National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-594-0975 (paul_theerman@nlm.nih.gov)

b) John Rees, Associate Curator of Manuscripts, History of Medicine Division, Room 1 E-21, Building 38, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-8953 (john_rees@nlm.nih.gov)

VI. Period of Agreement

The agreement becomes effective upon signature of both parties and will continue without expiration. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

APPROVED AND ACCEPTED FOR THE NATIONAL LIBRARY OF MEDICINE

By Jon G. Retzlaff

Jon G. Retzlaff
Executive Officer,
National Library of Medicine

Date 12/30/03

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By

Jeff Weber
Associate Commissioner for Management
Office of Management
Food and Drug Administration

Date 12/23/03

[FR Doc. 04–2905 Filed 2–10–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0035]

Draft Guidance for Industry on the Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on a draft guidance entitled ''Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis.'' The guidance was issued in 1994 (1994 draft guidance). During the past decade, a significant body of data related to the diagnosis, prevention, and treatment of osteoporosis has been published. Much of this information is relevant to osteoporosis drug development and, in particular, relates to issues surrounding clinical trial design and duration. The agency is preparing to develop an updated draft guidance on the same topic and is seeking comment on the 1994 draft guidance.

DATES: Submit written or electronic comments on the 1994 draft guidance by April 12, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 1994 draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 1994 draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document

FOR FURTHER INFORMATION CONTACT: Randy Hedin, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6392.

SUPPLEMENTARY INFORMATION:

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