DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

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

ACTION: Meeting announcement and request for comments.

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 meeting of SACATM on June 16–17, 2011, at the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, VA 22203. The meeting is open to the public with attendance limited only by the space available. The meeting will be videocast at the NTP Web site (http://ntp.niehs.nih.gov/go/32822) or available on-site, although time allowed for presentation by on-site registrants may be less than for pre-registered speakers and will be determined by the number of persons who register at the meeting. In addition to in-person oral comments at the meeting, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 8 a.m. until 5 p.m. on June 16 and 8:30 a.m. to adjournment on June 17, although public comments will be received only during the formal public comment periods, which will be indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting.

Persons registering to make oral comments are asked to do so through the online registration form (http://ntp.niehs.nih.gov/go/32822) and to send a copy of their statement to Dr. White (see ADDRESSES above) by June 9, 2011, to enable review by SACATM, NICEATM–ICCVAM, 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 and to supplement the record.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing 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 that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285x) established ICCVAM as a permanent interagency committee of the NIEHS under

Policy and Review. NIEHS, P.O. Box 12233, MD K2–03, Research Triangle Park, NC 27709; telephone: 919–541–9834 or e-mail: whitel@niehs.nih.gov. Courier address: NIEHS, 530 Davis Drive, Room 2136, Morrisville, NC 27560. Persons needing interpreting services in order to attend should contact 301–402–8180 (voice) or 301–435–1908 (TTY). Requests should be made at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda Topics and Availability of Meeting Materials

- NICEATM–ICCVAM Update
- Regulatory Acceptance of ICCVAM-Recommended Alternative Test Methods
- Report on Peer Review Panel Meeting: Evaluation of an In Vitro Estrogen Receptor Transcriptional Activation Test Method for Endocrine Disruptor Chemical Screening
- Federal Agency Research, Development, Translation, and Validation Activities Relevant to the NICEATM–ICCVAM Five-Year Plan
- Nominations to ICCVAM: Botulinum In Vitro Assays, In Vitro Pyrogen Assay Validation
- Outcome/Recommendations from the ICCVAM Workshop Series on Best Practices for Regulatory Safety Testing
- Outcomes/Recommendations from the International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency Testing: State of the Science and Future Directions
- Update from the Korean Center for the Validation of Alternative Methods
- Update from Health Canada
- Update from the Japanese Center for the Validation of Alternative Methods
- Update from the European Centre for the Validation of Alternative Methods

Both written and oral public input on the agenda topics is invited. Written comments received in response to this notice will be posted on the NTP Web site. Persons submitting written comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document. Time is allotted during the meeting for presentation of oral comments and each organization is allowed one time slot per public comment period. At least 7 minutes will be allotted for each speaker, and if time permits, may be extended up to 10 minutes at the discretion of the chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than for pre-registered speakers and will be determined by the number of persons who register at the meeting. In addition to in-person oral comments at the meeting, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 8 a.m. until 5 p.m. on June 16 and 8:30 a.m. to adjournment on June 17, although public comments will be received only during the formal public comment periods, which will be indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting.

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NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (http://iccvam.niehs.nih.gov).

SACATM was established in response to the ICCVAM Authorization Act (Section 285) and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at http://ntp.niehs.nih.gov/go/167.

Dated: April 18, 2011.

John R. Bucher,
Associate Director, National Toxicology Program.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration for Children and Families
Proposed Information Collection Activity; Comment Request
Title: State Plan for the Temporary Assistance of Needy Families (TANF).

ANNUAL BURDEN ESTIMATES

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<th>Instrument</th>
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<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
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Estimated Total Annual Burden Hours: 594.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447. Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2011–N–0002]
Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

Title: State Plan for the Temporary Assistance of Needy Families (TANF).

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on May 19, 2011, from 8 a.m. to 5 p.m.


Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20903–0002, 301–796–9001, FAX 301–847–8533, e-mail: EDMAC@fda.hhs.gov, or FDA Advisory...