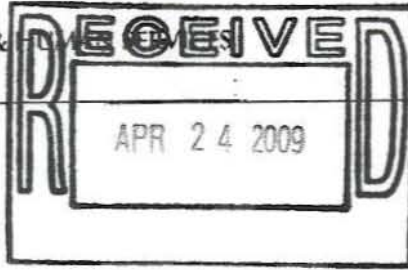




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DEPARTMENT OF HEALTH & HUMAN SERVICES



Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

APR 24 2009

RADM William S. Stokes, D.V.M.
Executive Director
Interagency Coordinating Committee on the Validation of Alternative Methods
National Institute of Environmental Health Sciences
P.O. Box 12233
Mail Code EC-17
Research Triangle Park, North Carolina 27709

Dear Dr. Stokes:

I am responding to the request of Samuel H. Wilson, M.D., Acting Director, National Institute of Environmental Health Sciences (NIEHS), that the Agency for Toxic Substances and Disease Registry (ATSDR) review recent test-method recommendations released by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). ATSDR has completed its review of the ICCVAM Background Review Document (NIH Publication No: 08-6391) and the Test Method Evaluation Report (NIH Publication No: 08-6392) for the "Validation Status of Five In Vitro Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products." Please excuse the delay of this response.

ATSDR commends the work of ICCVAM toward reduction, refinement, and replacement of animals in toxicity testing. This challenge is tremendous: promoting advances in alternative methods that maintain scientific quality is a laudable goal.

ATSDR concurs with the report recommendations regarding these methods for testing acute oral toxicity. The test results should be used in a weight-of-evidence approach for determining starting doses for *in vivo* studies.

Thank you for the opportunity to review and comment on these proposed test methods. If you need any further information, please contact Moiz Mumtaz, Ph.D., Science Advisor, Division of Toxicology and Environmental Medicine (DTEM), our principal agency representative to ICCVAM, at (770) 488-3349, or Bruce Fowler, Ph.D., Assistant Director of Science, DTEM, ATSDR at (770) 488-7250.

Sincerely,

(S)

Richard E. Besser, M.D.
Acting Director, Centers for Disease Control
and Prevention, and
Acting Administrator, ATSDR

cc:

Linda Birnbaum, Director, NIEHS
Moiz Mumtaz, Ph.D.
Bruce Fowler, Ph.D.