TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2015–2016 Data Collection (Healthcare Facilities)—Completion of Sections 1 and 3	400	1	400				2.5	1,000
2015–2016 Data Collection (Schools)—Completion of Sections 1 and 3	400	1	400				2	800
2015–2016 Data Collection (Retail Food Stores)—Completion of Sections 1 and 3	400	1	400				3	1,200
2015–2016 Data Collection-Completion of Section 2—All Facility Types	1,200	1	1,200				0.5	600
2017–2018 Data Collection-Entry Refusals—All Facility Types				24	1	24	0.08 (5 minutes)	1.92
Total Hours								3,601.92

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

II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://regulations.gov*.

1. ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123546.pdf.*

2. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at: *http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf*

3. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf.*

4. FDA National Retail Food Team. ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224152.pdf.*

5. FDA Food Code. Available at: *http://www.fda.gov/FoodCode.*

Dated: June 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15077 Filed 6–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's procedures for early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use, including bioengineered food plants.

DATES: Submit either electronic or written comments on the collection of information by August 18, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (OMB Control Number 0910–0583)—Extension

Since May 29, 1992, when we issued a policy statement on foods derived from new plant varieties, we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984). The guidance, entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,'' continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

We believe that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins produced by new plant varieties, including bioengineered food plants, and the procedures for communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. Form FDA 3666 is entitled, ''Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation),'' and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of a NPC in a standard format and helps the respondent organize their submission to focus on the information needed for our safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway, or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by us to evaluate the food safety of a specific new protein produced by a new plant variety.

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	Form FDA 3666	6	1	6	4	24
Two other data components	Form FDA 3666	6	1	6	16	96
Total						120

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

The estimated number of annual responses and average burden per response are based on our experience with early food safety evaluations. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (*e.g.,* on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

For purposes of this extension request, we are re-evaluating our estimate of the annual number of responses that we expect to receive in the next 3 years. We received 12 NPCs during the 5-year period from 2005 through 2009, for an average of 2.4 NPCs per year. However, during the last extension period, we saw a decrease in the number of NPCs submitted by developers, with no NPCs submitted in 2010 through 2014. More recently, we received 4 NPCs in the first 4 months of 2015. Based on an approximate average from the years 2005 through 2009, and our experience in 2015, we are revising our estimate of the annual number of NPCs submitted by developers to be 6 or fewer.

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. We estimate that completing these data components will take about 4 hours per NPC. We estimate the reporting burden for the first four data components to be 24 hours (4 hours × 6 responses).

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in a NPC. We estimate that completing these data components will take about 16 hours per NPC. We estimate the reporting burden for the two other data components to be 96 hours (16 hours × 6 responses). Thus, we estimate the total annual hour burden for this collection of information to be 120 hours.

Dated: June 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15078 Filed 6–18–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0052]

Food Allergen Labeling Exemption Petitions and Notifications; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (''FDA'' or ''we'') is announcing the availability of a guidance for industry entitled ''Food Allergen Labeling Exemption Petitions and Notifications.'' This guidance explains FDA's current thinking on the preparation of regulatory submissions for obtaining exemptions for ingredients from the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (FD&C Act) through submission of either a petition or a notification.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., 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 guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard Bonnette, Center for Food and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1235.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 8, 2014 (79 FR 26435), we announced the availability of a draft guidance entitled ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications'' and gave interested parties an opportunity to submit comments on the draft guidance at any time and comments on the proposed collection of information by September 25, 2014. We received several comments and revised the guidance accordingly.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of 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 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.

In some cases, the production of an ingredient derived from a major food allergen may eliminate the allergenic proteins in that derived ingredient such that it is not a risk for food allergic individuals. 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 presents a risk for food allergic individuals. 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 (21 U.S.C. 343(w)(1)). 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).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on Food Allergen Labeling Exemption Petitions and Notifications. It does not create or confer any rights for or on any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0792.

III. Comments

Interested persons may submit either electronic comments regarding the guidance 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15119 Filed 6–18–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Announcement of Food and Drug Administration Demo Day for the 2014 Food and Drug Administration Food Safety Challenge; Public Meeting

AGENCY: Food and Drug Administration, HHS.