4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0711]

Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket; 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 to May 13, 2013, the comment period for the notice entitled "Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket," that appeared in the Federal Register of December 14, 2012 (77 FR 74485). In that document, we requested comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). The document requested comments (including data) that we can use to design and carry out a quantitative risk assessment for establishing regulatory thresholds for major food allergens. We are extending the comment period in response to a request from an industry association.

DATES: Submit either electronic or written comments by May 13, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0711, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- 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-2012-N-0711. 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:

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SUPPLEMENTARY INFORMATION

I. Background

In the Federal Register of December 14, 2012 (77 FR 74485), we published a document entitled "Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket." In that document, we requested comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in FALCPA (Title II of Public Law 108-282). The document requested comments (including data) that we can use to design and carry out a quantitative risk assessment for establishing regulatory thresholds for major food allergens.

Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(qq)) 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, (exempting highly refined oils). FALCPA establishes that foods regulated under the FD&C Act are misbranded unless they declare the presence of major food allergens on the product label using the common or usual name of that major food allergen. FALCPA also provides two mechanisms through which ingredients may become exempt from the major food allergen labeling requirement. An individual may petition for an exemption by providing scientific evidence, including the analytical method used, that an ingredient "does not cause an allergic response that poses a risk to human health." (21 U.S.C. 403(w)(6)(C)). Alternatively, an individual may submit a notification that contains either scientific evidence showing that an ingredient "does not contain allergenic protein" or that a determination has

previously been made through a premarket approval process that the ingredient "does not cause an allergic response that poses a risk to human health." (21 U.S.C. 403(w)(7)(A)).

In addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. Most cross-contact can be avoided by controlling the production environment. While we have used several risk management strategies to reduce the risk of exposure to unlabeled major food allergens, we have not established regulatory thresholds or action levels for major food allergens. The establishment of regulatory thresholds or action levels for major food allergens would help us determine whether, or what type of, enforcement action is appropriate when specific problems are identified and also help us establish a clear standard for evaluating claims in FALCPA petitions that an ingredient "does not cause an allergic response that poses a risk to human health" or "does not contain allergenic protein." Regulatory thresholds also would help industry to conduct allergen hazard analyses and develop standards for evaluating the effectiveness of allergen preventive controls. We have previously evaluated the approaches that could be used for establishing thresholds for food allergens, as we reported in March 2006. Since the publication of that report, there have been significant advances in both scientific tools and data resources related to food allergens. Therefore, we intend to determine if the currently available data and analysis tools are sufficient to support a quantitative risk assessment and, if so, to use these data and tools to evaluate the public health impact of establishing specific regulatory thresholds for one or more of the major food allergens.

We recently received requests from trade associations for an extension of the comment period until either April 1, 2013, or May 13, 2013. These requests conveyed the concern that the

current 60-day comment period does not allow sufficient time to collect responsive information and data to submit to FDA.

We considered the requests and, through this notice, are extending the comment period for all interested persons until May 13, 2013.

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.

III. References

FDA has placed the following reference on display. To view the reference, 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. The reference may also be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

1. Threshold Working Group. 2006. Approaches to Establish Thresholds for Major Food Allergen and for Gluten in Food. Available at http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106108.htm.

Dated: January 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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