



4160-01-P

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Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications;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SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled "Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications." The draft guidance, when finalized, will explain our current thinking on the preparation of regulatory submissions for obtaining exemptions for ingredients from the labeling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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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We are announcing the availability of a draft guidance entitled, "Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications." This draft guidance is intended to help industry prepare petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food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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