

within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 10, 2006.

**David R. Sadowski,**

*Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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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 Availability of the Genistein and Soy Formula Expert Panel Reports; Request for Public Comment

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

**ACTION:** Request for comments.

**SUMMARY:** CERHR announces the availability of the genistein and soy formula expert panel reports on the CERHR Web site (<http://cerhr.niehs.nih.gov>) or in print from CERHR (see **ADDRESSES** below). These expert panel reports are evaluations of the reproductive and developmental toxicity of genistein and soy formula conducted by a 14-member expert panel composed of scientists from the federal government, universities, and private organizations. CERHR invites the submission of public comments on these expert panel reports.

**DATES:** The final genistein and soy formula expert panel reports are presently available and written public comments on these reports should be received by July 5, 2006.

**ADDRESSES:** Public comments 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, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

#### SUPPLEMENTARY INFORMATION:

##### Background

Genistein is a phytoestrogen found in some legumes, especially soybeans. Phytoestrogens are non-steroidal, estrogenic compounds that occur naturally in some plants. In plants, nearly all genistein is linked to a sugar molecule and this genistein-sugar complex is called genistin. Genistein and genistin are found in many food products, especially soy-based foods such as tofu, soy milk, and soy infant formula, and in some over-the-counter dietary supplements. Soy formula is fed to infants as a supplement or replacement for human milk or cow milk. CERHR selected genistein and soy formula for expert panel evaluation because of (1) the availability of 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.

The CERHR convened an expert panel on March 15-17, 2006, to review and revise the draft expert panel reports and reach conclusions regarding whether exposure to genistein or soy formula is a hazard to human development or reproduction. The expert panel also identified data gaps and research needs. Prior to the meeting, CERHR solicited public comment on the draft expert panel reports (**Federal Register** Vol. 70, No. 241 pp. 74834-74835).

Following receipt of public comments on the genistein and soy formula expert panel reports, CERHR staff will prepare NTP-CERHR monographs on each of these substances. NTP-CERHR monographs are divided into four major sections: (1) The NTP Brief which provides the NTP's interpretation of the potential for the chemical to cause adverse reproductive and/or developmental effects in exposed humans, (2) a roster of expert panel members, (3) the final expert panel report, and (4) any public comments received on that report. The NTP Brief is based on the expert panel report, public comments on that report, and any new information that became available after the expert panel meeting.

##### Request for Comments

CERHR invites written public comments on the genistein expert panel report and on the soy formula expert

panel report. Written comments should be sent to Dr. Michael Shelby at the address provided above. 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). All comments received will be posted on the CERHR Web site and will be included in the NTP-CERHR monograph on the chemical. The NTP will consider all public comments during preparation of the NTP Brief.

##### Background Information on CERHR

The NTP established CERHR in June 1998 [**Federal Register**, December 14, 1998 (Vol. 63, No. 239, pp. 68782)]. CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by CERHR in public forums.

CERHR invites the nomination of agents for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its Web site (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (see **ADDRESSES** above). CERHR selects chemicals 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** notice July 16, 2001 (Vol. 66, No. 136, pp. 37047-37048) and is available on the CERHR Web site under "About CERHR" or in printed copy from CERHR.

Dated: May 8, 2006.

**Samuel H. Wilson,**

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

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