DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Announcement of a Second Meeting of the Independent Scientific Peer Review Panel on the Murine Local Lymph Node Assay; Availability of Draft Background Review Documents (BRD); Request for Comments

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

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 second meeting of an independent scientific peer review panel (hereafter, Panel) to evaluate three non-radioactive modified versions and new applications for the Murine Local Lymph Node Assay (LLNA). The LLNA is an alternative test method that can be used to determine the allergic contact dermatitis potential of chemicals and products.

The Panel will consider additional data and information for the three non-radioactive modified versions and new applications of the LLNA obtained by NICEATM subsequent to the original Panel meeting in March 2008. Based on this new information, the Panel will review the following:

- The validation status of three modified LLNA test methods.
- The proposed applicability domain of the LLNA.

The Panel will peer review revised draft BRDs for each topic and evaluate the extent that established validation and acceptance criteria have been appropriately addressed. The Panel also will be asked to comment on the extent to which draft ICCVAM test method recommendations are supported by the data analyses provided in the BRDs.

NICEATM invites public comments on the draft BRDs and draft ICCVAM test recommendations. All documents will be available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm* by March 3, 2009.

DATES: The meeting is scheduled for April 28–29, 2009 from 8:30 a.m. to 5 p.m. each day. The deadline for registration and submission of written comments is April 14, 2009.

ADDRESSES: The meeting will be held at the Natcher Conference Center, National Institutes of Health, 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). Requests should be made at least seven business days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, 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, Mail Stop: K2–16, Durham, NC 27713.

SUPPLEMENTARY INFORMATION:

Background

In January 2007, the U.S. Consumer Product Safety Commission (CPSC) submitted a nomination to NICEATM (*http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf*) requesting that ICCVAM assess the validation status of (1) the LLNA limit dose procedure; (2) three modified LLNA test method protocols that use non-radioactive probe chemicals; (3) the use of the LLNA to test mixtures, aqueous solutions, and metals (applicability domain for the LLNA); and (4) the use of the LLNA to determine potency (potential for causing allergic contact dermatitis). NICEATM compiled draft BRDs that provided comprehensive reviews of the available data and relevant information, which were used as the basis for draft ICCVAM test method recommendations. These documents were released to the Panel and the public for review and comment in January 2008 (73FR1360).

In March 2008, NICEATM and ICCVAM convened the public Panel meeting during which the Panel concluded that more information and data were required for the three modified LLNA test methods before recommendations could be made regarding their use for regulatory safety testing. Similarly, the Panel concluded that more data would be needed before a recommendation on the usefulness and limitations on the current applicability domain of the traditional LLNA could be made. The Panel's conclusions are detailed in a report, which was made available in May 2008 (73FR29136), and includes consideration of public comments made prior to and during their deliberations.

Subsequent to the Panel meeting, NICEATM received additional LLNA data for pesticide formulations and other products, as well as new data for the three modified LLNA test methods. Using the additional information, NICEATM revised the BRDs for each of these modified test methods and new applications of the LLNA. The revised draft BRDs provide all of the data and analyses supporting the scientific validity of the modified test methods and proposed applications. ICCVAM prepared revised draft test method recommendations regarding the proposed usefulness and limitations, standardized protocol, and future studies. NICEATM will reconvene the Panel to consider the additional information and revised recommendations.

Peer Review Panel Meeting

This meeting will take place April 28–29, 2009, at the Natcher Conference Center, National Institutes of Health, 45 Center Drive, Bethesda, Maryland, 20892. It will begin at 8:30 a.m. and is scheduled to conclude at approximately 5 p.m. on each day. The meeting is open to the public at no charge, with attendance limited only by the space available. The Panel will consider the revised draft BRDs for each of these modified versions and new applications of the LLNA and evaluate the extent that established validation and acceptance criteria are appropriately addressed for each test method and application (as described in the ICCVAM document, *Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods*, NIH Publication No. 97–3981, available at *http://iccvam.niehs.nih.gov/docs/about_docs/validate.pdf*). The Panel will then comment on the extent to which each of the revised draft ICCVAM test method recommendations is supported by the information provided in the corresponding revised draft BRDs. The Panel is expected first to review the three modified LLNA test methods, and then review the use of the LLNA for testing pesticide formulations and other products.

Additional information about the Panel meeting, including a roster of the Panel members and the draft agenda, will be made available two weeks prior to the meeting on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*). This information will also be available after that date by

contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT** above).

Attendance and Registration

In order to facilitate planning for this meeting, persons wishing to attend are asked to register by April 14, 2009, via the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/contact/reg_LLNAPanel.htm*). Visitor parking is located in the multi-level parking garage accessible via NIH Gateway Drive. All visitors should proceed to the Gateway Center to receive a visitor badge. Note: parking is limited and a government-issued ID is required for access (an area map, driving directions, and NIH contact information are available at *http://www.nih.gov/about/visitor/index.htm*).

Availability of the Revised Documents

The revised draft BRDs and revised draft ICCVAM test method recommendations will be available from the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm*) by March 3, 2009, or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT** above).

Request for Public Comments

NICEATM invites the submission of written comments on the revised draft BRDs and revised draft ICCVAM test method recommendations and prefers that comments be submitted by April 14, 2009, electronically via the NICEATM–ICCVAM Web site *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm* or via e-mail at *niceatm@niehs.nih.gov*. Written comments may also be sent by mail, fax, or e-mail to Dr. William Stokes, Director of NICEATM, at the address listed above (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). All comments received will be placed on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*), and identified by the individual's name and affiliation or sponsoring organization (if applicable). Comments will also be provided to the Panel and ICCVAM agency representatives, and made available at the meeting.

Time will be provided for the presentation of oral comments by the public at designated times during the peer review. Members of the public who wish to present oral statements at the meeting (one speaker per organization) should contact NICEATM (see **FOR FURTHER INFORMATION CONTACT** above) by April 14, 2009 and provide a written copy of their comments. Each speaker is asked to provide contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable) when registering to make oral comments. Up to seven minutes will be allotted per speaker. If this is not possible, please bring 40 copies of your comments to the meeting for distribution 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 and performance standards for these methods.

Background Information on ICCVAM, NICEATM, and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) 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 U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (*http://iccvam.niehs.nih.gov*).

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, to ICCVAM, and to NICEATM regarding the statutorily-mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/*; see ''Advisory Board & Committees'' (or directly at *http://ntp.niehs.nih.gov/go/167*).

Dated: February 19, 2009.

John R. Bucher,

Associate Director, NTP.

[FR Doc. E9–4280 Filed 2–26–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Unsolicited Multi-Project (P01) Grant Applications.

Date: March 20, 2009.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700–B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Roberta Binder, PhD, Scientific Review Officer, Division of Extramural Activities, NIAID, 6700B Rockledge Drive, Rm 2155, Bethesda, MD 20892, 301–496–7966, *rb169n@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 20, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–4191 Filed 2–26–09; 8:45 am]

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