DEPARTMENT OF HEALTH AND HUMAN SERVICES

Independent Scientific Peer Review Panel Meeting on an *In Vitro* Estrogen Receptor Transcriptional Activation Test Method for Endocrine Disruptor Chemical Screening; National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Announcement of an Independent Scientific Peer Review Panel Meeting on an *In Vitro* Estrogen Receptor Transcriptional Activation Test Method for Endocrine Disruptor Chemical Screening; Availability of Draft Background Review Document (BRD); Request for Comments

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Meeting announcement and request for comments.

SUMMARY: NICEATM, in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), announces a public meeting of an independent scientific peer review panel (Panel) to evaluate the validation status of LUMI–CELL® ER (BG1Luc ER TA), an *in vitro* transcriptional activation (TA) assay used to identify chemicals that can interact with human estrogen receptors (ERs). Validated assays that can detect the interaction of chemicals with specific hormone receptors, including ERs, have been accepted and included in the U.S. Environmental Protection cy (EPA) Endocrine Disruptor Screening Program (EDSP) (*http://www.epa.gov/endo/pubs/assayvalidation/status.htm*). Consequently, the BG1Luc ER TA may be applicable for addressing the ER TA component of the EPA EDSP Tier 1 screening battery.

At this meeting, the Panel will review the draft BRD for the BG1Luc ER TA and evaluate the extent to which established validation and acceptance criteria have been appropriately addressed. The Panel also will be asked to comment on the extent to which the information included in the BRD supports ICCVAM's draft test method recommendations.

NICEATM invites public comments on the draft BRD and draft ICCVAM test method recommendations. These documents are available on the NICEATM–ICCVAM Web site at: *http://iccvam.niehs.nih.gov/methods/endocrine/PeerPanel11.htm*.

DATES: The meeting will be held on March 29–30, 2011, from 8:30 a.m. to 5 p.m. each day. In order to facilitate planning for this meeting, persons wishing to attend are asked to register by March 15, 2011, via the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/contact/reg-form-EDpanel.htm*). Comments should be sent by March 10, 2011.

ADDRESSES: The meeting will be held at the National Institutes of Health (NIH), William H. Natcher Conference Center, 45 Center Drive, Bethesda, MD 20892. Persons needing special assistance in order to attend, such as sign language interpretation or other reasonable accommodation, should contact 301–402–8180 (voice) or 301–435–1908 TTY (text telephone) at least seven business days before the event.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Deputy Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail)

niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, 530 Davis Drive, Room 2035, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

In January 2004, Xenobiotics Detection Systems, Inc. (XDS, Durham, NC) nominated their LUMI–CELL® TA (BG1Luc ER TA) Test Method for an interlaboratory validation study to be coordinated by NICEATM. This method uses BG–1 cells, a human ovarian carcinoma cell line that was stably transfected with an estrogen-responsive luciferase reporter gene, to measure whether and to what extent a substance induces or inhibits TA activity via ER mediated pathways. Included in the nomination package were test results from XDS for 56 of the 78 ICCVAM Reference Substances for agonist activity and 16 of the 78 ICCVAM Reference Substances for antagonist activity. These studies were funded primarily by a Small Business Innovation Research (SBIR) grant (SBIR43ES010533–01) from the NIEHS.

In accordance with the ICCVAM nomination process, NICEATM conducted a pre-screen evaluation of the nomination package to determine the extent to which it addressed the ICCVAM prioritization criteria and adherence to the ICCVAM recommendations for the standardization and validation of *in vitro* endocrine disruptor test methods. Based on this evaluation, ICCVAM recommended a high priority for validation studies for the BG1Luc ER TA test method. The NIEHS subsequently agreed to support the validation study in light of its participation as one of the three NTP agencies, whose mission includes the development and validation of improved testing methods.

The international interlaboratory validation study of the BG1Luc ER TA test method has been completed. The study included three laboratories sponsored by NICEATM, the European Centre for the Validation of Alternative Methods, and the Japanese Center for the Validation of Alternative Methods.

NICEATM and ICCVAM have prepared a draft BRD that provides comprehensive summaries of data, analyses of test method accuracy and reliability, and related information characterizing the current validation status of the test method. The draft BRD forms the basis for ICCVAM test method recommendations on usefulness and limitations, standardized test method protocols, future studies, and performance standards.

Peer Review Panel Meeting

This meeting will take place March 29–30, 2011, at the National Institutes of Health (NIH) William H. Natcher Conference Center, 45 Center Drive, Bethesda, MD 20892. It will begin at 8:30 a.m. and is scheduled to conclude each day at approximately 5 p.m. The meeting is open to the public at no charge, with attendance limited only by the space available. The Panel will consider the draft ICCVAM BRD, recommendations, and performance standards for the test method and evaluate the extent to which the draft ICCVAM test method recommendations are supported by the information provided in the draft BRD.

Additional information about the meeting, including a roster of the Panel members and the draft agenda, will be posted on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/endocrine/PeerPanel11.htm* two weeks before the meeting. This information will also be available after that date by contacting NICEATM (*see* **FOR FURTHER INFORMATION CONTACT**).

Attendance and Registration

In order to facilitate planning for this meeting, persons wishing to attend are asked to register by March 15, 2011, via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/contact/reg-form-EDpanel.htm*.

Availability of the Documents

The draft BRD and draft ICCVAM test method recommendations will be posted no later than February 1, 2011 on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/methods/endocrine/PeerPanel11.htm*) or may be obtained by contacting NICEATM (*see* **FOR FURTHER INFORMATION CONTACT**).

Request for Public Comments

NICEATM invites the submission of written comments on the draft BRD, draft ICCVAM test method recommendations, and draft performance standards by March 10, 2011. NICEATM prefers that comments be submitted electronically via the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm*) or via e-mail to *niceatm@niehs.nih.gov*. Written comments may also be sent by mail, fax, or e-mail to Dr. Casey (*see* **FOR FURTHER INFORMATION CONTACT**). When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). NICEATM will post all comments on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*) identified by the individual's name and affiliation or sponsoring organization (if applicable). NICEATM will provide these comments to the Panel and ICCVAM agency representatives and make them available to the public at the meeting.

Opportunity will be provided for members of the public to present oral comments at designated times during the peer review. Up to seven minutes will be allotted per speaker. If you wish to present oral statements at the meeting (one speaker per organization), contact NICEATM (*see* **FOR FURTHER INFORMATION CONTACT**) by March 2, 2011. Please provide a written copy of your comments with contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable) when registering to make oral comments. If it is not possible to provide a copy of your statement in advance, please bring 40 copies to the meeting for distribution to the Panel and to supplement the record. Written statements can supplement and expand the oral presentation. Please provide NICEATM with copies of any supplementary written statement using the guidelines outlined above.

Summary minutes and the Panel's final report will be available following the meeting on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*). ICCVAM will consider the Panel's conclusions and recommendations and any public comments received in finalizing their test method recommendations for the test method.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*-3, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for 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 is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov*.

Dated: January 13, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–1329 Filed 1–21–11; 8:45 am]

BILLING CODE 4140–01–P