UNITED STATES FOOD AND DRUG ADMINISTRATION

Food Labeling Regulations

OMB Control No. 0910-0381 – Revision

SUPPORTING STATEMENT – **Part A: Justification**

Terms of Clearance:

In accordance with the terms of clearance established December 5, 2017 upon OMB approval for the information collection, FDA has discontinued OMB control nos. 0910-0374, 0910-0626, and 0910-0642.

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration ("FDA" or "we") food labeling regulations, programs, and guidance. Food labeling regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials (21 CFR part 1 – *General Enforcement Regulations*). Finally, certain regulations provide for the submission of food labeling petitions to FDA. Regulations governing food labeling may be found in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105), and are issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the 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 (the FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of the regulations derive from section 403 of the FD&C Act, which provides that 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. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

We are revising the information collection to include requirements found in part 101 that govern the format and content of the Nutrition Facts (§ 101.9 (21 CFR 101.9)) and Supplement Facts (§ 101.36 (21 CFR 101.36)) labels (currently approved under OMB control number 0910-0813). The associated information collection was established in support of rulemaking (RIN 0910-AF22) for which the resulting regulations have now become effective.

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 (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 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food); and

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

We have also developed Form FDA 3570 - *Model Small Business Nutrition Labeling Exemption Notice*, which enables small entities to request certain exemptions from the labeling requirements.

Accordingly, we are requesting 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 is to ensure that products offered to consumers includes 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. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants. Respondents include 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 the respondents will use electronic means to submit the request 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

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 have provided a Small Business Guide on our website 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, and established at intervals that facilitate efficient agency review.

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 February 5, 2020 (85 FR 6551). One comment was received suggesting we consider including labeling requirements pertaining to folic acid. We appreciate this comment. A second comment was received but was not responsive to the information collection topics solicited. Neither comment suggested we revise our burden estimates, and we therefore retain those estimates provided in our 60-notice and included in this supporting statement.

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 with our Privacy Office to ensure appropriate handling of information collected. 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)).

Privacy Act

This ICR does not collect personally identifiable information (PII) or information of a personal nature. PII collected via Form FDA 3570 (*Small Business Nutrition Labeling Exemption Notice Model Form*) includes the respondent's name and telephone number. The information collected is for business contact purposes only. In addition, the information collected and stored 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 (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected.

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

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

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 a RACC	5	1	5	80	400

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			10,042		80,943

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

Manufacturers of food products that contain an isolated or synthetic non-digestible carbohydrate that is not listed in the definition of dietary fiber have the option of submitting a citizen petition to FDA requesting us to amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber, by demonstrating the physiological benefits of the isolated or synthetic non-digestible carbohydrate to human health.

We estimate that there are approximately 28 isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen petition filed by a manufacturer related to a particular isolated or synthetic non-digestible carbohydrate is granted or denied, or the carbohydrate is the subject of an authorized health claim, and the dietary fiber is listed in the definition of dietary fiber, the use of the dietary fiber as an ingredient in any food product must be included in the total amount of dietary fiber declared in nutrition labeling for such product.

Thus, we estimate that 28 manufacturers would incur burden associated with filing a citizen petition to amend the listing of dietary fiber related to an isolated and synthetic non-digestible carbohydrate that is not currently listed in the definition of dietary fiber and that the required reporting burden is 1 hour per manufacturer. This calculation is shown in Table 1, row 1.

Also, while § 101.108 was promulgated to provide a petition procedure for certain food labeling exemptions, no such petitions have been received in the recent past, and we therefore provide an estimate of 1 to reserve approval of any future collection under this part.

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[2]	31,283	1	31,283	1	31,283
101.9(c)(6)(i); dietary fiber[2]	31,283	1	31,283	1	31,283
101.9(c)(6)(i)(A); soluble fiber[2]	31,283	1	31,283	1	31,283
101.9(c)(6)(i)(B); insoluble fiber[2]	31,283	1	31,283	1	31,283

101.9(c)(8); vitamin E[3]	31,283	1	31,283	1	31,283
101.9(c)(8); folate/folic acid[3]	31,283	1	31,283	1	31,283
New Products	216	1	216	1	216
101.7(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents	100	1	100	1	100
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
TOTAL			1,089,064		864,064

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

[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars, added sugars that undergo fermentation in certain fermented foods, and products with non- digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, records that are required to be retained are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, e.g., analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the recordkeeping burden of this collection of information consists of the time required to identify and assemble the records for copying and retention.

The declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate roughly 31,283 food manufacturers would incur this recordkeeping burden and the required recordkeeping would be 1 hour per manufacturer. These calculations are reflected in Table 2, rows 1 to 4. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients

are directly added to the food for enrichment purposes. However, we conservatively estimate that 31,283 respondents would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. These calculations are reflected in Table 2, rows 5 and 6.

We estimate that the number of newly introduced products that are covered under this collection of information is 216. We assume the required recordkeeping is 1 hour per product, for an annual recurring recordkeeping burden of 216 hours, as reflected in Table 2, row 7. Adding all of the burden from OMB Control Numbers 0910-0381 and 0910-0813 results in a total of 864,064 annual recordkeeping burden hours.

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

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
101.3, 101.22, 102 and 104; statement of identity labeling requirements	25,000	1.03	25,750	0.5	12,875
101.4, 101.22, 101.100, 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 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), 101.13(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
TOTAL			1,513,799		1,030,258

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

Under §§ 101.9 and 101.12, some manufacturers of retail food products make labeling changes to modify the serving sizes and other nutrition information based on changes to what products may be or are required to be labeled as a single serving, or based on updated, modified, or established RACCs. We estimate that about 500 new products will be affected by these requirements each year and that the associated disclosure burden is 2 hours per product, for an annual burden of 1,000 hours. The estimated annual reporting, recordkeeping, and third-party disclosure burdens are based on our communications with industry and our knowledge of and experience with food labeling and the submission of petitions and requests to us.

12b. Annualized Cost Burden Estimate

We estimate that the total annualized cost burden to respondents associated with the requirements of part 101 of the regulations to be approximately $194,326,570.70. 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 2020, $49.19 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated cost burden to the respondent $98.38 per hour. Using these figures, the agency estimates the cost burden for reporting to be $7,963,172.34 (80,943 hours x $98.38 per hour), the burden hour cost for recordkeeping to be $85,006,616.32 (864,064 hours x $98.38 per hour); and, the cost burden for third-party disclosure to be $101,356,782.04 (1,030,258 hours x $98.38 per hour), for a total annualized burden hour cost of $194,326,570.70.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	80,943	$98.38	$7,963,172.34
Recordkeeping	864,064	$98.38	$85,006,616.32
Third-Party Disclosure	1,030,258	$98.38	$101,356,782.04
Total			$194,326,570.70

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 $5,900,498. We assume collecting and analyzing samples to determine compliance with requirements for dietary supplements to require 14.2 FTEs annually. Using a fully-loaded salary cost of $180,000 annually, we calculate that $2,556,000 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 $180,000 annually to calculate a cost of $2,646,000 per 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 rate of $98.38 per hour, we calculate a cost of $698,498 annually.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustment. As a result of consolidating burden applicable to provisions associated with the Nutrition Facts and Supplemental Facts labels (previously included under OMB control no. 0910-0813), we have increased the number of annual responses by 188,442 and associated burden hours by 188,942.

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

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.