Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: October 6, 2009.

Bruce Gellin,

Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. E9–25079 Filed 10–16–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0302] (formerly Docket No. 2007D–0185)

Guidance for Industry and Review Staff on Labeling for Human Prescription Drug and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and review staff entitled ''Labeling for Human Prescription Drug and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to provide applicants and review staff with a definition of established pharmacologic class and to help them identify the most appropriate word (term) or phrase that describes the established pharmacologic class for a drug or biological product for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling. This guidance finalizes the draft guidance published in the **Federal Register** on May 16, 2007.

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Laurie B. Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993–0002, 301–796–0136; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration,1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and review staff entitled ''Labeling for Human Prescription Drug and Biological Products—determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to provide applicants and review staff with a definition of established pharmacologic class and to help them identify the most appropriate word (term) or phrase that describes the established pharmacologic class for a drug or biological product for inclusion in the *Indications and Usage* section of *Highlights* of approved labeling, as required under 21 CFR 201.57(a)(6).

In January 2006, FDA published a final rule that amended the requirements for the content and format of labeling for human prescription drug and biological products.[1]

The new labeling format is intended to make it easier for health care professionals to access, read, and use the information in prescription drug labeling, thereby facilitating professionals' use of labeling to make prescribing decisions.

The rule requires that the following statement appear under the *Indications and Usage* section of *Highlights* if a drug is a member of an established pharmacologic class:[2]

''(Drug) is a (name of class) indicated for (indication(s)).''

If the drug is not a member of an established pharmacologic class, the name of class component of this statement should be omitted.

Knowing the established pharmacologic class can provide health care professionals with important information about what to expect from a drug and how it relates to other therapeutic options. Such information can also help reduce the risk of duplicative therapy and drug interactions. This guidance provides recommendations for identifying the established pharmacologic class and its appropriate term for inclusion in the *Indications and Usage* section of *Highlights*.

A draft version of this guidance was made available for public comment in 2007 (72 FR 27576, May 16, 2007). All of the public comments we received have been considered and the guidance has been revised as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection associated with the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' is approved by OMB under Control Number 0910–0572. The submission of prior-approval labeling supplements, as described in section VI of the guidance, is approved by OMB under Control Numbers 0910–0001 and 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic

[1] See ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (71 FR 3922, January 24, 2006; 21 CFR parts 201, 314, 601).

[2] See § 201.57(a)(6).

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