comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: October 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24991 Filed 10–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Availability of the Draft Expert Panel Report on Soy Formula; Request for Public Comment on the Draft Report; Announcement of the Soy Formula Expert Panel Meeting

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

ACTION: Availability of draft report, request for public comment, and announcement of a meeting.

SUMMARY: The CERHR announces the availability of the draft expert panel report on soy formula on October 19, 2009, on the CERHR Web site (*http://cerhr.niehs.nih.gov*) or in printed text from CERHR (*see* **FOR FURTHER INFORMATION CONTACT** below). The CERHR invites the submission of public comments on chapters 1–4 of the draft expert panel report (*see* **SUPPLEMENTARY INFORMATION** below). The expert panel will meet on December 16–18, 2009, at the Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314 (*Tel:* 1–703–837–0440) to review and revise the draft expert panel report and reach conclusions regarding whether exposure to soy formula is a hazard to human development. 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 meeting room space. Following the expert panel meeting and completion of the expert panel report, the CERHR will post the final report on its Web site and solicit public comment on it through a **Federal Register** notice.

DATES: The expert panel meeting for soy formula will be held on December 16–18, 2009. Chapters 1–4 of the draft expert panel report will be available for public comment on October 19, 2009. Written public comments on the draft report must be received by December 2, 2009. Time is set aside at the expert panel meeting on December 16, 2009, for oral public comments. Individuals wishing to make oral public comments are asked to register online (*http://cerhr.niehs.nih.gov*) or contact Dr. Kristina A. Thayer, CERHR Acting Director, by December 9, 2009, and if possible, send a copy of the statement and/or slide presentation at that time. Persons wishing to attend are asked to register by December 9, 2009 via the CERHR Web site (*http://cerhr.niehs.nih.gov*).

ADDRESSES: Public comments and any other correspondence should be submitted to Dr. Kristina A. Thayer, CERHR Acting Director, NIEHS, P.O. Box 12233, Mail Drop K2–04, Research Triangle Park, NC 27709 (mail), 919–541–5021 (telephone), or *thayer@niehs.nih.gov* (e-mail). *Courier address:* NIEHS, 530 Davis Drive, Room K2154, Morrisville, NC 27560.

FOR FURTHER INFORMATION CONTACT: Dr. Kristina A. Thayer (*telephone:* 919–541–5021 or e-mail: *thayer@niehs.nih.gov*). Persons needing interpreting services in order to attend should contact (301) 402–8180 (voice) or (301) 435–1908 (TTY). Requests should be made at least seven business days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

Background

Soy formula is fed to infants as a supplement or replacement for human milk or cow milk. Soy formula contains isoflavones such as genistein (CAS RN: 446–72–0), daidzein (CAS RN: 486–66–8), and glycitein (CAS RN: 40957–83–3). Genistein, daidzein, glycitein, and the daidzein metabolite equol are non-steroidal, estrogenic compounds that occur naturally in some plants and are often referred to as ''phytoestrogens.'' In plants, nearly all genistein, daidzein, and glycitein is linked to a sugar molecule and these isoflavone-sugar complexes are called genistin, daidzin, or glycitin.

On March 15–17, 2006, CERHR convened an expert panel to conduct evaluations of the potential developmental and reproductive toxicities of soy formula and its predominant isoflavone constituent genistein. CERHR selected soy formula and genistein 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. The expert panel reports were released for public comment on May 5, 2006 (71 FR 28368). On November 8, 2006 (71 FR 65537), CERHR staff released draft NTP Briefs on Genistein and Soy Formula that provided the NTP's interpretation of the potential for genistein and soy formula to cause adverse reproductive and/or developmental effects in exposed humans. CERHR has not completed these evaluations, finalized the briefs, or issued NTP–CERHR monographs on these substances. Since 2006, a substantial number of new publications related to human exposure or reproductive and/or developmental toxicity have been published for these substances. CERHR has determined that updated evaluations of genistein and soy formula are needed. However, the current evaluation will focus on soy formula and the potential developmental toxicity of its major isoflavone components, *e.g.,* genistein, daidzein, and glycitein. This evaluation will not include an assessment on the potential reproductive toxicity of genistein following exposures during adulthood as was done in the 2006 evaluation. CERHR is narrowing the scope of the evaluation because the assessment of reproductive effects of genistein following exposure to adults was not considered relevant in the consideration of soy formula use in infants during the initial evaluation in 2006.

At the meeting, the expert panel will review and revise the draft expert panel report and reach conclusions regarding whether exposure to soy formula is a hazard to human development. The draft expert panel report has the following chapters:

1.0 Chemistry, Use, and Human Exposure
2.0 General Toxicological and Biological Effects
3.0 Developmental Toxicity Data
  a. Developmental Toxicity Data for Genistein, Daidzein, Equol, and Glycitein
  b. Developmental Toxicity Data for Soy Formula and Other Soy

Products
4.0 Reproductive Toxicity Data
5.0 Summary, Conclusions, and Critical Data Needs (to be developed at the expert panel meeting).

Request for Comments

CERHR invites written public comments on chapters 1–4 of the draft expert panel report on 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 report and/or preparing for the expert panel meeting. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone number, e-mail, and sponsoring organization, if any) and send them to Dr. Thayer (*see* **ADDRESSES** above) for receipt by December 2, 2009. Comments will be identified on the Web site by the submitter's name, affiliation, and/or sponsoring organization.

Time is set aside on December 16, 2009 for the presentation of oral public comments at the expert panel meeting. Seven minutes will be available for each speaker (one speaker per organization). Online registration is available on the CERHR website or persons wishing to make oral remarks can contact Dr. Thayer. If possible, send a copy of the statement, talking points, and/or slide presentation to Dr. Thayer by December 2. This statement will be provided to the expert panel to assist them in identifying issues for discussion and noted in the meeting record. Registration for presentation of oral comments will also be available at the meeting on December 16, 2009, from 7:30–8:30 a.m. Persons registering at the meeting are asked to bring 30 copies of their statement, talking points, and/or slide presentation for distribution to the expert panel and for the record.

Attendance and Registration

In order to facilitate planning for this meeting, persons wishing to attend are asked to register by December 9, 2009, via the CERHR Web site (*http://cerhr.niehs.nih.gov*).

Preliminary Agenda

The meeting begins each day at 8:30 a.m. On December 16 and 17, 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 expected to adjourn by noon on December 18, 2009; 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.

December 16, 2009

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

December 17, 2009

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

December 18, 2009

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

Background Information on the CERHR

The NTP established CERHR in 1998 (63 FR 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. CERHR follows a formal process for the evaluation of selected substances that includes opportunities for public input.

CERHR invites the nomination of substances for review 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. Thayer (*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. Expert panels conduct scientific evaluations of substances selected by CERHR in public forums. Following these evaluations, CERHR prepares the NTP–CERHR monograph on the substance evaluated. The monograph is transmitted to appropriate Federal and State agencies and made available to the public.

Dated: October 8, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. E9–25122 Filed 10–16–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0143]

Risk Evaluation and Mitigation Strategies for Certain Opioid Drugs; Notice of Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 19, 2010, the comment period for the notice of public meeting published in the **Federal Register** of April 20, 2009 (74 FR 17967). In that notice, FDA announced a public meeting that took place on May 27 and 28, 2009, to solicit input on developing Risk Evaluation and Mitigation Strategies (REMS) for certain opioid drugs. FDA is reopening the comment period in light of continued public interest in this topic and to provide an opportunity for all interested parties to provide information and share views on the matter.

DATES: Submit written or electronic comments by October 19, 2010.

ADDRESSES: Submit written comments 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Theresa (Terry) Martin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6196, Silver Spring, MD 20993–0002, 301–796–3448; FAX: 301–847–8752, e-mail: *OpioidREMS@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 20, 2009 (74 FR 17967), FDA published a notice of a public meeting on developing REMS for certain opioid drugs. The affected opioid drugs include long acting and extended release brand name and generic products that are formulated with the following active ingredients: Fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The REMS would be intended to ensure that the benefits of these drugs continue to outweigh risks associated with: (1) Use of high doses of long acting opioid and extended release