I. Background

FDA, with input from an ad hoc workshop and an advisory committee, first issued guidance on osteoporosis drug development in 1979. The guidance was issued in response to the need for effective and safe drugs to prevent and treat osteoporosis. The agency revised the guidance in 1984. Most recently, FDA issued the 1994 draft guidance entitled ''Guidelines for Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis.''

The 1994 draft guidance recommends study designs, patient populations for study, and techniques for evaluating skeletal mass and fracture frequency that are considered central to demonstrating the efficacy and safety of drugs used to treat and prevent osteoporosis. Since issuance of the 1994 guidance, a number of drugs have been approved for the prevention and treatment of osteoporosis. In general, approval of these drugs was based on favorable bone mineral density and decreased fracture incidence from 2- and 3–year placebo-controlled trials.

Results from these trials and other published data have raised a number of issues and questions that the agency plans to address in an updated draft osteoporosis guidance. To aid in the development of the draft guidance, FDA is requesting comment on the 1994 draft guidance. The agency seeks specific comment on the following questions:

• Is it appropriate to continue to use placebo controls in fracture end-point trials?

• Do fracture end-point trials need to be 3 years in duration, or could shorter studies provide adequate evidence of a new osteoporosis drug's effectiveness and safety?

The 1994 draft guidance was issued before the 1997 publication of FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). In accordance with the GGPs, the agency will take into account any comments received on the 1994 draft guidance, develop a new draft guidance, and make it available for comment. When finalized, that guidance will represent the agency's current thinking on the preclinical and clinical evaluation of agents used in the prevention or treatment of postmenopausal osteoporosis. Agency guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 1994 draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 1994 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–2999 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 March 10–11, 2004, in the Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, MD (301–657–1234 or 800–233–1234). The meeting begins each day at 8:30 a.m. The SACATM provides advise on the statutorily mandated duties of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

Agenda

The meeting is being held on March 10–11, 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 asked to register with the NTP Executive Secretary (Dr. Kristina Thayer at the NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919–541–5021; facsimile: 919–541–0295; or E-mail: *thayer.niehs.nih.gov).*

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).

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). 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 (919–541–2384, or e-mail: *niceatm@niehs.nih.gov).*

Preliminary Agenda

Scientific Advisory Committee on Alternative Toxicological Methods—March 10–11, 2004

Hyatt Regency Hotel, 301–657–1234 or 800–233–1234, One Bethesda Metro Center, Bethesda, MD 20814.

March 10, 2004

8:30 a.m.

1. Call to Order and Introductions
2. Welcome and Remarks from NIEHS/NTP
3. Welcome and Remarks from ICCVAM Chair
4. Update on Activities of the NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
5. Update on Activities of the European Centre for the Validation of Alternative Methods (ECVAM)
6. Toxicology in the 21st Century: The Role of the National Toxicology Program

a. Public Comment

7. Update on Animal Use

12 p.m.
Lunch Break (on your own)
1 p.m.
8. ICCVAM Strategic Planning Process
a. Public Comment
9. ICCVAM Recommended Performance Standards for In Vitro Dermal Corrosivity Methods
a. Public Comment
10. Evaluation of the Predictivity of In Vivo Dermal Corrosivity Test Methods
a. Public Comment
11. Overview of ILSI/HESI Subcommittee's Activities on Identification of Biomarkers of Toxicity and Summary of First Meeting
12. Validation of Genetically Modified Mouse Models
a. Public Comment
5 p.m.
Adjourn

March 11, 2004

8:30 a.m.
1. Introductions and Call to Order
2. ICCVAM–NICEATM–ECVAM Workshop on Validation of Toxicogenomics-Based Test Systems
a. Public Comment
3. In Progress Test Method Evaluation Nomination: In Vitro Test Methods for Identifying Substances Causing Irreversible Ocular Damage
4. New Test Method Nominations: EPA Test Method Nomination for Test Methods to Identify Negative, Mild, and Moderate Ocular Irritants (*i.e.* Those With Reversible or No Effect)
a. Public Comment
11:30 p.m.
Lunch (on your own)
12:30 p.m.
New Test Method Nominations continued: In Vitro Vaccine Potency Tests for Veterinary Leptospira Vaccines
a. Public Comment
6. Report on the ECVAM Workshop on In Vitro Replacements for Acute Systemic Toxicity
a. Public Comment
2:45 p.m.
7. Other Issues
3:15 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 March 1, 2004, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than 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 March 1, 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 should be received by March 1, 2004, to enable review by the SACATM and NIEHS/NIH 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 National Institute of Environmental Health Sciences (NIEHS), the Interagency Coordinating Committee on the Validation of Alternative Toxicological Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (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 ''Advisory Committee'' and is available in hard copy upon request from the NTP Executive Secretary (contact information above).

Dated: February 2, 2004.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–2931 Filed 2–10–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

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 Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to 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.

Name of Committee: Advisory Committee to the Director, National Cancer Institute.

Date: March 2, 2004.

Time: 2 p.m. to 4 p.m.

Agenda: The purpose of this meeting will be to discuss the Cancer Health Disparities Progress Review Group Report.

Place: National Institutes of Health, Building 31, Room 11A03, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Cherie Nichols, Executive Secretary, National Cancer Institute, National Institute of Health, Building 31, Room 11A03, Bethesda, MD 20892, (301) 496–5515.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/joint/htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,