nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from food manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 26, 2013.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1317]

Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the Federal Register of November 8, 2013 (78 FR 67169). In the notice, we requested comments on our tentative determination that partially hydrogenated oils (PHOs) are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence, and therefore are subject to regulation as food additives. We are taking this action in response to multiple requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice. Submit either electronic or written comments by March 8, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–1317 by any of the following methods:

Electronic Submissions
Submit electronic comments in the following way:

Written Submissions
Submit written submissions in the following ways:
- Mail/Hand delivery/Courier (for paper or CD–ROM submissions):
Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–1317 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Background
In the Federal Register of November 8, 2013 (78 FR 67169), FDA published a notice announcing our tentative determination that PHOs, which are the primary dietary source of industrially-produced trans fatty acids, or trans fat, are not GRAS for any use in food based on current scientific evidence establishing the health risks associated with the consumption of trans fat with a 60-day comment period ending on January 7, 2014. The notice also invited comments and additional scientific data and information related to this tentative determination and, in particular, requested comment on a number of specific questions (78 FR 67169 at 67174).

We have received multiple requests for a 60-day extension of the comment period for the notice. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to collect data and information and develop a comprehensive and thoughtful response to the notice.

FDA has considered the requests and is extending the comment period for the notice for 60 days, until March 8, 2014. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying our final determination on this important issue.

II. Request for Comments
Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

Dated: December 24, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in
general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 et seq., provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register.” Set forth below is a list of petitions received by HRSA on November 1, 2013, through November 30, 2013. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has required the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and
2. Any allegation in a petition that the petitioner either:
   (a) “Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or
   (b) “Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading “For Further Information Contact”), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857. The Court’s caption (Petitioner’s Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.


Mary K. Wakefield, Administrator.

List of Petitions Filed

1. Ronda Odom, Weatherford, Texas, Court of Federal Claims No: 13–0865V
2. Kendy Sue Wilson, Sterling Heights, Michigan, Court of Federal Claims No: 13–0866V
5. Karen Schuler, Mesa, Arizona, Court of Federal Claims No: 13–0872V
6. Cynthia Winward on behalf of James Winward, Yuba City, California, Court of Federal Claims No: 13–0873V
7. Elaine S. Tito, Saco, Maine, Court of Federal Claims No: 13–0878V
8. Samuel Gray, Lewiston, Maine, Court of Federal Claims No: 13–0880V
10. James and Valerie Myers on behalf of Malakai Myers, Phoenix, Arizona, Court of Federal Claims No: 13–0885V
11. Valerie Cozby, Columbus, Georgia, Court of Federal Claims No: 13–0886V
17. Laura J. Lefeb, Hartford, Connecticut, Court of Federal Claims No: 13–0897V
22. Patricia Huhmann, Fishers, Indiana, Court of Federal Claims No: 13–0903V
23. James D. Saffold, Brandon, Florida, Court of Federal Claims No: 13–0905V
24. Mary-Lou A. Green, Syracuse, New York, Court of Federal Claims No: 13–0911V
25. Courtney Miller and Bernard Miller on behalf of Ella Mae Miller, Spokane, Washington, Court of Federal Claims No: 13–0914V
27. Sharon Bosc, New Haven, Connecticut, Court of Federal Claims No: 13–0916V
29. Roberta Green, Hurricane, West Virginia, Court of Federal Claims No: 13–0920V
31. Charles W. Brown on behalf of Kathryn C. Brown, Decedent, Wichita, Kansas, Court of Federal Claims No: 13–0922V
32. David W. Crippen, Pittsburgh, Pennsylvania, Court of Federal Claims No: 13–0923V
33. Maria and Joel Gonzalez on behalf of Joel Gonzalez, Jr., San Jose, California, Court of Federal Claims No: 13–0927V
34. Michael Swann, Leeds, Massachusetts, Court of Federal Claims No: 13–0928V
35. Debbie Bretag, Chicago, Illinois, Court of Federal Claims No: 13–0930V
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Application Process for Clinical Research Training and Medical Education at the Clinical Center and Its Impact on Course and Training Program Enrollment and Effectiveness

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on October 2, 2013, page 60885 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Clinical Center (CC), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: 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: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Robert M. Lembo, MD, Deputy Director, Office of Clinical Research Training and Medical Education, NIH Clinical Center, 10 Center Drive, MSC 1158, Bethesda, MD 20892–1352, or call non-toll-free number (301)-594–4193, or Email your request, including your address to: lembor@mail.nih.gov.

Formal requests for additional plans and instructions must be requested in writing.

Proposed Collection: Application Process for Clinical Research Training and Medical Education at the Clinical Center and its Impact on Course and Training Program Enrollment and Effectiveness—Existing collection in use without OMB control number—Clinical Center, National Institutes of Health (NIH).

Need and Use of Information Collection: The primary objective of the application process is to allow OCRTME to evaluate applicants’ qualifications to determine applicants’ eligibility for courses and training programs managed by the office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director or training program selection committee for review and decisions regarding acceptance for participation. A secondary objective of the application process is to track enrollment in courses and training programs over time.

OMB approval is requested for 3 years. There are additional costs to the respondents other than their time. The total estimated annualized burden hours are 2,210.

ESTIMATED ANNUALIZED BURDEN HOURS

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<th>Burden per application (in hours)</th>
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Dated: December 18, 2013.

Laura Lee,

Project Clearance Liaison, Clinical Center, National Institutes of Health.