UNITED STATES FOOD AND DRUG ADMINISTRATION

Food Labeling:
Nutrition Facts Label and Supplement Facts Label

OMB Control No. 0910-0813

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports requirements for the Nutrition Facts and Supplemental Facts labels. Section 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)) specifies certain nutrients to be declared in nutrition labeling and authorizes the Secretary of Health and Human Services (Secretary) to require other nutrients to be declared if the Secretary determines that provide such information will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section. We have also taken these actions consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States.

Regulations in § 101.9 (21 CFR 101.9) establish standards defining serving size and requiring that certain products provide additional information within the Nutrition Facts label that conveys that information to consumers. The regulations are based on current scientific evidence and dietary recommendations of most recent consensus reports.

Regulations at 21 CFR 101.9, 101.12, and 101.36 provide the list of nutrients that are required or permitted to be declared; provide Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; provide requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups; and provide the format and appearance of the Nutrition Facts label.

Section 101.12 defines a single-serving container; requires dual-column labeling for certain containers; establishes several reference amounts customarily consumed (RACCs); and provides the label serving size for breath mints.

We therefore request extension of OMB approval for the information collection provisions found in the applicable regulations and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We believe that the information collection provisions are necessary because analytical methods are not available that would allow us to verify labeling declarations. Consumers rely on this information to make healthy dietary choices. Because of the increased prevalence of obesity and diabetes and high rates of chronic diseases such as heart disease and stroke in the United States, treatment and prevention of these diseases continue to be a major public health concern and a national priority.

We believe that the regulations associated with this collection of information better align the information provided in the Nutrition Facts label with data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic disease; improve the design and content of the Nutrition Facts label to make relevant label information more salient and easy to understand so that consumers may make more informed decisions; and potentially prompt industry to reformulate products to maintain health and nutrient content claims. We also believe that the information collection provisions associated with RACCs and breath mints better inform consumers who purchase these food products.

Description of Respondents: Respondents to the collection of information are manufacturers of food products sold in the United States.

3. Use of Improved Information Technology and Burden Reduction

While this collection of information does not require the use of electronic reporting or recordkeeping, we encourage this approach and believe respondents currently utilize information technology to satisfy information collection provisions required under other Federal regulations regarding the labeling and manufacture of food and its delivery or introduction for delivery into interstate commerce. Similarly, we expect that third-party disclosure provisions imposed by the collection of information will be addressed through automated labeling processes currently employed by respondents to the collection of information. Therefore, we estimate that one-hundred percent (100%) of the notifications will be submitted electronically over next three years.

4. Efforts to Identify Duplication and Use of Similar Information

Information about the nutrient content of foods is mandated under the Nutrition Labeling and Education Act (NLEA) of 1990 and the Dietary Supplement Health and Education Act of 1994 (DSHEA). We believe these information collection requirements are consistent with these statutory authorities in conjunction with authority under the FD&C Act, and we are unaware of any duplicative collection requirements.

5. Impact on Small Businesses or Other Small Entities

We estimate approximately 98 percent of respondents are small businesses, however the regulations do provide for certain exemptions. Specifically, we allow certain small

businesses whose products do not sell more than 100,000 units to apply for a labeling exemption for that particular product. Such an exemption is granted for 12 months (on a per product basis) and the business has the option to re-apply for a continuation of this exemption.

6. Consequences of Collecting the Information Less Frequently

Information collection occurs on an occasional basis and is consistent with statutory and regulatory requirements.

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

There are no special circumstances for 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), we published a 60-day notice inviting public comment in the Federal Register of April 19, 2019 (84 FR 16513). We received one comment that suggested increasing font size for the number of servings and supported the overall goals of food labeling and making information available to consumers. As explained in our 30-day publication of July 22, 2019 (84 FR 35119), because the Nutrition Facts label has limited space to inform consumers of the nutritional content of the product, increasing the font size for the number of servings would impact other nutritional information that is included and we decline to adopt the suggestion.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

Records that may be reviewed during FDA inspections are subject to FDA regulations in 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

Privacy Act

This ICR request does not contain any personally identifiable information and does not include a form that requires a Privacy Act Statement under 5 U.S.C. § 552a(e)(3).

11. Justification for Sensitive Questions

The information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

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

Type of Declaration; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Added Sugars; 101.9(c)(6)(iii)[2]	31,283	1	31,283	1	31,283
Dietary Fiber; 101.9(c)(6)(i)[2]	31,283	1	31,283	1	31,283
Soluble Fiber; 101.9(c)(6)(i)(A)[2]	31,283	1	31,283	1	31,283
Insoluble Fiber; 101.9(c)(6)(i)(B)[2]	31,283	1	31,283	1	31,283
Vitamin E; 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
Folate/Folic Acid; 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
New Products	216	1	216	1	216
Total					187,914

[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. Based on our previous experience with similar information collections, we estimate the recordkeeping burden to be 1 hour per product as estimated in table 1.

The declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate all of the 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 1, 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 all 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 1, 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 1, row 7. Adding the burden from new products to the burden for existing products results in a total of 187,914 annual recordkeeping burden hours.

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

Filing of citizen petition regarding a particular isolated or synthetic non-digestible carbohydrate	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Dietary Fiber; 101.9(c)(6)(i)	28	1	28	1	28

[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 recordkeeping would be 1 hour per manufacturer. This calculation is shown in table 2.

Table 3.--Estimated Annual Third-Party Disclosure Burden

21 CFR 101.9	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Nutritional labeling for new products	500	1	500	2	1,000

[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.

12b. Annualized Cost Burden Estimate

The mean hourly wage of an operations manager in the food manufacturing industry is $59.37 (Bureau of Labor Statistics. May 2018 National Industry-Specific Occupational Employment and Wage Estimates; NAICS 31100 – Food Manufacturing). We increase this cost by 100 percent to account for benefits and overhead, for a total of $118.74 ($59.37 x 2). We therefore estimate the annualized cost incurred by respondents to be $22,434,973.08 (188,942 burden hours x $118.74/hr).

Table 4. -- Estimated Respondent Burden Cost

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Recordkeeping	187,914	$118.74	$22,312,908.36
Reporting	28	$118.74	$3,324.72
3rd Party Disclosure	1,000	$118.74	$118,740
Total			$22,434,973.08

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

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

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine inspection activities. We estimate that our review of the retained records would take five hours per inspection. We estimate the hourly cost for review and evaluation to be $18.19 to $61.77 per hour, the GS 5/Step 1 rate to the GS 13/Step 10 rate for the Washington-Baltimore locality pay area for the year 2019. To account for overhead, this cost is increased by 100 percent, making the total cost $36.38 to $123.54 per hour. The midpoint of this range is $79.96 per hour. Thus, we estimate the cost to the Federal Government for the review of records to be $399.80 per review ($79.96/hour x 5 hours). We estimate that it will review records for an average of 500 inspections per year. Thus, we estimate that the total annual cost to the Federal Government for reviewing records during inspections would be $199,900 ($399.80 x 500 inspections) in 2019 dollars.

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustments resulting from regulations that have become effective since last OMB review (RIN 0910-AF22). Accordingly, we have lowered our third-party disclosure estimate to reflect that burden associated with changes in labeling resulting from the new requirements has since been realized by respondents. This results in a decrease of 1,149,158 annual disclosures and 2,299,816 burden hours attributable to those labeling changes. We have also made corresponding cost adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated or manipulated.

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

We are not seeking approval not to display the expiration date. We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.