

the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.html>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Custom Device Exemption," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1820 to identify the guidance you are requesting.

Draft Guidance for Custom Device Exemption

This guidance is intended to assist industry by providing draft definitions of terms used in the custom device exemption, to explain how FDA proposes to interpret the "five units per year of a particular device type" language contained in section 520(b)(2)(B) of the FD&C Act, to describe what information FDA proposes that should be submitted in a custom device annual report, and to provide recommendations on how to submit an annual report for devices distributed under the custom device exemption. In addition, manufacturers

of custom devices are required to sign and submit a Custom Devices Annual Report Truthful and Accurate certificate with their annual report.

Description of Respondents: The respondents of this collection of information are manufacturers of medical devices deemed to be custom devices subject to FDA's laws and regulations.

In the **Federal Register** of January 14, 2014 (79 FR 2446), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Guidance Title: Custom Device Exemption	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section VI. Annual Reporting	33	1	33	40	1,320

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates it will receive 33 reports for custom devices annually. The Agency reached this estimate by the number of pre-FDASIA manufacturers who qualified for custom devices and that percentage of current manufacturers that qualify under post-FDASIA requirements. Only 10 percent of manufacturers would meet this qualification, which was calculated by adding the number of estimated old custom device manufacturers with the estimated new manufacturers submitting annual reports of custom devices each year. FDA estimates it will take custom device manufacturers approximately 40 hours to complete the annual report described in section VI of the draft guidance. FDA reached this time estimate based on its expectation of the amount of information that should be included in the report.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the

PRA (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120.

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0052]

Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications." The draft guidance,

when finalized, will explain our current thinking on the preparation of regulatory submissions for obtaining exemptions for ingredients from the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) through submission of either a petition or a notification.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 5, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

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.

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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