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

opioid products in non-opioid tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional. REMS for these opioids would likely include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of and understand the risks and proper use of these products. The opioid drugs expected to be subject to REMS are widely prescribed by a large number of physicians who practice in a wide variety of areas. A REMS that will adequately manage the risks of these products without unduly burdening the health care system or reducing patient access to these medications must be carefully designed. Recognizing this challenge, we identified several specific areas in which FDA wishes to obtain information and public comment in our April 2009 notice of public meeting.

Interested persons were originally given until June 30, 2009, to comment. As a result of continued public interest, FDA is reopening the comment period until October 19, 2010 to allow interested persons additional time to provide information and share views on this topic.

II. How to Submit Comments

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

Dated: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25022 Filed 10–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: OMB–48, InfoPass System; New Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: OMB–48, InfoPass System.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 28, 2009, at 74 FR 37234, allowing for a 60-day public comment period. USCIS did not receive any comments.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 18, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*, and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov.*

When submitting comments by e-mail, please make sure to add OMB–48 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Information collection.

(2) *Title of the Form/Collection:* InfoPass System.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number; File No. OMB–48. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or Households. The InfoPass system allows an applicant or petitioner to schedule an interview appointment with USCIS through USCIS' Internet Web site.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,043,319 responses at 6 minutes (.10) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 104,332 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/*

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529–2210, Telephone number 202–272–8377.

Dated: October 14, 2009.

Stephen Tarragon,

Deputy Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services.

[FR Doc. E9–25042 Filed 10–16–09; 8:45 am]

BILLING CODE 9111–97–P