DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of a Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on October 20, 2004, at the U.S. Environmental Protection Agency (EPA), 109 TW Alexander Drive, Durham, NC (Building C, Room C111, Auditorium sections A. and B). The SACATM provides advice on the statutorily mandated duties of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the activities of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

The meeting is being held on October 20, 2004, from 8:30 a.m. until adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are strongly encouraged to register with the NTP Executive Secretary by October 13, 2004, in order to ensure access to the EPA campus (Dr. Kristina Thayer at the NTP Liaison and Scientific Review Office, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-5021; facsimile: 919-541-0295; or e-mail: thayer@niehs.nih.gov) or online on the NTP Web site (http:// ntp-server.niehs.nih.gov) under "What's New." A map of the EPA campus, including visitor parking, is available at http://www.epa.gov/rtp/transportation/ parking/map.htm. Please note that a photo ID is required to access the EPA

Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting (see contact information above).

Agenda

A preliminary agenda is provided below. A copy of the agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site (http://ntp-server.niehs.nih.gov) under "What's New" or available upon request to the NTP Executive Secretary (contact information provided above).
Additional information about SACATM is available through the NICEATM/ICCVAM Web site (http://iccvam.niehs.nih.gov) under "Advisory Committee." Following the meeting, summary minutes will be prepared and available at this Web site and upon request to the NTP Liaison and Scientific Review Office (contact information above).

Preliminary Agenda

Scientific Advisory Committee on Alternative Toxicological Methods, October 20, 2004. U.S. Environmental Protection Agency, Building C, Room C111 (Auditorium sections A. and B), 109 TW Alexander Drive, Durham, NC 27709. (A photo ID is required to access the EPA campus.)

October 20, 2004

8:30 a.m.

- Call to Order and Introductions.
- Welcome and Remarks from the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP).
- Welcome and Remarks from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Chair.
- Update on Activities of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and ICCVAM.
- Update on the European Center for the Validation of Alternative Methods (ECVAM) Workshop Recommendations and Validation Studies.
- Evaluation of the Under-Prediction Rate for the *In Vivo* Rabbit Dermal Irritation Test.
 - Public Comment.
- Evaluation of the Under-Prediction Rate for the *In Vivo* Rabbit Occular Irritation Test.
 - Public Comment.

12 p.m.

Lunch break (on your own, the EPA campus has a cafeteria).

1 p.m.

- ICCVAM Nominations.
- Public Comment.
- NTP Roadmap.
- Public Comment.
- ECVAM-ICCVAM-NICEATM Workshop on Validation of Toxicogenomic-Based Test Systems.
 - General Discussion.

4:30 p.m. Adjourn

Public Comment Welcome

Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the NTP Executive Secretary (contact information above) by October 13, 2004, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration to present oral public comments or to submit written comments can be completed online at the NTP Web site (http://ntp-server.niehs.nih.gov) under "What's New." Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less then that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the NTP Executive Secretary (contact information above) by October 13, 2004, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the SACATM and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (http://ntp-server.niehs.nih.gov) under "What's New". Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the NTP Executive Secretary and received by October 13, 2004, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background

The SACATM was established January 9, 2002, to fulfill section 3(d) of Public Law 106–545, the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3(d)) and is composed of scientists from the public and private sectors (Federal Register: March 13, 2002: vol. 67, no. 49, page 11358). The SACATM provides advice to the Director of the

NIEHS, the ICCVAM, and the NICEATM regarding statutorily mandated duties of the ICCVAM and activities of the NICEATM. The committee's charter is posted on the Web at http:// iccvam.niehs.nih.gov under "Advisorv Committee" and is available in hard copy upon request from the NTP Executive Secretary (contact information above). Information about NICEATM and ICCVAM activities can also be found at the NICEATM/ICCVAM Web site (http://iccvam.niehs.nih.gov) or by contacting the Director of NICEATM, Dr. William Stokes (telephone: 919-541-2384, or e-mail: niceatm@niehs.nih.gov).

Dated: August 26, 2004.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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