ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Police Officials	Law Enforcement Interview	35	1	1	35
Total					70

Dated: December 10, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director.

[FR Doc. 2012–30183 Filed 12–13–12; 8:45 am]

BILLING CODE 4163–18–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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing a docket to obtain 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.

DATES: Submit either electronic or written comments by February 12, 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 ways:

- *Fax:* 301–827–6870.
- *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: Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1056.

SUPPLEMENTARY INFORMATION:

I. Background

Food allergy is an immune-mediated sensitivity to foods that can lead to life-threatening adverse reactions. Because there is no cure for food allergy, allergic consumers must use avoidance to prevent allergic reactions. Successful avoidance requires, among other things, that allergic consumers and their caregivers be able to read and understand the ingredient lists on packaged foods.

To help consumers more easily identify ingredients in foods that may cause an allergic reaction, the President signed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Pub. L. 108–282), which amended the Federal Food, Drug, and Cosmetic Act (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 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.

FALCPA 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. These controls can include a wide range of activities, such as establishing personnel and traffic patterns that minimize the potential to transfer an allergen from one product to another.

FDA has used several risk management strategies to reduce the risk from unlabeled major food allergens, such as targeted inspections or discussions with industry organizations. However, 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.

II. Food Safety Risk Assessment for Establishing Food Allergen Thresholds

The FDA Threshold Working Group (the working group) has previously evaluated the approaches that could be used for establishing thresholds for food allergens (Ref. 1). Of the four approaches that were identified (methods-based, safety assessment-based, risk assessment-based, and statutorily-derived), the working group identified the quantitative risk assessment-based approach as being the ''strongest, most transparent'' approach. Further, the working group determined that this approach provides the most insight into both the level of protection and the degree of uncertainty associated with an exposure level. The working group also acknowledged the need for clinical and epidemiological data to support a quantitative risk assessment and to develop applicable risk assessment tools.

Since the working group's report was published in March 2006, 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.

III. Establishment of a Docket and Request for Information

We are establishing a docket to provide an opportunity for interested individuals to submit comments (including data) that we can use to design and carry out a quantitative risk assessment for establishing regulatory thresholds for major food allergens. In particular, we invite comments on the following matters:

1. How should we define ''an allergic response that poses a risk to human health?''

2. Which major food allergens are of greatest public health concern and what is the size of the at-risk population?

3. How should clinical dose distribution data be used when establishing regulatory thresholds for the major food allergens?

4. What approaches exist for using biological markers or other factors related to the severity of allergic responses in a threshold risk assessment?

5. What data and information exist on dietary exposure patterns for individuals on allergen avoidance diets?

6. What data or other information exist on current levels of exposure associated with the consumption of undeclared major food allergens in packaged foods?

7. What other information or data should we consider in establishing regulatory thresholds for major food allergens?

IV. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

V. Reference

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,* accessed December 5, 2012. (FDA has verified this Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

Dated: December 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30123 Filed 12–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 7, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee