DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
NTP Interagency Center for the
Evaluation
of Alternative Toxicological Methods
P. O. Box 12233
Research Triangle Park, NC 27709
919-541-2384
http://iccvam.niehs.nih.gov

February 5, 2007

Dr. Jerry Smrchek
U.S. National Coordinator for the
OECD Test Guidelines Program
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Mail Code 7403M
Washington, DC 20460

Dear Dr. Smrchek:

On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), we are pleased to provide the enclosed comments on the most recent revised version of the proposed draft OECD Test Guideline (TG) "The Uterotrophic Bioassay in Rodents: a short-term screening test for oestrogenic properties." These comments are in response to your January 29, 2007 notification that the OECD has requested a round of comments on a second revised version of the original draft TG. The previous sets of comments relating to this test method are attached and it is requested that they be addressed before proceeding with further consideration of this draft TG.

As stated in previous comments submitted by ICCVAM to the U.S. National Coordinator on this test method and the proposed test guideline, ICCVAM and its Endocrine Disruptor Working Group have concluded, with only one agency in disagreement, that the uterotrophic bioassay has not been adequately validated for its intended purpose. Thus, ICCVAM's recommendation is that this material be placed in an OECD Guidance Document, which could then be used as the basis for further studies that could lead to an adequate demonstration of validation. This is identical with the approach proposed by the OECD for the uterotrophic bioassay to detect estrogen antagonists.

In addition, the OECD needs to fully recognize the importance of having TGs based on adequately considered and evaluated draft TGs and that providing a revised TG with only a few days to consider it is entirely inappropriate. It is critical to the success of the TG program and the acceptance of data under MAD that adequate time for a careful review be provided.

We appreciate the opportunity for the ICCVAM to provide comments on this draft TG. If you have questions or concerns regarding these comments, please contact myself or Dr. Marilyn Wind (301-504-7246).

Sincerely,

William S. Stokes, D.V.M., D.A.C.L.A.M.
Director, NTP Interagency Center for
the Evaluation of Alternative
Toxicological Methods (NICEATM)

Marilyn L. Wind, Ph.D.
Chair, Interagency Coordinating
Committee on the Validation of
Alternative Methods (ICCVAM)

Enclosure

cc:
Mr. Gary Timm
ICCVAM
ICCVAM EDWG