docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Steven Gendel, Center for Food and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1056.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.'' This draft guidance is intended to help industry prepare petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108–282) amended the FD&C Act by defining the term ''major food allergen'' and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the common or usual name of that major food allergen.

Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) now defines a major food allergen as ''[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans'' and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)). An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act). Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our 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 applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register**.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10578 Filed 5–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Awareness and Beliefs About Cancer Survey, National Cancer Institute (NCI)

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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 19, 2013, Vol. 78, page 36788 and allowed 60 days for public comment. Three public comments, questions, and requests for information were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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.

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, submit comments in writing, or request more

information on the proposed project, contact: Sarah Kobrin, Division of Cancer Control and Population Sciences, 9609 Medical Center Dr., MSC 9761, Rockville, MD 20852, or call non-toll-free number 240–276–6931or Email your request, including your address to: *kobrins@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Awareness and Beliefs about Cancer Survey, OMB No. 0925–0684, Expiration Date 11/30/2014, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The objective of the study is gather data about American adults' awareness and beliefs about cancer. The ultimate goal is to determine how individuals' perceptions of cancer may influence their decisions to report signs and symptoms to health care providers, perhaps affecting the disease stage of diagnosis and the effectiveness of treatment. Data will be collected from approximately 1,500 adults aged 50 years or older across the United States will be recruited for the NCI Awareness and Beliefs about Cancer survey over a one-year period. This request is to include cellphone-only households in the ABC survey; the original request was to survey only landline households.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,667.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Screener	General Public	14,000	1	5/60	1,167
Survey	Adults 50+ years old	1,500	1	20/60	500

Dated: May 1, 2014.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–10591 Filed 5–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Evaluation of Center for Global Health's (CGH) Workshops (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Sudha Sivaram, Program Director, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., RM 3W528, Rockville MD, 20850 or call non-toll-free number 240–276–5804 or Email your request, including your address to: *sudha.sivaram@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Evaluation of Center for Global Health's (CGH) Workshops (NCI), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is a request for OMB to approve the Evaluation of Center for Global Health's (CGH) Workshops for three years. These workshops are organized and funded by the National Cancer Institute's CGH in conjunction with various partners ranging from foreign Ministries of Health and research institutions, to international non-governmental organizations (NGOs) and U.S. academic institutions. The workshops to be evaluated are the Symposiums on Global Cancer Research, Workshops in Cancer Control Planning and Implementation, the Summer Curriculum in Cancer Prevention, Women's Empowerment Cancer Advisory Network Workshops (WE–CAN), Regional Grant Writing and Peer Review Workshops and other similar workshops. While these workshops differ in content and delivery style, their underlying goals are the same; they intend to initiate and enhance cancer control efforts, increase capacity for cancer research, foster new partnerships, and create research and cancer control networks. The proposed evaluation requests information about the outcomes of each of these workshops including (1) new cancer research partnerships and networks (2) cancer control partnerships and networks, (3) effects on cancer research, and (4) effect on cancer control planning and implementation efforts. The information will be collected 3–12 months after the workshops and is needed to evaluate the effectiveness of these workshops in order to inform future programming and funding decisions.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 203.