DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH) Notice of an Expert Panel Meeting To Assess the Current Validation Status of In Vitro Endocrine Disruptor Screening Methods; Request for Comments

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and organized by the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). At this meeting, an expert panel (Panel) will assess the current validation status of in vitro endocrine disruptor screening methods and develop recommendations for their further validation. The meeting will take place on May 21–22, 2002, from 8:30 a.m. to 5 p.m., at the Sheraton Imperial Hotel and Convention Center, 4700 Emperor Boulevard, Durham, NC 27703. The meeting is open to the public with attendance limited only by the space available.

Evaluation of In Vitro Endocrine Disruptor Screening Methods

A request for data evaluating the performance and reliability of endocrine disruptor screening methods and the nomination of expert scientists 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 ICCVAM and NICEATM are coordinating an expert 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

the Background Review Documents (BRDs) for the in vitro ER and AR assays being considered at this review, ICCVAM and NICEATM determined that no validation studies have been completed. With agreement from EPA, the NICEATM and ICCVAM decided to proceed with an expert panel evaluation of the current status of ER and AR binding and transcriptional activation assays and with development of recommendations for their future validation. At this meeting, the Panel will review each of four BRDs (see below) and develop 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.

Following the completion and submission of validation studies on in vitro ER and AR assays, an independent peer review panel will be convened to review these studies and propose minimum performance criteria.

Agenda

The public meeting will take place May 21–22, 2002, at the Sheraton Imperial Hotel and Convention Center, 4700 Emperor Boulevard, Durham, NC 27703. The meeting will begin at 8:30 a.m. and conclude at 5 p.m. each day. On the morning of May 21st, there will be a brief orientation on ICCVAM and the ICCVAM test method review process, followed by the Panel's evaluation of the BRDs for the ER binding and transcriptional activation assays. It is anticipated that review of the ER BRDs will continue on the morning of May 22nd, after which the review of the BRDs for the AR binding and transcriptional activation assays will take place. The Panel will evaluate the current status of each of the four different types of in vitro assays and develop recommendations for their future validation. A detailed agenda will be available prior to the meeting at the ICCVAM/NICETATM web site (*http://iccvam.niehs.nih.gov*) or by contacting NICEATM (contact information below). Summary minutes and a final report of the Panel will be available following the meeting at the ICCVAM/NICEATM web site. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NICEATM.

Availability of Background Review Documents

NICEATM has prepared four BRDs, one for each type of assay being evaluated (ER and AR binding assays and ER and AR transcriptional activation assays). Copies of each BRD may be obtained on the ICCVAM/NICEATM web site at *http://iccvam.niehs.nih.gov*, or by contacting NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–3398, (fax) 919–541–0947, (email) *iccvam@niehs.nih.gov*.

Request for Comments

NICEATM invites the submission of written comments on each of the BRDs. 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 NICEATM at the address listed above by noon, May 10, 2002. All written comments received before the meeting will be posted on the ICCVAM/NICEATM web site and made available to the Panel members, ICCVAM agency representatives and experts, and also to attendees at the meeting.

The meeting is open to the public and time will be provided for the presentation of public oral comments at designated times during the Panel review. Members of the public who wish to present oral statements at the meeting (one speaker per organization) should contact NICEATM (at the address above) no later than noon, May 10, 2002. Speakers will be assigned on a consecutive basis and up to seven minutes will be allotted per speaker. Persons registering to make comments are asked to provide a written copy of their statement in advance so that copies can be distributed to the Panel. Written statements can supplement and expand the oral presentation. Each speaker is asked to provide contact information (name, affiliation, mailing address, phone, fax, email and sponsoring organization, if applicable).

Background Information on ICCVAM and NICEATM

ICCVAM was established in 1997 to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. Composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information, 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. ICCVAM was authorized as a permanent interagency committee of the NIEHS, under the NICEATM, on December 19, 2000, through passage of the ICCVAM Authorization Act of 2000 (Public Law 106–545, available at *http://iccvam.niehs.nih.gov/PL106545.htm*). Public Law 106–545 directs the ICCVAM to coordinate the technical review of new, revised, and alternative test methods of interagency interest. NICEATM provides operational and 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: March 27, 2002.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

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