TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR section/[FDA form No.]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					4,634,247.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For most elements, ''Total Hours'' reflects estimated average burden as calculated by multiplying the number of respondents by the frequency of response and time necessary for the corresponding activity. In other instances, ''Total Hours'' is the average burden we attribute to all respondents, where individual respondent and time-frequency values have been estimated. All figures have been rounded to the nearest whole number.

We retain the currently approved burden estimate for the information collection associated with the provisions identified above. At the same time, we have added burden estimate associated with § 314.103, although in an effort to reduce burden, we have issued associated guidance to assist respondents with the relevant information collection.

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26670 Filed 12–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for declaring major food allergens under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2014–N–1030 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Allergen Labeling and Reporting

OMB Control Number 0910–0792—Extension

This information collection supports the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens, and the Agency's associated guidance document.

I. Background

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 name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of 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. 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. 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).

A. Third-Party Disclosure

The labeling requirements of section 403(w)(1) of the FD&C Act apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. As noted, section 403(w)(1) of the FD&C Act requires that the label of a food product declare the presence of each major food allergen. We estimate the information collection burden of the third-party disclosure associated with food allergen labeling under section 403(w)(1) of the FD&C Act as the time needed for a manufacturer to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act and the time needed to make any needed modifications to the labels of those products. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchases that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers use food labeling information to help determine their product choices.

FDA estimates the third-party disclosure burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

FD&C Act section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

FD&C Act section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
403(w)(1); redesign labels to comply with food allergen labeling requirements	3,875	1	3,875	16	62,000
Total					139,500

[1] There are no operating and maintenance costs associated with this collection of information.

We have retained the currently approved burden estimate associated with the information collection. Based on our experience with the information collection since it was established 3 years ago, we estimate that there are approximately 690,000 Universal Product Codes (UPCs) of FDA-regulated foods and approximately 85,000 UPCs of FDA-regulated dietary supplements for a total of 775,000 UPCs (Ref. 1). Using the labeling cost model, we estimate the entry rate of new UPCs to be 8 percent per year. Based on the entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 × 10 percent). Thus, we estimate that, annually, 77,500 new or reformulated products are sold in the United States. Assuming an association of one respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products. We estimate an average of 1 hour for the review of labels for compliance with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act, for a total of 77,500 hours annually, as reflected in table 1, row 1.

We have no data on how many label reviews would identify the need to redesign the label. For purposes of this analysis, therefore, we estimate 5 percent, or 3,875 labels (77,500 × 5 percent) will be redesigned to comply with the requirements of section 403(w)(1) of the FD&C Act. Assuming an association of one respondent to each of the 3,875 redesigned labels and averaging 16 hours to complete the label redesign, we estimate a total of 62,000 hours annually for this activity, as reflected in table 1, row 2.

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, respondents may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. 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). This section also states that ''the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.'' 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 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).

The guidance document entitled, ''Food Allergen Labeling Exemption Petitions and Notifications: Guidance for Industry,'' sets forth our recommendations with regard to the information that respondents should submit in such a petition or notification. The guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes: (1) The identity or composition of the ingredient; (2) the methods used to produce the ingredient; (3) the methods used to characterize the ingredient; (4) the intended use of the ingredient in food; and (5) either (a) for a petition—data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient, when manufactured and used as described, does not cause an allergic response that poses a risk to human health; or (b) for a notification, data and information that demonstrate that the ingredient, when manufactured as described, does not contain allergenic protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption.

We estimate the reporting burden associated with the collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act Section/Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

[1] There are no capital or operating and maintenance costs associated with the information collection.

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]

BILLING CODE 4164–01–P

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