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[Notices]
[Page 13289-13290]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH): Notice of Expert Panel Meeting on the Frog Embryo Teratogenesis Assay--Xenopus

SUMMARY: Pursuant to Public Law 103-43, notice is hereby given of a public meeting sponsored by the NIEHS and the National Toxicology Program (NTP), and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The agenda topic is an expert panel assessment on the current validation status of the frog embryo teratogenesis assay (**FETAX**), an in vitro method proposed for evaluating the developmental toxicity potential of chemicals. The meeting will take place at the Sheraton Imperial Hotel and Convention Center, 4700 Emperor Blvd., Durham, NC 27703 on May 16-17, 2000 from 8:00 a.m. to 5:30 p.m. and May 18 from 8:00 a.m. to noon and is open to the public.

Background

ICCVAM, with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to coordinate issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. ICCVAM seeks 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. NICEATM provides administrative and scientific support of ICCVAM-related activities. NICEATM and ICCVAM collaborate to carry out activities needed to develop, validate, and achieve regulatory acceptance of new and improved test methods applicable to Federal agencies. These activities may include:

Test Method Workshops that are convened, as needed, to evaluate the adequacy of current methods for assessing specific toxicities, to identify

areas in need of improved or new testing methods, and to identify research efforts that may be needed to develop a new test method.

Expert Panel Meetings that are typically convened to evaluate the validation status of a method following the completion of initial development and pre-validation studies. An Expert Panel is asked to recommend additional validation studies, which might be helpful in further characterizing the usefulness of a method, and to identify any

additional research and development efforts that might enhance the effectiveness of a method.

Independent Peer Review Panel Meetings that are typically convened following the completion of comprehensive validation studies on a test method. Peer Review Panels are asked to develop scientific consensus on the usefulness and limitations of test methods to generate information for specific human health and/or ecological risk assessment purposes. Following the independent peer review of a test method, ICCVAM forwards recommendations on its usefulness to agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

Evaluation of **FETAX**

ICCVAM and NICEATM are coordinating an Expert Panel Meeting to assess the current validation status of **FETAX** which is proposed as a screening method for evaluating the developmental toxicity potential of chemicals (Bantle, J.A., 1995, **FETAX**--A Developmental Toxicity Assay Using Frog Embryos, in: Fundamentals of Aquatic Toxicology, 2nd Ed., (Rand, G.M., ed), Taylor and Francis:USA, pp. 207-230). An ICCVAM Developmental Toxicity Working Group composed of Federal employees determined that the assay may have potential for use in screening and prioritizing compounds for further testing, evaluating complex mixtures and environmental samples, and as supplemental information in a weight-of-evidence evaluation of toxicity hazards. NICEATM has prepared a comprehensive Background Review Document (BRD) summarizing available **FETAX** data and performance characteristics.

Agenda

During the morning session on the first day of the meeting, May 16, the Expert Panel will meet in a plenary session and then divide into five Breakout Groups that will meet on the afternoon of May 16 and all day on May 17. For these sessions, the Breakout Groups will address potential uses of **FETAX** and develop recommendations for research, additional test method development, and validation efforts that might be considered to further enhance and/or characterize the usefulness of **FETAX**. On May 18 in a plenary session, the Breakout Groups will individually present their conclusions and recommendations for consideration and discussion by the entire panel. A final report from the Expert Review Panel will be prepared and made publicly available (see below). The public is invited to attend all sessions of the Expert Panel Meeting, and designated times throughout the meeting will be set aside for presentation of public comments.

Summary minutes for the meeting and the final report from the Expert Panel will be prepared and made available upon request to NICEATM and on the web at http://iccvam.niehs.nih.gov. Copies of the **FETAX** BRD and supporting materials may be obtained from NICEATM, MD: EC-17, P.O. Box 12233, Research Triangle Park, NC, 27709 (919-541-3398), FAX (919-541-0947), e-mail:

ICCVAM@niehs.nih.gov. Additionally, the **FETAX** BRD will be available for viewing Monday through Friday, from noon to 4:00 p.m. EST at: Office of Prevention, Pesticides and Toxic Substances, Non-Confidential Information Center, Room 607B, Northeast Mall, 401 M Street SW, Washington, DC 20406. Thirty days prior to the meeting, a detailed agenda will be available online at: http://iccvam.niehs.nih.gov or by contacting NICEATM.

Public Comment

NICEATM invites the submission of written comments on the **FETAX** test method and BRD, as well as other available information regarding the usefulness of **FETAX** including information about completed, ongoing, or planned studies. Written comments and additional information should include name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any). This material should be sent by mail, fax, or e-mail to NICEATM at the address given. Information and comments may be sent at any time prior to the meeting; however, materials should be received by April 15, 2000 in order to ensure adequate review by the Expert Panel. This information will be added to the resource materials assembled on **FETAX**. Copies of written comments will be available for attendees at the meeting.

The Expert Panel Meeting will be open to the public, and time will be provided for presentation of public oral comments at designated times during the meeting. Speakers will be assigned on a first-come, first-serve basis, and at least seven minutes will be allotted to each speaker. In order to facilitate planning for the meeting, persons requesting time for an oral presentation should notify NICEATM at the address given above no later than May 1, 2000. Persons registering to make comments are asked to provide, if possible, a written copy of their statement by May 1st so copies can be made and distributed to the Expert Panel and ICCVAM representatives and experts for their timely review prior to the meeting. Written statements can supplement and expand the oral presentation, and each speaker is asked to provide his/her name, affiliation, mailing address, phone, fax, e-mail and supporting organization (if any). Registration for making public comments will also be available on-site. If registering on-site to speak and reading oral comments from printed copy, the speaker is asked to bring 50 copies of the text. These copies will be distributed to the Chair and Expert Panel members and supplement the record.

Persons needing special assistance, such as sign language interpretation or other special accommodations should contact NICEATM (contact information given above).

Dated: March 6, 2000.
Samuel H. Wilson,
Deputy Director, National Institute of Environmental Health Sciences.
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