Dated: June 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15078 Filed 6–18–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0052]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (''FDA'' or ''we'') is announcing the availability of a guidance for industry entitled ''Food Allergen Labeling Exemption Petitions and Notifications.'' This guidance explains FDA's 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 (FD&C Act) through submission of either a petition or a notification.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), 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 guidance.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: Richard Bonnette, Center for Food and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1235.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 8, 2014 (79 FR 26435), we announced the availability of a draft guidance entitled ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications'' and gave interested parties an opportunity to submit comments on the draft guidance at any time and comments on the proposed collection of information by September 25, 2014. We received several comments and revised the guidance accordingly.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of 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 allergens 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 eliminate the allergenic proteins in that derived ingredient such that it is not a risk for food allergic individuals. 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 presents a risk for food allergic individuals. 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).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on Food Allergen Labeling Exemption Petitions and Notifications. It does not create or confer any rights for or on any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information in this guidance was approved under OMB control number 0910–0792.

III. Comments

Interested persons may submit either electronic comments regarding the guidance 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: June 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15119 Filed 6–18–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Announcement of Food and Drug Administration Demo Day for the 2014 Food and Drug Administration Food Safety Challenge; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting entitled ''Demo Day for the 2014 FDA Food Safety Challenge.'' The 2014 FDA Food Safety Challenge (*http://www.foodsafetychallenge.com*) is a prize competition under the America COMPETES Reauthorization Act of 2010 which granted us (and other federal Agencies) broad authority to conduct prize competitions to spur innovation, solve tough problems, and advance our core mission. The purpose of the public meeting is for each of the five challenge finalists to present their concepts to the judges for selection of one or more winners.

DATES: The public meeting will be held on July 7, 2015, from 1 p.m. to 5 p.m.

ADDRESSES: The public meeting will be held at the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Building Auditorium (Rm. 1A003–AR), College Park, MD 20740. Parking is extremely limited, so we encourage public meeting participants to use public transportation (Metro: College Park-U of MD station on the Green Line). Entrance for the public meeting participants (non-FDA employees) is through the main entrance of the Wiley Building where routine security check procedures will be performed.

FOR FURTHER INFORMATION CONTACT: Chad P. Nelson, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4643, FAX: 301–847–3534, email: *chad.nelson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The 2014 FDA Food Safety Challenge is a prize competition under the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358) which granted us (and other federal Agencies) broad authority to conduct prize competitions to spur innovation, solve tough problems, and advance our core mission. In the 2014 FDA Food Safety Challenge, we asked for potential breakthrough ideas on how to find disease-causing organisms—especially *Salmonella*—in food. We encouraged food safety experts, such as scientists, academics, entrepreneurs, and innovators, to participate in the challenge and to develop concepts specifically to address the detection of *Salmonella* in minimally processed fresh produce and the ability of a solution to address testing for other microbial pathogens and in other foods. The panel of food safety and pathogen detection experts from FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture will judge the finalists' concepts and select a winner or winners.

II. Registration and Webcast Information

If you are interested in attending the meeting, submit your online registration information (including name, title, firm name, address, telephone number, and email) by June 29, 2015 at: *http://www.foodsafetychallenge.com/demoday/.* There is no registration fee for the public meeting. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to disability, please contact Chad Nelson (see Contact Person) at least 7 days in advance.

For those who are unable to attend in person, the public meeting will also be Webcast. Information about how to register to view the live Webcast of this meeting will be provided on the Challenge Web site at *http://foodsafetychallenge.com/demoday/.*

Dated: June 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15124 Filed 6–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Dental Preventive and Clinical Support Centers Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on June 5, 2015 for the FY 2015 New and Competing Continuation Funding Announcement for the Dental Preventive and Clinical Support Centers Program. The notice contained incorrect dates.

FOR FURTHER INFORMATION CONTACT: Patrick Blahut, DDS, MPH, Deputy Director, IHS Division of Oral Health, 801 Thompson Avenue, Suite 332, Rockville, MD 20852, Telephone: (301) 443–4323. (This is not a toll-free number.)

Corrections

In the **Federal Register** of June 5, 2015, 80 FR 32160, under the heading ''Key Dates'' replace the following dates to read as follows:

''Application Deadline Date: August 5, 2015,'' ''Anticipated Review Dates: August 12–14, 2015,'' ''Signed Tribal Resolutions Due Date: August 5, 2015,'' and ''Proof of Non-Profit Status Due Date: August 5, 2015.''

Dated: June 12, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015–15156 Filed 6–18–15; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2015–IHS–NIHOE–3–Health–Reform–0002; Catalog of Federal Domestic Assistance Number: 93.933]

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education—Health Reform Funding Opportunity Announcement Type: New Limited Competition

Key Dates

Application Deadline Date: August 16, 2015.

Review Date: August 24–26, 2015.

Earliest Anticipated Start Date: September 30, 2015.

Proof of Non-Profit Status Due Date: August 16, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Direct Service and Contracting Tribes (ODSCT) and the Office of Resource Access and Partnerships (ORAP) is accepting cooperative agreement applications for the National Indian Health Outreach and Education (NIHOE) III—Health Reform funding opportunity that includes outreach and education activities on the following: The Patient Protection and Affordable Care Act, Pub. L. 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, collectively known as the Affordable Care Act (ACA), and the Indian Health Care Improvement Act (IHCIA), as amended. This program is authorized under: The Snyder Act, codified at 25 U.S.C. 13, and the Transfer Act, codified at 42 U.S.C. 2001(a). This program is described in the Catalog of Federal Domestic Assistance under 93.933.