,

A handwritten signature in black ink, appearing to be "KS" or "K Shea", written in a cursive style.

Kevin Shea
Acting Administrator



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