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United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

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

Dear Dr. Birnbaum:

Thank you for your letter of June 10, 2010, to Secretary Thomas J. Vilsack regarding test method evaluation reports and recommendations from the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

We provided these ICCVAM reports and recommendations on the LLNA: BrdU-ELISA and the LLNA: DA, two nonradioactive versions of the murine local lymph node assay (LLNA), as well as on an expanded LLNA applicability domain, 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, our officials determined that the reports and recommendations do not apply to the safety testing done under the mandates of the VSTA for veterinary biologics. However, we certainly appreciate the opportunity to review these materials. 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,

Jose R. Diez
Associate Deputy Administrator
Emergency Management
Veterinary Services



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