DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP), Liaison and Scientific Review Office; Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

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

ACTION: Meeting announcement and request for comment.

SUMMARY: 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 teleconference meeting of the SACATM on August 3, 2006. The teleconference is scheduled from 1 p.m. to 4 p.m. and is open to the public. At the teleconference, SACATM will discuss the conclusions of a peer review panel that met on May 23, 2006 to evaluate the validation status of the in vitro 3T3 and normal human keratinocyte (NHK) neutral red uptake (NRU) basal cytotoxicity test methods (see "Background" for more detail). The public is invited to participate in the teleconference and will be provided with an opportunity to make oral comments during the public comment period. Participation is limited only by the number of phone lines available.

DATES: In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify Dr. Kristina Thayer via phone or e-mail by July 25, 2006, (see **ADDRESSES** below). Please note that a request for written comments on the peer review report is being announced in a separate **Federal Register** notice (available at http://ntp.niehs.nih.gov/go/frn).

ADDRESSES: Correspondence should be directed to Dr. Kristina Thayer, Executive Secretary for SACATM (NTP Liaison and Scientific Review Office. NIEHS, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709; telephone: 919-541-5021, fax: 919-541-0295; or e-mail: thayer@niehs.nih.gov). Persons needing special assistance to participate should contact 919-541-2475 voice, 919-541-4644 TTY (text telephone), through the Federal TTY Relay System at 800-877-8339, or by e-mail to niehsoeeo@niehs.nih.gov. Requests should be made at least 7 days in advance of the event.

SUPPLEMENTARY INFORMATION:

Background

The National Toxicology Program (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), organized an independent, scientific peer review meeting on May 23, 2006, to evaluate the validation status of the in vitro 3T3 and normal human keratinocyte (NHK) neutral red uptake (NRU) basal cytotoxicity test methods. These two in vitro cytotoxicity test methods are proposed as adjuncts (for the purpose of determining the starting dose) to in vivo acute oral toxicity tests. The peer review panel prepared a report that contains (1) a summary of the peer review evaluation and (2) the peer review panel's conclusions on the draft ICCVAM test method recommendations regarding the proposed usefulness, limitations, and validation status of the 3T3 and NHK cytotoxicity test methods. The availability of the report, entitled Peer Review Panel Evaluation of the Use of In Vitro Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing, and a request for written public comments on the peer review panel's conclusions regarding the draft ICCVAM test method recommendations are announced in a separate Federal **Register** notice (available at http:// ntp.niehs.nih.gov/go/frn). Copies of the report may be obtained on the ICCVAM/ NICEATM Web site at http:// iccvam.niehs.nih.gov or by contacting the Dr. Kristina Thayer (see ADDRESSES above).

At the teleconference, SACATM will discuss peer review panel's report, focusing on the panel's conclusions regarding the draft ICCVAM recommendations for the proposed use of these test methods, draft test method protocols, draft performance standards, and draft recommended future studies. ICCVAM will consider the peer review report, SACATM comments, and any written public comments received on that report as it prepares final ICCVAM recommendations for the two in vitro basal cytotoxicity test methods. An ICCVAM test method evaluation report, which will include the final ICCVAM recommendations, will be forwarded to the appropriate federal agencies for their consideration and made available to the public.

Request for Comments

Public input at the SACATM teleconference is invited and time is set aside for the presentation of public comments. Each organization is allowed one time slot per public comment period. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Persons registering to make oral comments are asked, if possible, to send a copy of their statement to Dr. Kristina Thayer by July 25, 2006, to enable review by SACATM and NTP staff prior to the meeting. Please not that this teleconference provides an additional opportunity for the public to provide comment on the peer review panel's conclusions regarding the draft ICCVAM test method recommendations. Written comments submitted to NICEATM in response to a NICEATM notice published in this issue of the Federal Register do not need to be resubmitted. Any written comments on the peer review report received prior to July 25, 2006, will be distributed to SACATM.

Background Information on ICCVAM, NICEATM, and SACATM

The SACATM was established January 9, 2002, to fulfill section 3(d) of the ICCVAM Authorization Act of 2000 [42 U.S.C. 285*l*–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, ICCVAM, and NICEATM regarding 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/go/167. Information about NICEATM and ICCVAM activities can 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: June 30, 2006.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.

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