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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 8:45 a.m. to 4:00 p.m. on October 14, 1999 in the Conference Center, Building 101, South Campus, NIEHS, 111 Alexander Drive, Research Triangle Park, North Carolina, 27709. The meeting will be entirely open to the public from 8:45 a.m. to adjournment with attendance limited only by space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the contact person listed below 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 functions to provide advice on the activities and priorities of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (Center) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and to provide advice on ways to foster partnership activities and productive interactions among all stakeholders. The Advisory Committee is composed of knowledgeable representatives drawn from academia, industry, public interest organizations, other state and Federal agencies, and the international community.

The National Toxicology Program established the Center and ICCVAM to fulfill specific mandates provided to the National Institute of Environmental Health Sciences by Public Law 103-43, Section 1301. The NIEHS was directed to: (1) Develop and validate toxicological testing methods, including alternative methods than can reduce or eliminate the use of animals in acute or chronic toxicity testing, (2) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (3) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use. Criteria and processes for validation and regulatory acceptance were developed in conjunction with 14 other Federal agencies and programs with broad input from the public. These are described in the 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 97-3981, March 1997, which is available on the internet at http://ntp-server.niehs.nih.gov /htdocs/ICCVAM/ICCVAM/htm, or by request to the Center at the address provided below.

A standing Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was subsequently established as a collaborative effort by NIEHS and 13 other Federal regulatory and research agencies and programs. The ICCVAM facilitates cross-agency communication and coordination on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The

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ICCVAM works with the Center to carry out the scientific review of proposed methods of multi-agency interest, and provides recommendations regarding their usefulness to appropriate agencies. The ICCVAM also provides a mechanism for interagency communication with stakeholders throughout the process of test method development and validation. The following Federal regulatory and research agencies and organizations are participating in this effort:

Consumer Product Safety Commission
Department of Defense
Department of Energy
Department of Health and Human Services
    Agency for Toxic Substances and Disease Registry
    Food and Drug Administration
    National Institute for Occupational Safety and Health/CDC
    National Institutes of Health
    National Cancer Institute
    National Institute of Environmental Health Sciences
    National Library of Medicine
Department of the Interior
Department of Labor
    Occupational Safety and Health Administration
Department of Transportation
    Research and Special Programs Administration
Environmental Protection Agency

The Center was established to provide operational support for the ICCVAM and to assist Federal Agencies by coordinating and facilitating: (1) The interagency review and adoption of toxicological test methods of multi-agency interest and (2) the participation and communication with other stakeholders throughout the process of test method development and validation. The Center organizes, in collaboration with ICCVAM, independent scientific peer reviews and workshops for test methods of interest to Federal agencies. Peer review panels are convened to develop scientific consensus on the usefulness of test methods to generate information for specific human health and/or ecological risk assessment purposes. Expert workshops are convened to evaluate the adequacy of current test methods for assessing specific toxicities, to identify areas in need of improved or new methods, to evaluate proposed validation studies, and to evaluate the validation status of methods. The Center provides an opportunity for partnerships with other agencies and organizations to facilitate the development,

validation, and review of alternative testing methods. The Center and ICCVAM seek to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assess risks and make decisions, and that will refine, reduce, and replace animal use whenever possible. The Center Office is located at NIEHS and can be contacted by telephone 919-541-3398, fax 919-541-0947, or email, iccvam@niehs.nih.gov.

Tentative Agenda--National Toxicology Program Advisory Committee on Alternative Toxicological Methods; October 14, 1999

Building 101, Conference Center, South Campus, National Institute of Environmental Health Science (NIEHS), Research Triangle Park, North Carolina
8:45-8:55 a.m.
Call to Order, Introductions--Dr. K. Stitzel, Chair,The Procter & Gamble
8:55-9:10 a.m.
Welcome and NTP Update--Dr. G. Lucier, NIEHS
9:10-9:50 a.m.
Updates--Dr. W. Stokes, NIEHS
<bullet> NTP Center and ICCVAM
<bullet> The Corrositex() Peer Review Panel Report (25 minutes)
Discussion (15 minutes)
9:50-12:15 p.m.
Regulatory Agency Processes for Consideration of ICCVAM
Test Method Recommendations; Acceptance Consideration of the LLNA
<bullet> EPA, EPA
<bullet> FDA, FDA
<bullet> CPSC, CPSC
<bullet> OSHA, OSHA

Potential Partnership Opportunities for Center/ICCVAM

1:15-2:15 p.m.
Endocrine Disruptor Testing and Screening Methods:
<bullet> Update on EPA Standardization and Validation Task Force Activities--Dr. T. Maciorowski, EPA
<bullet> Update on OECD Endocrine Screening and Testing Validation Efforts (30 minutes)--Dr. G. Lucier
<bullet> Discussion (30 minutes)
2:30-3:00 p.m.
Overview of the Multilaboratory Evaluation of in vitro Cytotoxicity (MEIC) Test Program (20 Minutes)--Dr. John Harbell, Institute for In Vitro Sciences
<bullet> Discussion (10 minutes)
3:00-3:30 p.m.
Potential Use of In Vitro Cytotoxicity Tests to Predict Acute Oral Lethality of Science,s Chemicals (20 minutes)--Dr. Rodger Curren, Institute for In Vitro
<bullet> Discussion (10 minutes)
3:30-4:00 p.m.
General Discussion (30 minutes)--Dr. K. Stitzel
4:00-4:15 p.m.
Public Comment
4:15

Adjourn

The Executive Secretary's Office, Environmental Toxicology Program, P.O. Box 12233, NIEHS, Research Triangle Park, North Carolina 27709, telephone (919) 541-3971, FAX (919) 541-0295, will have available an agenda with times and a roster of Committee members prior to the meeting and summary minutes subsequent to the meeting.

Dated: September 3, 1999.
Samuel H. Wilson,
Deputy Director, National Institute of Environmental Health Sciences.
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