

accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://www.iccvam.niehs.nih.gov>.

Dated: December 5, 2005.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of the Genistein and Soy Formula Expert Panel Meeting; Availability of the Draft Expert Panel Reports on Genistein and Soy Formula and Request for Public Comment on the Draft Reports

**AGENCY:** National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

**ACTION:** Meeting announcement and request for public comment.

**SUMMARY:** The Center for the Evaluation of Risks to Human Reproduction (CERHR) announces availability of the two draft expert panel reports on genistein and soy formula on January 16, 2006, from the CERHR Web site (<http://cerhr.niehs.nih.gov>) or in printed text from CERHR (see **ADDRESSES** below). CERHR invites public comments on sections 1-4 of both draft expert panel reports (see **SUPPLEMENTARY INFORMATION** below). An expert panel will meet on March 15-17, 2006, at the Radisson Hotel Old Town in Alexandria, Virginia to review and revise each draft expert panel report and reach conclusions regarding whether exposure to genistein or soy formula is a hazard to human development or reproduction. The expert panel will also identify data gaps and research needs.

CERHR expert panel meetings are open to the public with time scheduled for oral public comment. Attendance is limited only by the available space in the meeting room. Following the expert panel meeting and completion of the expert panel reports, CERHR will post the final reports on its website and solicit public comment on them through a **Federal Register** notice.

**DATES:** The expert panel meeting for genistein and soy formula will be held on March 15-17, 2006. Sections 1-4 of both draft expert panel reports will be available for public comment on January 16, 2006. Written public comments on the draft report must be received by March 1, 2006. Time will be set-aside at the expert panel meeting on March 15, 2006, for oral public comments. Individuals wishing to make oral public comments are asked to contact Dr. Michael D. Shelby, CERHR Director, by March 8, 2006, and if possible, send a copy of their statement or talking points at that time. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919-541-2475 voice, 919-541-4644 TTY (text telephone), through the Federal TTY Relay System at 800-877-8339, or by e-mail to [niehsoeeo@niehs.nih.gov](mailto:niehsoeeo@niehs.nih.gov). Requests should be made at least 7 days in advance of the meeting.

**ADDRESSES:** The expert panel meeting for genistein and soy formula will be held at the Radisson Hotel Old Town, 901 N. Fairfax Street, Alexandria, Virginia 22314-1501 (telephone: 703-683-6000, facsimile: 703-683-7597). Comments on the draft expert panel reports and any other correspondence should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709 (mail), (919) 316-4511 (fax), or [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov) (e-mail). Courier address: CERHR, NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

#### SUPPLEMENTARY INFORMATION:

##### Background

Genistein (CAS RN: 446-72-0) is a phytoestrogen found in some legumes, such as soybeans and clover, or in products obtained from animals ingesting genistein-containing feed. Phytoestrogens are non-steroidal, estrogenic compounds that occur naturally in plant products. Genistein is found in food and over-the-counter dietary supplements and is the primary phytoestrogen in soy formula. Soy formula is administered to infants as a

supplement or replacement for maternal breast milk or cow's milk. CERHR selected genistein and soy formula for expert panel evaluation because of (1) the availability of numerous reproductive and developmental toxicity studies in laboratory animals and humans, (2) the availability of information on exposures in infants and women of reproductive age, and (3) public concern for effects on infant or child development.

At the meeting, the expert panel will review and revise the draft expert panel reports and reach conclusions regarding whether exposure to genistein or soy formula is a hazard to human reproduction or development. Each draft expert panel report has the following sections:

- 1.0 Chemistry, Use, and Human Exposure
- 2.0 General Toxicological and Biological Effects
- 3.0 Developmental Toxicity Data
- 4.0 Reproductive Toxicity Data
- 5.0 Summary, Conclusions, and Critical Data Needs (to be prepared at expert panel meeting)

#### Request for Comments

CERHR invites the submission of written public comments on sections 1-4 of the draft expert panel reports on genistein and soy formula. Any comments received will be posted on the CERHR Web site prior to the meeting and distributed to the expert panel and CERHR staff for their consideration in revising the draft reports and preparing for the expert panel meeting. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Shelby (see **ADDRESSES** above) for receipt by March 1, 2006.

Time is set-aside on March 15, 2006, for the presentation of oral public comments at the expert panel meeting. Seven minutes will be available for each speaker (one speaker per organization). When registering to comment orally, please provide your name, affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization (if any). If possible, send a copy of the statement or talking points to Dr. Shelby by March 8, 2005. This statement will be provided to the expert panel to assist them in identifying issues for discussion and will be noted in the meeting record. Registration for presentation of oral comments will also be available at the meeting on March 15, 2006, from 7:30-8:30 a.m. Persons registering at the

meeting are asked to bring 20 copies of their statement or talking points for distribution to the expert panel and for the record.

#### Preliminary Agenda

The meeting begins each day at 8:30 a.m. . On March 15 and 16, it is anticipated that a lunch break will occur from noon-1 p.m. and the meeting will adjourn at 5-6 p.m. The meeting is anticipated to adjourn by noon on March 17; however, adjournment may occur earlier or later depending upon the time needed by the expert panel to complete its work. Anticipated agenda topics for each day are listed below.

#### March 15, 2006

- Opening remarks
- Oral public comments (7 minutes per speaker; one representative per group)
- Review of sections 1-4 of the draft expert panel reports on genistein and soy formula
- Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs

#### March 16, 2006

- Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs
- Preparation of draft summaries and conclusion statements

#### March 17, 2006

- Presentation, discussion of, and agreement on summaries, conclusions, and data needs
- Closing comments

#### Expert Panel Roster

The CERHR expert panel is composed of independent scientists selected for their scientific expertise in reproductive and/or developmental toxicology or other areas of science relevant for these evaluations.

Karl K. Rozman, Ph.D., D.A.B.T.  
(Chair)—University of Kansas Medical Center, Kansas City, KS  
Jatinder Bhatia, M.B.B.S.—Medical College of Georgia, Augusta, GA  
Antonia M. Calafat, Ph.D.—National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA  
Christina Chambers, Ph.D., M.P.H.—University of California San Diego Medical Center, San Diego, CA  
Martine Culty, Ph.D.—Georgetown University Medical Center, Washington, DC  
Ruth Ann Eitzel, Ph.D.—Alaska Native Medical Center, Anchorage, AK  
Jody Anne Flaws, Ph.D.—University of Maryland School of Medicine, Baltimore, MD  
Deborah K. Hansen, Ph.D.—National Center for Toxicological Research, Jefferson, Arkansas

Patricia B. Hoyer, Ph.D.—University of Arizona, Tucson, AZ

Elizabeth Hutt Jeffery, Ph.D.—University of Illinois, Urbana, IL

James S. Kesner, Ph.D.—National Institute for Occupational Safety and Health, Cincinnati, OH

M. Sue Marty, Ph.D.—The Dow Chemical Company, Midland, MI

John A. Thomas, Ph.D.—University of Texas, San Antonio, TX

David M. Umbach, Ph.D.—National Institute of Environmental Health Sciences, Research Triangle Park, NC

#### Background Information on the CERHR

The NTP established CERHR in June 1998 [**Federal Register**, December 14, 1998 (Volume 63, Number 239, page 68782)]. CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with environmental and/or occupational exposures. Expert panels conduct scientific evaluations of environmental chemicals, drugs, physical agents, or mixtures (collectively referred to as “substances”) selected by the CERHR in public forums.

The CERHR invites the nomination of substances for expert panel evaluation or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (see **ADDRESSES** above). CERHR selects substances for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and extent of data from reproductive and developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** on July 16, 2001 (Volume 66, Number 136, pages 37047-37048) and is available on the CERHR Web site under “About CERHR” or in printed copy from the CERHR.

Dated: December 5, 2005.

#### David A. Schwartz,

Director, National Institute of Environmental Health Sciences and the National Toxicology Program.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Toxicology Program; Hormonally-Induced Reproductive Tumors: Relevance of Rodent Bioassays Workshop

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Workshop announcement.

**SUMMARY:** For more than a quarter century, the National Toxicology Program (NTP) testing program has provided extensive and useful scientific information for predicting human health hazards and protecting public health. The NTP periodically conducts reviews of animal models used in its bioassays to critically analyze their predictive power and determine whether the protocols for these studies should be altered. As part of this effort, the NTP is convening a workshop titled “Hormonally-Induced Reproductive Tumors: Relevance of Rodent Bioassays.” The 2½ day workshop will be held on May 22-24, 2006, at the Marriott Raleigh Crabtree Valley, 4500 Marriott Drive, Raleigh, NC 27612.

The workshop’s overall goal is to determine the adequacy and relevance to human disease outcome of rodent models for four types of hormonally-induced reproductive tumors (ovary, mammary gland, prostate, and testis). Other topics for discussion include proposed modes of action (for each tumor type and for hormonal tumors in general), dose response for tumor induction, predictiveness of rodent pre-neoplastic events for humans, the importance of the inclusion of an *in utero exposure* in the etiology of specific tumors, and the concept of “additivity to background” when normal hormones are present with homeostatic control mechanisms. The program will include plenary sessions as well as four breakout group sessions for in-depth discussions.

This meeting is open to the public with time set aside for public comments. Attendance is limited by the space available to approximately 100 public attendees. Individuals may register to attend the workshop on a first-come, first-served basis per the procedures outlined below. A copy of the agenda and any additional information about the workshop, including background materials, public comments, and invited participants, will be posted on the NTP Web site when available (see NTP Web site