UNITED STATES FOOD & DRUG ADMINISTRATION

Food Allergen Labeling and Reporting

OMB Control No. 0910-0792-- Revision

SUPPORTING STATEMENT - **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory requirements pertaining to ingredients derived from major food allergens. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term "*major food allergen*" (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))) and provides that foods 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 or are exempt from the requirement. Under sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)), respondents may request an FDA determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. Alternatively, 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).

To assist respondents with the information collection in this regard, the document entitled "*Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications*" (June 2015), available on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications, communicates information we recommend respondents include in petitions submitted under sections 403(w)(6) and (7) of the FD&C Act or notifications submitted under section 409 of the FD&C Act. 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. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers rely upon food labeling information to help determine their product choices.

Respondents may submit petitions or notifications via the CFSAN Online Submission Module (COSM). COSM is a web-based tool that supports electronic submissions, thereby eliminating the need for printing and mailing of paper submissions. COSM is available 24 hours a day and 7 days a week. Further information about COSM, including user instruction, is available on the internet at: https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm.

On April 23, 2021, the definition of the term "*major food allergen*" was amended by the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Pub. L. 117-11) to include sesame. Accordingly, we are revising the information collection to account for burden attributable to required declarations and/or associated requests for exemption as they pertain to foods that include sesame. We issued the draft guidance document entitled "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)" (November 2022), available on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5, that once finalized, will communicate our current thinking regarding the labeling of food allergens, including sesame in food products regulated under section 403 of the FD&C Act. The guidance was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We are therefore requesting OMB approval of the third-party disclosure requirements of food allergen labeling under section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1). We are also requesting approval of the reporting associated with petition and notification submissions 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 guidance entitled, "*Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications*," (June 2015). Lastly, we are requesting approval for declarations and/or associated requests for exemption as they pertain to foods that include sesame as provided in the FASTER Act and discussed in the draft guidance document entitled "*Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)*."

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: Respondents to the collection of information are manufacturers and packers of packaged foods sold in the United States subject to the labeling requirements and prohibitions found in section 403 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 complying with the FD&C Act requirements for major food allergens. We estimate that ninety percent (90%) of the respondents will use electronic means such as COSM or CD to submit petitions and notifications for exemption.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

   Although we estimate ten percent (10%) of respondents are small businesses, we do not believe the information collection imposes undue burden on small entities. At the same time, we assist small businesses in complying with regulatory requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

   The information collection schedule is consistent with statutory and regulatory authorities. There are no consequences to Federal program or policy activities if the information is collected less frequently.

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 the *Federal Register* of December 8, 2023 (88 FR 85640), we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the information collection topics solicited in the notice.

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

Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted may include submitter/agent name, workplace address, workplace email address, and workplace telephone number. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA has limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

FD&C Act Section; Information Collection Activity	Number of Respondents	Number of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
403(w)(1); review product labeling for compliance w/applicable statutory requirements	77,500	1	77,500	1	77,500
403(w)(1); redesign/ modifications to product labeling for compliance with applicable statutory requirements	775	1	775	16	12,400
Total					89,900

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

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

FD&C Act Section; information collection activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(w)(6); petition for exemption	6	1	6	100	600
403(w)(7); notification submissions	6	1	6	68	408
Total					1,008

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

Our estimate of the third-party disclosure burden associated with food allergen labeling under section 403(w)(1) of the FD&C Act includes the time we assume respondents need to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act, along with the time needed to make any needed modifications to the labels of those products. We believe firms have already redesigned their labels to comply with requirements under the Food Allergen Labeling and Consumer Protection Act of 2004. However, this estimate accounts for firms that will redesign their label to comply with requirements under the FASTER Act. Our estimated reporting burden is based on our past experience with these submissions. We have increased our cumulative estimate by 12,552 hours and 776 responses annually to reflect the inclusion of sesame as a major food allergen.

12b. 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 $37.11 reported for "Legal Support Workers, All Others" in the Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates, (https://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 $74.22/hour. The overall estimated cost incurred by respondents to review and redesign labels for compliance with food allergen labeling requirements is $6,672,378 ($74.22/hour x 89,900 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 $78.74 reported for "Lawyers" in the Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates, (https://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 $157.48/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 $158,739.84, rounded up to $158,740 ($157.48/hour x 1,008 hours).

Table 3.--Annual Cost Burden Estimate

Type of Respondent	**Total Burden Hours**	Hourly Wage Rate	Total Respondent Costs
Label Reviewers	**89,900**	$74.22	$6,672,378
Lawyers	**1,008**	$157.48	$158,740
Total			$6,831,118

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

We estimate that there will be a capital cost of $1,414,375 associated with relabeling products that needs to declare sesame as a major food allergen. This is the cost of revising the label and incorporating it into the manufacturing process. We believe that this will be a one-time cost.

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 ($133,692/year) in 2024, and doubling it to account for overhead, we obtain a cost of approximately $267,384 per FTE. Consequently, we estimate a cost to the Federal government of approximately $3,930,545 per year for inspecting firms and collecting and analyzing samples for compliance with the FD&C Act ($267,384 per FTE x 14.7 FTEs). Moreover, we estimate that an additional FTE per year, at a cost of $267,384, 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 408 hours annually (6 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 2024, which is $64.06. Doubling this amount to account for overhead costs, we estimate an average hourly cost to the Federal government of $128.12. Thus, the total annual cost to the Federal government for reviewing notifications is estimated to be $52,272.96, rounded up to $52,273 (408 hours x $128.12/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 100 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 2024, which is $64.06. Doubling this amount to account for overhead costs, we estimate an average hourly cost to the Federal government of $128.12. Thus, the total annual cost to the Federal government for reviewing petitions is estimated to be $76,872 (600 hours x $128.12/hour).

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

Table 4.--Estimated Annual Cost to Federal Government

Agency Activity	Estimated Cost
Inspecting firms; analyzing samples	$3,930,545
Response to violations	$267,384
Reviewing notifications	$52,273
Reviewing petitions	$76,872
TOTAL	$4,305,550

15. Explanation for Program Changes or Adjustments

We believe firms have already redesigned their labels to comply with requirements under the Food Allergen Labeling and Consumer Protection Act of 2004. However, this estimate accounts for firms that will redesign their label to comply with requirements under the FASTER Act. We have increased our cumulative estimate by 12,552 hours and 776 responses to reflect the inclusion of sesame as a major food allergen.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.