DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Meeting of the 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 National Toxicology Program (NTP) Advisory Committee on Alternative Toxicological Methods, U.S. Public Health Service. The meeting will be held from 9:00 a.m. to adjournment on September 25, 2001 in the Rodbell Auditorium, Rall Building, South Campus, National Institute of **Environmental Health Sciences** (NIEHS), 111 T.W. Alexander Drive. Research Triangle Park, North Carolina. The meeting is open to the public and time is allotted during the meeting for the public to present comments to the Committee and NTP staff on agenda topics. Attendance is limited only by the space available. Individuals who plan to attend and need special assistance are asked to notify the Executive Secretary in advance of the meeting.

Background

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services has established an Advisory Committee on Alternative Toxicological Methods (the Committee). The Committee provides advice to the NTP on the activities and priorities of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (the Center) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and on ways to foster partnership activities and productive interactions among all stakeholders. The Committee is composed of knowledgeable representatives drawn from academia, industry, public interest organizations, and may include representation from state and federal agencies and the international community, as appropriate [Federal Register: September 15, 1997 (Volume 62, Number 178, Page 48290)].

Agenda

The September 25th meeting is open to the public from 9:00 AM to adjournment with attendance limited only by the space available. A draft agenda with tentative schedule is provided below. Primary agenda topics

include updates on recent NTP Center and ICCVAM activities and areas for future priorities and activities.

A detailed agenda with meeting schedule and the Committee roster will be available prior to the meeting on the Center's web site (http:// iccvam.niehs.nih.gov) or by contacting the NTP Executive Secretary, Dr. Mary S. Wolfe (National Toxicology Program, P. O. Box 12233, 111 T.W. Alexander Drive, A3–07, NIEHS, Research Triangle Park, North Carolina 27709, telephone: 919-541-3971 and FAX: 919-541-0295). Following the meeting, summary minutes will be posted on the Center's web site (http://iccvam.niehs.nih.gov, see ACATM) or can be obtained by contacting the Executive Secretary. The minutes for past committee meetings are also available on the web.

Public Comment Encouraged

Public input at the meeting is invited and time is set aside for the presentation of public comments on any agenda topic. At least seven minutes will be allotted to each speaker, and if time permits, may be extended to ten minutes. Persons registering to make oral comments are asked to provide their name, affiliation, mailing address, telephone, FAX, e-mail, and sponsoring organization (if any). Each organization is allowed one time slot per agenda topic. To facilitate planning for the meeting, persons interested in providing formal oral comments are asked to notify the Executive Secretary at the address given above. Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the Executive Secretary by September 19, to enable review by the Committee and NTP staff prior to the meeting. Individuals will also be able to register to give oral comments on-site at the meeting. However, if registering onsite and reading from written text, please bring 25 copies of the statement for distribution to the Committee and NTP staff and to supplement the record.

Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the Executive Secretary and should be received by September 19, 2001 to enable review by the Committee and NTP staff, as well as to supplement the record. Persons submitting written comments should include with the document their name, affiliation, mailing address, telephone, FAX, email, and sponsoring organization (if any).

Dated: August 23, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

Draft Agenda (8/18/01)—National Toxicology Program Advisory Committee on Alternative Toxicological Methods

September 25, 2001

9:00 am—Call to Order and Introductions

Updates

- NTP
- NTP Center and ICCVAM Updates Guidance Document on Using In Vitro Data to Estimate In Vivo Starting Doses for Acute Toxicity (ACTION)
 - Public Comments

Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity

Public Comments

12:30 pm-Lunch

1:30 pm

Toxicogenomics as An Alternative Toxicological Test Method: Priorities for Validation and Applications and Their Validation

Public Comments

NIEHS Extramural SBIR Contracts for Test Method Development and Validation

Other Issues

- International Validation Issues
- Agenda Topics for Next Meeting
- Other Topics

Public Comments

4:30 pm—Adjourn

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