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United States Department of Agriculture

Animal and Plant Health Inspection Service

4700 River Road Riverdale, MD 20737 APR - 7 2008

Dr. Samuel H. Wilson Acting Director U.S. Department of Health and Human Services National Institutes of Health Post Office Box 12233 Research Triangle Park, North Carolina 27709

Dear Dr. Wilson:

Thank you for your letters of October 25, 2007, and February 28, 2008, to former Secretary Mike Johanns concerning toxicological test method recommendations forwarded by the National Institute of Environmental Health Sciences' Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

We are pleased to respond. We provided ICCVAM's test recommendations on the use of four *in vitro* methods for ocular toxicity testing and the use of two *in vitro* methods for estimating starting doses for acute oral systemic toxicity tests 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,

Levin Shea / for Cindy J. Smith Administrator

