Food Allergen Labeling and Reporting
SUPPORTING STATEMENT

OMB Control No. 0910-NEW

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Public Law 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 (21 U.S.C. 343(w)(6)). 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 (21 U.S.C. 343(w)(7)).

In the *Federal Register* of May 8, 2014 (79 FR 26435), we announced the availability of a draft guidance document entitled, "Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications." The draft guidance is intended to help industry prepare petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens. The guidance can be found at http://www.fda.gov/FoodGuidances.

In response to public comment regarding the draft guidance, the agency made some editorial changes it feels improves the document. Specifically the final guidance explains that alternative scientific methods may be used to demonstrate the safety of a food ingredient, it better clarifies the kinds of ingredients that may present a potential hazard, and refines the description of the possible affected populations respondents should consider in its communication with the agency.

We are requesting OMB approval of the third party disclosure requirements of food allergen labeling under section 403(w)(1) of the FD&C Act. We are also requesting OMB approval of the reporting burden associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens under section 403(w)(6) and (7) of the FD&C Act as outlined in the draft guidance entitled, "Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications."

2. Purpose and Use of the Information Collection

The primary user of the allergen information disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to help them make choices concerning their purchase of a food product, including choices related to substances that the consumer wishes to avoid due to their potential to cause adverse reactions. Additionally, we intend to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403(w)(1) of the FD&C Act may result in a product being misbranded under the FD&C Act and the manufacturer or packer and the product subject to regulatory action.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States that declare the presence of a major food allergen on the product label. In terms of reporting, the respondents are manufacturers and packers of packaged foods sold in the United States that seek an exemption from the labeling requirements of section 403(w)(1) of the FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

Section 403(w) of the FD&C Act does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in developing petitions and notifications or meeting FALCPA requirements for food. We estimate that ninety percent (90%) of the respondents will use electronic means to submit petitions and notifications for exemption.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of Federal regulations concerning the requirements for the labeling of food products is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to the labeling of foods as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses. The requirements are the minimum requirements for complying with the provisions of FALCPA. In most cases, the information that is required to be disclosed or submitted to the agency is information that is available to a firm, including a small business, as a normal course of its doing business. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is collected less frequently. As noted above, failure of a firm to comply with the requirements for disclosure of the information on the labels or labeling of its food products may result in those products being misbranded under section 403 of the FD&C Act and the products and the firm subject to regulatory action.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the *Federal Register* of August 12, 2014 (79 FR 47145), we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it did not respond to any of the four collection of information topics solicited, and therefore is not addressed.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA under the food labeling regulations may contain trade secret and commercial confidential information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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12 a. Annualized Hour Burden Estimate

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

Table 1. – Estimated Annual Third Party Disclosure Burden [1]

FD&C Act Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours	Total Capital Costs
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500	0
403(w)(1); redesign labels to comply with food allergen labeling requirements	3,875	1	3,875	16	62,000	$7,071,875
Total					139,500	$7,071,875

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

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. Using FDA's labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate 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 77,500 new or reformulated products are sold annually 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, as reported in Table 1, row 1. We have no data on how many label reviews would identify the need to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 5 percent of the reviewed labels of new or reformulated products, or 3,875 labels (77,500 ×5 percent) would need to 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 labels, we estimate that 3,875 respondents will each redesign one label, as reported in Table 1, row 2.

Our estimate of the average burdens per disclosure reported in Table 1 is based on our experience with food labeling and our labeling cost model. We estimate the average burden for

the review of labels for compliance with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act to be 1 hour. Consequently, the burden of reviewing the labels of new or reformulated products is 77,500 hours, as reported in Table 1, row 1. Using our labeling cost model, we estimate that it takes an average of 16 hours to complete the administration and internal design work for the redesign of a label to comply with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act. Consequently, the burden of redesigning the 3,875 labels of new or reformulated products is 62,000 hours, as reported in Table 1, row 2.

Table 2.--Estimated Annual Reporting Burden[1]

FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. 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 costs or operating and maintenance costs associated with this collection of information.

Based on the number of petitions and notifications received in recent years, 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, as reported in Table 2, rows 1 and 2.

We base our estimate of the average burdens per response reported in Table 2 on our experience with other petition processes. We estimate that a petition would take, on average, 100 hours to develop and submit. Therefore, we estimate that the burden associated with petitions will be 500 hours annually (5 petitions × 100 hours per petition), as reported in Table 2, row 1.

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 would submit scientific evidence demonstrating that the ingredient when manufactured as described does not contain allergenic protein. We estimate that it would take 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 that it would take a respondent approximately 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. 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 reported in Table 2, row 2.

12 b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents that review labels for compliance with food allergen labeling requirements and redesign labels to comply with food allergen labeling requirements is reflected by the mean hourly wage of $27.96 reported for "First-Line Supervisors of Production and Operating Workers" in the Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates, (http://www.bls.gov/oes/current/oes_nat.htm#23-0000). Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $55.92/hour. The overall estimated cost incurred by respondents to review and redesign labels for compliance with food allergen labeling requirements is $7,800,840 ($55.92/hour x 139,500 hours).

We estimate the average hourly wage for respondents that seek an exemption from the labeling requirement of section 403(w)(1) of the FD&C Act is reflected by the mean hourly wage of $63.46 reported for "Lawyers" in the Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates, (http://www.bls.gov/oes/current/oes_nat.htm#23-0000). Doubling this wage to account for overhead costs, we estimate the average hourly cost to these respondents to be $126.92/hour. The overall estimated cost incurred by respondents that seek an exemption from the labeling requirement of section 403(w)(1) of the FD&C Act is $106,612.80 ($126.92/hour x 840 hours).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/ Capital Costs

We estimate that 5 percent of all reviewed labels, or 3,875 labels (77,500 x 5 percent) would need to be redesigned to comply with the requirements of section 403(w)(1) of the FD&C Act. We estimate that capital costs would be incurred by respondents for redesigning labels. Using our labeling cost model, we estimate the capital cost to be $1,825 per label for external design services for the redesign of a label. Consequently for 3,875 labels, the total capital costs are $7,071,875 (3,875 labels x $1,825/label), as reported in Table 1. There are no start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Based on our experience with food labeling, we estimate that we will utilize 14.7 FTEs per year to inspect firms and collect and analyze samples of conventional foods to determine compliance with section 403(w)(1) of the FD&C Act. Using the salary of an inspector at the GS-13, step 5 level in the locality pay area of Washington-Baltimore in 2014, and doubling it to account for overhead, we obtain a cost of approximately $203,828 per FTE. Consequently, we estimate a cost to the Federal government of approximately $2,996,272 per year for inspecting firms and collecting and analyzing samples for compliance with the FD&C Act ($203,828 per FTE x 14.7 FTEs = 2,996,271.60, rounded up to 2,996,272). Moreover, we estimate that an additional FTE per year, at a cost of $203,828, would be required for FDA to respond to violations of the FD&C Act.

We estimate that the average time for FDA to review a notification is the same as the time for a respondent to prepare and submit a notification, or 68 hours annually. Therefore, we estimate that the burden associated with reviewing notifications will be 340 hours annually (5 notifications x 68 hours per notification). FDA consumer safety officers review submitted notifications with input from technical reviewers. The dollar estimate for FDA consumer safety officer wages corresponds roughly to a GS-13, step 5 level in the locality pay area of Washington-Baltimore in 2014, which is $48.83. Doubling this amount to account for overhead costs, we estimate an average hourly cost to the Federal government of $97.66. Thus, the total annual cost to the Federal government for reviewing notifications is estimated to be $33,204.40 (340 hours x $97.66/hour).

We estimate that the average time for FDA to review a petition received under this information collection is the same as the time for a respondent to prepare and submit a petition, or 500 hours annually. The dollar estimate for FDA consumer safety officer wages, who review petitions, corresponds roughly to a GS-13, step 5 level in the locality pay area of Washington-Baltimore in 2014, which is $48.83. Doubling this amount to account for overhead costs, we estimate an average hourly cost to the Federal government of $97.66. Thus, the total annual cost to the Federal government for reviewing petitions is estimated to be $48,830 (500 hours x $97.66/hour).

Thus, the total annualized cost to the Federal government is as follows:

Agency Activity	Estimated Cost
Inspecting firms; analyzing samples	2,996,272
Response to violations	203,828
Reviewing notifications	33,204
Reviewing petitions	48,830
TOTAL	3,282,134

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA has no reason for not displaying the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.