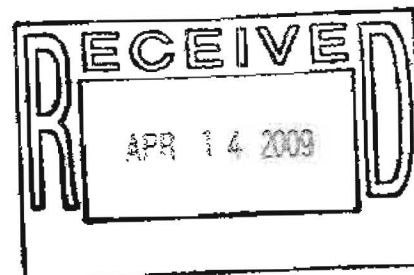




April 13, 2009



Rear Admiral William S. Stokes
Executive Director, ICCVAM, NIEHS
P.O. Box 12233 Mail Code EC-17
Research Triangle Park, NC 27709

Dear Rear Admiral Stokes:

I am responding to Dr. Samuel H. Wilson's October 23, 2008 letter requesting the NLM's review of the *ICCVAM Test Method Evaluation Report (TMER): Validation Status of Five In Vitro Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products* (NIH Publication No. 08-6392). This review is required by Section 3(e)(4) of the ICCVAM Authorization Act 01'2000 (42 U.S.c. 285/-3).

The TMER's recommendations include that the five methods should be considered on a case-by-case basis as described in this report before animals are used for detection of Gram-negative endotoxin in human parenteral drugs. The ICCVAM evaluation process that led to these recommendations included review by an independent scientific peer review panel, and comments from the public and the federally chartered Scientific Advisory Committee on Alternative Toxicological Methods (SACATM).

As you know, we do not have any regulatory or testing authority that would need to be in compliance with this report's recommendations. We do, however, heartily endorse the recommendations and the continued work to promote and encourage the development and use of alternative test methods that are found to be effective and applicable.

We will be including these methods in ALTBIB, our NLM database on "Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing" (<http://toxnet.nlm.nih.gov/altbib.html>). This database provides bibliographic references on many issues related to animal testing, and uses pre-formulated strategies to help users find literature citations in PubMed. It also provides links to additional useful sources of information related to alternatives to animal testing.

We are happy to participate in the important efforts of the ICCVAM, and look forward to continuing to serve on this committee as it works to facilitate the evaluation and adoption of test methods that provide improved animal welfare as while protecting human health and the environment.

Yours truly,

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Donald A.B. Lindberg, M.D.
Director