UNITED STATES FOOD & DRUG ADMINISTRATION

Food Labeling Requirements

OMB Control No. 0910-0381 - Revision

SUPPORTING STATEMENT

Terms of Clearance: In accordance with terms of clearance established on August 17, 2020, upon OMB approval for this information collection, FDA has discontinued OMB control no. 0910-0813.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports statutory and regulatory requirements that govern food labeling, and information collection recommendations discussed in associated agency guidance. Sections 4 5, and 6 of the Fair Packaging Labeling Act (FPLA) (15 U.S.C. 1453, 1454, and 1455) and sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e), establish provisions under which a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. Implementing regulations are codified in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105). While regulations in part 101 sets forth general food labeling provisions, requirements pertaining to the common or usual name for non-standardized foods; guidelines for nutritional quality to prescribe the minimum level or range of nutrient composition appropriate for a given class of food; and requirements for foods for special dietary use are found in parts 102, 104, and 105, respectively. The requirements are intended to ensure the safety of food products produced or sold in the United States and enable consumers to be knowledgeable about the foods they purchase and include corresponding information disclosure requirements, along with the reporting and recordkeeping provisions, subject to enforcement by the Food and Drug Administration (FDA or Agency).

We provide information resources regarding food labeling under the FD&C Act and its amendments on our website at https://www.fda.gov/food/food-labeling-nutrition. Food labeling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary. We refer to these products as "conventional" foods. For detailed information on dietary supplement labeling requirements visit our website at https://www.fda.gov/food/dietary-supplements. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables consumers to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to us provide the basis for us to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping

requirements enable us to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the FD&C Act or the FPLA. Requirements include general content and format for the labeling of food packaging, including nutrition and ingredient information. Additional regulations provide for nutrient content claims.

The information collection includes **Form FDA 3570** entitled, "*Small Business Nutrition Labeling Exemption Notice*," for use as applicable and available for download from our website at https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption-notice-model-form.

For operational efficiency, we are revising the information collection to account for burden associated with the requirements for the labeling of certain beers, currently approved under OMB control number 0910-0728. The Tobacco Tax and Trade Bureau (TTB) is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (FAA Act). However, and as discussed in the associated guidance document, certain bottled or otherwise packaged beers are subject to section 403 of the FD&C Act. We are also revising the information collection to include requirements applicable to the gluten-free labeling of fermented or hydrolyzed foods established through rulemaking (RIN 0910-AH00) and approved under OMB control number 0910-0817.

To assist respondents with the information collection, we have developed the following agency guidance documents:

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (June 1998) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-notification-health-claim-or-nutrient-content-claim-based-authoritative-statement);

Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (January 2009) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food);

Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (September 2009) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-labeling-dietary-supplements-required-dietary); and

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration (issued December 2014; updated April 2023 to refer to 21 CFR part 117, to include the allergen sesame, to remove outdated enforcement discretion text, and to make other non-substantive formatting or editorial revisions)

(https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration).

We therefore request OMB approval of the information collection provisions in 21 CFR parts 101, 102, 104, and 105; Form FDA 3570; and the agency guidance documents identified and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of our food labeling requirements, including labeling of certain beers and gluten-free fermented or hydrolyzed foods, is to ensure that products offered to consumers include specific disclosures and is not misbranded. Consumers need to be knowledgeable about foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to us provide the basis for us to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable us to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the FD&C Act or the FPLA. Products not in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of our implementing food labeling regulations may be rendered misbranded under the FD&C Act and the manufacturer and the product subject to regulatory action. We use information submitted in nutrient content claim or health claim petitions to verify nutrient and health claims. The requirements in §§ 101.69 and 101.70 are those that we believe are necessary to fulfill the requirements of the FD&C Act. We also use information submitted to verify that a Scientific Body of the United States Government or the National Academy of Sciences has published an authoritative statement which is currently in effect about the level of the nutrient to which the nutrient content claim refers, or about the relationship between the nutrient and the disease or health-related condition to which the health claim refers, and that the claim is an accurate representation of that statement.

We use information reported under the provisions of §§ 101.9(j)(18) and 101.36(h)(2) to determine whether and, if appropriate, to grant small businesses exemption requests regarding nutrition labeling for low-volume food products. Under section 403(q)(5)(E) of the FD&C Act, a low-volume food product is exempt from the requirements for nutrition labeling if it is the subject of a notice from a small business claiming the exemption provided by the Nutrition Labeling and Education Act Amendments of 1993. Those food products that are not the subject of such a notice are not exempt from the mandatory nutrition labeling requirements of section 403(q) of the FD&C Act unless the food qualifies for another exemption. Section 403(q)(5)(E) of the FD&C Act does not require that the information in a notice claiming exemption be reviewed by FDA for the exemption to be in effect. However, we do review the information in each notice to determine whether it meets the requirements for the notice established in section 403(q)(5)(E)(iii) of the FD&C Act. We provide the information on the identity of firms submitting notices claiming exemption to our field personnel and to State enforcement agencies by posting the names and addresses of the firms on a website maintained by the agency.

We use information in petitions submitted under the provisions of § 101.12(h) to determine whether a new reference amount should be established, or an existing reference amount should be amended. The consequence of not having this information is that we would be restricted in obtaining the information necessary to amend or add to the regulation on reference amounts customarily consumed (RACCs).

We use information submitted in response to the provisions for alternative approaches contained in §§ 101.9(g)(9) and 101.36(f)(2) to determine whether such alternative approaches would be consistent with the requirements for nutrition labeling in section 403(q) of the FD&C Act. The consequences of not having this information would be a reduced flexibility of the manufacturer to use alternative approaches for complying with the requirements of section 403(q) of the FD&C Act for the nutrition labeling of food products.

Data generated by the food labeling experiments permitted under § 101.108 may form the basis for a citizen's petition to amend the existing food labeling regulations. The data could also be useful to FDA for evaluating whether changes in current food labeling requirements are warranted, and for developing alternative labeling formats that may be useful to consumers and manufacturers. The extent of the collection of information is determined by the firm proposing the labeling experiment and is of benefit to this firm. However, the labeling changes proposed by a firm could not be implemented without supporting information favoring the proposed changes.

Description of Respondents: Respondents to this information collection are manufacturers, packers, and distributors of food products, as well as certain food retailers, such as supermarkets and restaurants, subject to statutory and regulatory food labeling requirements. Respondents are from the private sector (including for-profit businesses, not-for-profit institutions and farms).

3. Use of Improved Information Technology and Burden Reduction

The regulations in parts 101, 102, 104, and 105 do 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 notifications or meeting labeling requirements for food. We have developed a web-based data entry system so small business may electronically claim exemption from the requirements for nutrition labeling. Information regarding this system is available from our website at https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption.

We estimate that ninety percent (90%) of respondents will use information technology (electronic means) to meet food labeling requirements or requests for exemption.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Congress has authorized FDA to 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). In addition, as noted in Item 1, TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages pursuant to the FAA Act. However, and as discussed in the associated guidance "*Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*," certain bottled or otherwise packaged beers are subject to section 403 of the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses, however we believe the information collection poses no undue burden on small entities. The requirements are the minimum requirements for complying with the provisions of the FD&C Act, however our regulations provide for certain exemptions. 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. Small businesses may claim exemption from the requirements for nutrition labeling under the provisions of 21 CFR 101.9(j)(18) and 101.36(h)(2). We aid small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our Small Business Assistance webpage at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection is consistent with statutory and regulatory requirements.

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

We published a 60-day notice for public comment in the *Federal Register* of April 12, 2023 (88 FR 22045). No comments were received.

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

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3570 (Small Business Nutrition Label Exemption

Notice) is point of contact name, work address, work phone number, work fax number, and work email. FDA 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, the contractor or 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.

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. 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 Cost

12a. Annualized Hour Burden Estimate

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.9(c)(6)(i); dietary fiber	28	1	28	1	28
101.9(j)(18) and 101.36(h)(2); procedure for small business nutrition labeling exemption notice using Form FDA 3570	10,000	1	10,000	8	80,000
101.12(h); petitions to establish or amend referenced amounts customarily consumed (RACC)	1	1	1	80	80
101.69; petitions for nutrient content claims	3	1	3	25	75
101.70; petitions for health claims	5	1	5	80	400
101.108; written proposal for requesting temporary exemptions from certain regulations for the purpose of conducting food labeling experiments	1	1	1	40	40

Total			0		80,623

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

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

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
101.9(c)(6)(iii); added sugars	31,283	1	31,283	1	31,283
101.9(c)(6)(i); dietary fiber	31,283	1	31,283	1	31,283
101.9(c)(6)(i)(A); soluble fiber	31,283	1	31,283	1	31,283
101.9(c)(6)(i)(B); insoluble fiber	31,283	1	31,283	1	31,283
101.9(c)(8); vitamin E	31,283	1	31,283	1	31,283
101.9(c)(8); folate/folic acid	31,283	1	31,283	1	31,283
New Products	216	1	216	1	216
101.12(e); recordkeeping to document the basis for density adjusted RACC	25	1	25	1	25
101.13(q)(5); recordkeeping to document the basis for nutrient content claims	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); recordkeeping to document nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500
101.22(i)(4); recordkeeping to document supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.100(d)(2); recordkeeping pertaining to agreements that form the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000
101.7(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quality of contents	100	1	100	1	100
101.91; documentation necessary to verify compliance with gluten-free labeling	5,000	56	280,000	0.45 (~27 minutes)	126,000
Total			1,369,064		0

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

Our estimate reflects the cumulative average burden we attribute to the reporting and recordkeeping requirements found in the applicable regulations; individual collection activities may not be evenly distributed among respondents and/or the corresponding requirements.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
101.3, 101.22, parts 102 and 104; statement of identity labeling requirements	25,000	1.03	25,750	0.5	12,875
101.4, 101.22, 101.100, parts 102, 104 and 105; ingredient labeling requirements	25,000	1.03	25,750	1	25,750
101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product	25,000	1.03	25,750	0.25	6,438
101.9, 101.13(n), 101.14(d)(3), 101.62, and part 104; labeling requirements for disclosure of nutrition information	25,000	1.03	25,750	4	103,000
101.9(g)(9) and 101.36(f)(2); alternative means of compliance permitted	12	1	12	4	48
101.10; requirements for nutrition labeling of restaurant foods	300,000	1.5	450,000	0.25	112,500
101.12(b); RACC for baking powder, baking soda, and pectin	29	2.3	67	1	67
101.12(e); adjustment to the RACC of an aerated food permitted	25	1	25	1	25
101.12(g); requirement to disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC	5,000	1	5,000	1	5,000
101.13(d)(1) and 101.67; requirements to disclose nutrition information for any food product for which a nutrient content claim is made	200	1	200	1	200
101.13(j)(2) and (k), 101.54, 101.56, 101.60, 101.61, and 101.62; additional disclosure required if the nutrient content claim compares the level of a nutrient in one food with the level of the same nutrient in another food.	5,000	1	5,000	1	5,000
101.13(q)(5); requirement that restaurants disclose the basis for nutrient content claims made for their food	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); general requirements for disclosure of nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500

101.15; requirements pertaining to prominence of required statements and use of foreign language	160	10	1,600	8	12,800
101.22(i)(4); supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.30 and 102.33; labeling requirements for fruit or vegetable juice beverages	1,500	5	7,500	1	7,500
101.36; nutrition labeling of dietary supplements	300	40	12,000	4.025	48,300
101.42 and 101.45; nutrition labeling of raw fruits, vegetables, and fish	1,000	1	1,000	0.5	500
101.45(c); databases of nutrient values for raw fruits, vegetables, and fish	5	4	20	4	80
101.79(c)(2)(i)(D); disclosure requirements for food labels that contain a folate/neural tube defect health claim	1,000	1	1,000	0.25	250
101.79(c)(2)(iv); disclosure of amount of folate for food labels that contain a folate/neural tube defect health claim	100	1	100	0.25	25
101.100(d); disclosure of agreements that form the basis for exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000
101.7 and 101.100(h); disclosure requirements for food not accurately labeled for quantity of contents and for claiming certain labeling exemptions	25,000	1.03	25,750	0.5	12,875
Nutritional labeling for new products	500	1	500	2	1,000
Guidance recommendations: "*Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*"	12	1	12	1	12
Total			0		0

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

These estimates reflect our continued experience with the information collection, related petition submissions, and informal communications with industry.

12b. Annualized Cost Burden Estimate

We estimate that the total annualized cost burden to respondents associated with the requirements of parts 101, 102, 104, and 105 of the regulations to be approximately $225,516,725. We estimate a respondent's average wage to be commensurate to that of a federal

government employee at the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023, $53.67 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated cost burden to the respondent $107.34 per hour. Using these figures, the agency calculates the cost burden for reporting to be $8,654,073 (80,623 hours x $107.34 per hour), the burden hour cost for recordkeeping to be $106,273,470 (990,064 hours x $107.34 per hour), and, the cost burden for third-party disclosure to be $110,589,182 (1,030,270 hours x $107.34 per hour), for a total annualized burden hour cost of $225,516,725.

Table 4.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	80,623	$107.34	$8,654,073
Recordkeeping	990,064	$107.34	$106,273,470
Third-Party Disclosure	1,030,270	$107.34	$110,589,182
Total			$225,516,725

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

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Our total cost to the Federal government estimate is $6,542,114. We assume collecting and analyzing samples to determine compliance with requirements for dietary supplements to require 14.2 FTEs annually. Using this fully loaded salary cost of $200,000 annually, we calculate that $2,840,000 will be allocated for this activity. Based on our experience, we also estimate that we will utilize annually 14.7 FTEs to inspect firms and collect and analyze samples of conventional foods to determine compliance with the various food labeling provisions. Similarly, we use a fully loaded salary cost of $200,000 annually to calculate a cost of $2,940,000per year. Finally, we estimate that 7,100 hours is expended in the review of petition and notice submissions. Assuming agency FTEs at a wage rate for a GS-13, Step 1 in the Washington-Baltimore area will review and evaluate the submissions at a fully loaded rate of $107.34 per hour, we calculate a cost of $762,114 annually.

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments since last approved by OMB. We have modified burden estimates associated with reporting, recordkeeping, and disclosure activities as reflected in the highlighted IC elements at Q-12 of this supporting statement. Specifically, we have reduced our estimate of the number of reports submitted under 101.12 (RACC); we have increased our estimate for recordkeeping to account for newly added 101.91 (gluten); and we have increased our estimated disclosure burden to account for labeling recommendations for beer subject to FDA jurisdiction as discussed in the referenced agency guidance. Upon this last entry, we noticed and have corrected an error previously overlooked. In our last supporting statement we reported a total disclosure burden of 1,030,258 but inadvertently recorded the figure 1,029,598 (-660) and we have corrected this error. Cumulatively these changes and adjustments result in an increase of 298,008 responses and

126,352 hours annually. Upon OMB approval of the ICR, we intend to discontinue control nos. 0910-0728 and 0910-0817.

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

Consistent with established practice, FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.