

Based on our experience with the collection thus far, we retain the currently approved burden estimate. Accordingly, we estimate that we will receive an average of five petitions and five notifications annually over the next 3 years. Assuming an association of one respondent to each petition or notification, we estimate that five respondents will each submit one petition and five respondents will each submit one notification. We estimate a petition takes, on average, 100 hours to develop and submit (Ref. 2). Therefore, we estimate the total burden associated with petitions will be 500 hours annually (5 petitions × 100 hours per petition).

The burden of a notification involves collecting documentation that a food ingredient does not pose an allergen risk. Either we can make a determination that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409 of the FD&C Act, or the respondent submits scientific evidence demonstrating that the ingredient when manufactured as described does not contain allergenic protein. We estimate it takes a respondent 20 hours to prepare and submit a notification based on our determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response. We estimate respondents may spend 100 hours to prepare a notification submitting scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein. We have no data on how many notifications would be based on our determination that the ingredient does not cause an allergic response or based on scientific evidence that demonstrates that the food ingredient does not contain allergenic protein. Therefore, we estimate that three of the five notifications would be based on scientific evidence, and two of the five notifications would be based on our determination. The average time per notification is then estimated to be 68 hours (2 × 20 hours + 3 × 100 hours/5). Therefore, we estimate that the burden associated with notifications will be 340 hours annually (5 notifications × 68 hours per notification), as reflected in table 2.

## II. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available

for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. RTI International, "Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Final Report." Prepared for Andrew Stivers, FDA/CFSAN. Prepared by Muth, M., M. Ball, M. Coglaiti, and S. Karns. RTI Project Number 0211460.005. March 2011.
2. Gendel, S.M., "Food Allergen Petitions and Notifications." Memorandum to File. August 8, 2011.

Dated: December 6, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-26690 Filed 12-11-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-6528]

#### Refusal of Inspection by a Foreign Food Establishment or Foreign Government; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Refusal of Inspection by a Foreign Food Establishment or Foreign Government." This draft guidance, when finalized, will provide information for foreign food establishments subject to our inspection, as well as foreign governments, on when we may consider that a foreign food establishment or a government of a foreign country has refused to permit an inspection by us as provided in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**DATES:** Submit either electronic or written comments on the draft guidance by February 26, 2018 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2017-D-6528 for "Refusal of Inspection by a Foreign Food Establishment or Foreign Government." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Compliance Policy Staff/Office of Compliance, Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5001 Campus Dr., 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.

**FOR FURTHER INFORMATION CONTACT:** Mischelle B. Ledet, Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-701-5986, or Eric Nelson, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5642, or Tyler Scandalios, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 240-402-4552.

**SUPPLEMENTARY INFORMATION:**

## I. Background

We are announcing the availability of a draft guidance for industry entitled “Refusal of Inspection by a Foreign Food Establishment or Foreign Government.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. The guidance is not subject to Executive Order 12866.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended the FD&C Act to expand and enhance our ability to ensure that imported food products meet U.S. standards and are safe for consumers. Among the FSMA changes to the FD&C Act, we now must refuse admission of a food into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary of Health and Human Services, upon request, to inspect such factory, warehouse, or other establishment (section 807(b) of the FD&C Act (21 U.S.C. 384c(b))). In addition, the FD&C Act, at section 807(b), states that an owner, operator, or agent in charge is considered to have refused an inspection if the owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after we submit an inspection request, or after such other time period, as agreed upon by FDA and the foreign factory, warehouse, or other establishment.

This draft guidance, when finalized, will provide information for foreign food establishments subject to our inspection, as well as foreign governments, on when we may consider that a foreign food establishment or a government of a foreign country has refused to permit an inspection by us as provided in section 807(b) of the FD&C Act.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous

sentence to find the most current version of the guidance.

Dated: December 6, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-4487]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

**DATES:** Fax written comments on the collection of information by January 11, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910—New and title “Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.