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Dated: April 14, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), NTP Interagency Center for the Evaluation of Alternative Test Methods (NICEATM); In Vitro Endocrine Disruptor Test Methods: Request for Comments and Nominations

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) have identified *in vitro* endocrine disruptor screening methods as a priority for validation. ICCVAM has published guidelines for development of *in vitro* endocrine-disruptor estrogen and androgen receptor binding and transcriptional activation assays. In these guidelines, ICCVAM recommends that priority be given to assays that (1) do not require the use of animal tissue as the receptor source, but rather use recombinant-derived proteins and (2) do not use radioactive materials. On behalf of the ICCVAM, NICEATM invites the nomination for validation studies of *in vitro* test methods that meet these recommendations and for which there are standardized test method protocols, pre-validation data, and proposed validation study designs. At this time, ICCVAM has received nominations for two *in vitro* endocrine-disruptor screening methods purported to meet these recommendations. Information on the nominated methods is posted on the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov*) or available from NICEATM (contact information provided below). ICCVAM will consider nominations and comments received in response to this notice and develop recommended priorities for proposed evaluation and validation studies of endocrine disruptor screening methods.

Request for Comments and Nomination of In Vitro Endocrine Disruptor Test Methods

Comments and nominations submitted in response to this notice should be sent by mail, fax, or e-mail to NICEATM (Dr. William S. Stokes, Director, NICEATM, NIEHS, 79 T. W. Alexander Drive, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *iccvam@niehs.nih.gov*) by June 7, 2004, in order to ensure their consideration by the ICCVAM.

SUPPLEMENTARY INFORMATION: In May 2003, ICCVAM published a report entitled, ''ICCVAM Evaluation of *In Vitro* Test Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays' (NIH Publication No. 03–4503; available: *http://iccvam.niehs.nih.gov/methods/endocrine.htm*). During its evaluation of *in vitro* endocrine disruptor screening assays, ICCVAM recommended that preference be given to development of assays that (1) do not require the use of animal tissue as the receptor source, but rather use recombinant-derived proteins and (2) do not use radioactive materials. ICCVAM also recommended minimum procedural standards that should be incorporated in standardized test method protocols and minimum lists of chemicals that should be used for validation studies. ICCVAM subsequently received nominations of two methods for validation studies. The first nomination is for a biosensor system that can assess estrogen receptor binding and transcriptional activation. The second nomination is for a stably transfected recombinant cell-based transcriptional method. The methods meet the ICCVAM's recommendations for studies that do not require the use of animals as a receptor source or use radioactive materials. Both methods detect receptor agonist and antagonist activity.

ICCVAM reviewed the two nominations described above and unanimously approved the following draft recommendation: ''Evaluation studies for *in vitro* receptor binding and transcriptional activation test methods that do not require the use of animals should receive a high priority for support. Prior to the initiation of such studies, the proposed validation studies should be evaluated for adherence to relevant recommendations in the report: ''ICCVAM Evaluation of *In Vitro* Test Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays'' (NIH Publication No. 03–4503) by the ICCVAM Endocrine Disruptor Working Group (EDWG) and NICEATM.''

ICCVAM subsequently presented these nominations and its recommendation to the SACATM at its March 10–11, 2004 meeting. SACATM concurred with ICCVAM that endocrine disrupting screening assays should be a priority.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM promotes the development, validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess the safety or hazards of chemicals and products and test methods that refine, reduce and replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) established ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://iccvam.niehs.nih.gov.*

Dated: April 9, 2004.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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