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) Notice of Availability of an Expert Panel Report on the Current Validation Status of *In Vitro* Endocrine Disruptor Screening Methods and a Proposed List of Substances for Validation of *In Vitro* Endocrine Disruptor Screening Methods; Request for Comments.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of a report entitled, ''The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Expert Panel Report on the Current Status of *In Vitro* Test Methods for Detecting Endocrine Disruptors'' and a list of substances proposed by the ICCVAM Endocrine Disruptor Working Group (EDWG) for the validation of in vitro endocrine disruptor screening methods. Final versions of the Background Review Documents (BRDs) reviewed at the May 21–22, 2002 expert panel meeting and the summary minutes of this meeting are also available. The NICEATM invites public comment on the expert panel report and the proposed list of substances for validation.

Availability of Expert Panel Report, Proposed List of Substances for Future Validation, and Final Background Review Documents

Copies of the expert panel report, the EDWG proposed list of substances for validation, and each BRD may be obtained on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov*, or by contacting NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) (919) 541–3398, (fax) (919) 541–0947, (email) *niceatm@niehs.nih.gov.*

Request for Comments

NICEATM invites the submission of written comments on the expert panel report and the proposed list of substances for validation of *in vitro* endocrine disruptor methods. When submitting written comments please include appropriate contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable). Written comments and additional information should be sent by mail, fax, or email to Dr. William S. Stokes, Director of NICEATM, at the address listed above by noon, December 6, 2002. All written comments received before this deadline will be posted on the ICCVAM/NICEATM Web site and made available to ICCVAM agency representatives for their consideration prior to the development by ICCVAM of final recommendations on these test methods and the proposed list of substances for validation.

The expert panel report, the final list of proposed substances for validation, and the ICCVAM recommendations will be compiled into a report and forwarded to the Director of the NIEHS and the heads of appropriate Federal agencies and posted on the ICCVAM/NICEATM Web site. The NIEHS and the Federal agencies will consider these recommendations and comments to determine if and how (chemicals and laboratories) additional validation studies will be conducted. If a decision is made to conduct validation studies on *in vitro* ER and AR assays, an independent peer review panel will be convened to review the results of these studies and to propose minimum performance criteria.

Background on the Evaluation of *In Vitro* Endocrine Disruptor Screening Methods and Development of the Proposed List of Substances for Future Validation

A request for data supporting the performance and reliability of endocrine disruptor screening methods and for the nomination of expert scientists for an independent scientific review panel was previously published (**Federal Register**, Vol. 66, No. 57, pp. 16278–16279, March 23, 2001, available at *http://iccvam.niehs.nih.gov/methods/endocrine.htm*). This notice also announced that NICEATM in collaboration with the ICCVAM would hold an independent peer review panel meeting to assess the current validation status of *in vitro* estrogen receptor (ER) and androgen receptor (AR) binding and transcriptional activation assays, and to review proposed minimum performance criteria for defining an acceptable screening assay. During development of Background Review Documents (BRDs) for *in vitro* ER and AR assays, ICCVAM and NICEATM determined that no validation studies using standardized protocols had been completed. As a result, NICEATM in collaboration with the ICCVAM held an expert panel meeting on May 21–22, 2002, to evaluate the current status of ER and AR binding and transcriptional activation assays and to develop recommendations for their future validation (**Federal Register**, Vol. 67, No. 66, pp. 16415–16416, April 5, 2002, available at *http://iccvam.niehs.nih.gov/methods/endocrine.htm*). At this meeting, the panel reviewed each of four BRDs (Estrogen and Androgen Receptor Binding and Transcriptional Activation Assays) and developed conclusions and recommendations on the following:

- The relative priority that should be given to specific assays recommended for further evaluation in validation studies.
- The adequacy of the specific protocols recommended for validation studies.
- The adequacy of the minimum procedural standards recommended for each type of assay.
- The adequacy and appropriateness of substances recommended for validation studies.

The expert panel's conclusions and recommendations are included in the report described above.

Based on the recommendations of the expert panel and in consultation with the EDWG, a combined list of proposed substances for future validation was developed. This list is proposed by the EDWG to facilitate future validation of *in vitro* endocrine disruptor screening methods and is available as described in this notice.

Background Information on ICCVAM and NICEATM

ICCVAM was authorized as a permanent interagency committee of the NIEHS, under the NICEATM, on December 19, 2000, by the ICCVAM Authorization Act of 2000 (P.L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*). ICCVAM is composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. P.L. 106–545 directs the ICCVAM to coordinate the technical review of new, revised, and alternative test methods of interagency interest. The committee also coordinates cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM promotes the scientific validation and regulatory acceptance of toxicological test methods that enhance agencies' ability to make decisions on health risks, while refining, reducing, and replacing animal use wherever possible. NICEATM provides operational and scientific support for ICCVAM and collaborates with ICCVAM to evaluate new and alternative 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: October 9, 2002.

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