USDA

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

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OCT - 9 2009

Dr. Linda S. Birnbaum
National Institute of Environmental Health Sciences
National Institutes of Health
U.S. Department of Health & Human Services
Post Office Box 12233
Research Triangle Park, North Carolina 27709

Dear Dr. Birnbaum:

Thank you for your letter of September 18, 2009, forwarding to Secretary Thomas J. Vilsack toxicological test method recommendations from the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

We provided ICCVAM's test recommendations for the reduced murine local lymph node assay (rLLNA), the updated LLNA test method protocol, and the LLNA test method performance standards to scientists with our Agency's Center for Veterinary Biologics (CVB) for their consideration. 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. It is the only regulatory unit within the U.S. Department of Agriculture (USDA) that requires animal testing.

After reviewing the information, CVB officials determined that these recommendations do not apply to the safety testing done under the mandates of the VSTA for veterinary biologicals. However, we certainly appreciate the opportunity to review the recommendations. Our Agency 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. 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. We look forward to receiving more such recommendations from ICCVAM.

Sincerely,

/S/

Cindy J. Smith
Administrator