



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

4700 River Road
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JUL 18 2011

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

Dear Dr. Birnbaum:

Thank you for your letter of June 30, 2011, to Secretary Thomas J. Vilsack regarding toxicological test method recommendations from the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

We provided these ICCVAM recommendations for a specific criterion for the murine local lymph node assay to be used in potency categorization of chemicals that may cause allergic contact dermatitis in humans 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 Department of Agriculture (USDA) that requires animal testing.

After reviewing the information, our officials determined that the recommendations do not apply to the testing done under the mandates of the VSTA for veterinary biologicals. 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. In addition, we will inform the inspectors in our Animal Care program that these test recommendations and the agencies' responses will be made available on the National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods-ICCVAM Web site.



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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 requirements.

We look forward to receiving more such recommendations from ICCVAM.

Sincerely,

/s/

Jose R. Diez
Associate Deputy Administrator
Emergency Management
Veterinary Services