

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.

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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

information line to learn about possible modifications before coming to the meeting.

Agenda: On March 7, 2013, the committee will discuss the new drug application (NDA) 204275, for fluticasone furoate and vilanterol dry powder inhaler (proposed tradename BREO ELLIPTA), sponsored by GlaxoSmithKline, for the long-term maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 21, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 12, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 13, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to

a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-30171 Filed 12-13-12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0001]

Agency Information Collection Activities: Petition for Alien Fiance(e), Form Number I-129F; Revision of a Currently Approved Collection

ACTION: 30-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on October 11, 2012, at 77 FR 61776, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 14, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: 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 DHS, and to the OMB USCIS Desk Officer. Comments may be submitted to: DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140.

Comments may also be submitted to DHS via email at uscisfrcomment@dhs.gov, to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via email at oir_submission@omb.eop.gov and via the Federal eRulemaking Portal Web site at <http://www.Regulations.gov> under e-Docket ID number USCIS-2006-0028. When submitting comments by email, please make sure to add OMB Control Number 1615-0001 in the subject box.

All submissions received must include the agency name, OMB Control Number and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.