Food Labeling: Nutrition Facts and Supplement Facts Label and
Reference Amounts Customarily Consumed Per Eating Occasion
RIN 0910-AF22 and RIN 0910-AF23
OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) specifies certain nutrients to be declared in nutrition labeling, and authorizes the Secretary of Health and Human Services to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FFDCA to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section. To provide updated nutrition information on food labels and improve how nutrition information is presented to consumers, the Food and Drug Administration (FDA, we, or us) has undertaken rulemaking to revise the Nutrition Facts and Supplement Facts labels. We have also promulgated regulations that establish standards to define serving size and requires that certain products provide additional information within the Nutrition Facts label that conveys that information to consumers. We have issued these final rules based on current scientific evidence, dietary recommendations of most recent consensus reports, and public comments received in response to proposed rulemaking. 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.

Specifically, we have amended the regulations at 21 CFR 101.9, 101.12, and 101.36 where revision to 21 CFR 101.9 and 101.36 updates the list of nutrients that are required or permitted to be declared; provides updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishes nutrient reference values specifically for these population subgroups; and revises the format and appearance of the Nutrition Facts label. Revisions to 21 CFR 101.12 define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish several reference amounts customarily consumed (RACCs); amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations.

We therefore request approval of the information collection provisions set forth in the final rules entitled: "*Food Labeling: Revision of the Nutrition and Supplement Facts Labels*" and "*Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments*"

2. Purpose and Use of the Information Collection

FDA believes that the information collection provisions associated with the revisions to the Nutrition and Supplement Facts labels are necessary because analytical methods are not available that would allow us to verify labeling declarations and 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 has become a major public health concern and a national priority. FDA believes that the information collection provisions associated with the rulemaking better aligns the information provided in the Nutrition Facts label with new data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic disease; improves 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 prompts industry to reformulate products to maintain health and nutrient content claims. We believe also that the information collection provisions associated with reference amounts customarily consumed per eating occasion, breath mints, and other technical amendments of the applicable regulations will better inform consumers who purchase these food products.

3. Use of Improved Information Technology and Burden Reduction

While the rulemaking 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 rulemaking will be addressed through automated labeling processes currently employed by respondents to the collection of information.

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 the information collection requirements under the rulemaking are consistent with these statutory authorities in conjunction with authority under the FFDCA 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. Exemption provisions that currently exists for some small businesses and specific products will continue to apply under the rulemaking. Currently, 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

The rulemaking requires that manufacturers make and keep records to verify the following declarations: added sugars, when a food product contains both naturally-occurring sugars and added sugars, and for specific foods containing added sugars, alone or in combination with naturally-occurring sugars, where the added sugars are subject to fermentation; isolated or synthetic non-digestible carbohydrates that do not meet the proposed definition of dietary fiber; different forms of vitamin E; and, folate/folic acid. The rulemaking also requires manufacturers to maintain the records to verify the label declaration of the aforementioned nutrients for a period of two years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction, and that records required may be retained either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records) or electronic records. Where reduction techniques such as microfilming are used, suitable reader and photocopying equipment would need to be readily available. We believe these information collection requirements impose minimum burden to respondents while consistent with statutory requirements under the NLEA, DSHEA, and FFDCA. Finally, to ensure necessary third-party disclosures to consumers, we believe the requirements of the rulemaking represent minimal burden to respondents.

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 the Federal Register of March 3, 2014, we published the proposed rule entitled, "*Food Labeling: Revision of the Nutrition and Supplement Facts Labels*" (79 FR 11879), and the proposed rule entitled, "*Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments*" (79 FR 11989) to solicit public comment on revisions to FDA regulations. At the same time, we also solicited public comment on the associated information collection provisions in accordance with 5 CFR 1320.8(d). In the Federal Register of July 27, 2015, we again sought public comment regarding certain limited additional provisions of revisions in a supplemental notice of proposed rulemaking (80 FR 44303), and again solicited comment on the associated information collection.

Comments in response to the rulemaking may be found under docket nos. FDA-2012-N-1210 and FDA-2004-N-0258 and are discussed in the agency's final rules published on May 27, 2016 in the Federal Register. As finalized, we believe the rulemaking imposes minimal burden on respondents while ensuring that necessary nutrition information is conveyed to consumers.

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.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

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

We estimate the burden associated with the information collection below. Upon reexamination of data we have reduced the number of respondents identified in our proposed rulemaking but retain our previous hourly burden estimates. Specific calculations are discussed more fully and may be found in the agency's Final Regulatory Impact Analysis (FRIA) under docket nos. FDA-2012-N-1210 and FDA-2004-N-0258 and available on the internet at http://www.fda.gov/aboutfda/reportsmanualsforms/reports/economicanalyses/default.htm

Recordkeeping

We require that firms make and keep certain records necessary to verify the amount of the nutrients in the finished food product. The Nutrition Facts label rule does not specify what records must be used to verify the amounts of these nutrients, but does specify the information that the records must contain. The Nutrition Facts label rule requires manufacturers to, upon request during an inspection, provide FDA with the records that contain the required information for each of these nutrients to verify the amount of the nutrient declared on the product label. These records may include analyses of nutrient databases, recipes or formulations, information from recipes or formulations, batch records, or any other records that contain the required information to verify the nutrient content in the final product.

Table 1 – Estimated Annual Recordkeeping Burden[1]

Type of Declaration; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. 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

Type of Declaration; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
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. Hours are annualized over 3 years.

[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, we believe that the new records that would be 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 the rulemaking consists of the time required to identify and assemble the records for copying and retention. Based on our previous experience with similar information collection, we estimate the recordkeeping burden of the Nutrition Facts Label rule to be 1 hour per product as estimated in Table 1.

Under the Nutrition Facts label rule, the declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate that all roughly 31,283 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. These calculations are reflected in Table 1, rows 1-4. 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 food 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.

It is hard to predict with certainty the exact number of newly introduced products that would be covered under the Nutrition Facts label rule each year, but based on the industry growth rate using U.S. Census Bureau Business and Industry data, we estimate that number to be 216. Thus, we estimate that 216 new products would be affected by the Nutrition Facts Label rule, and that the required recordkeeping would be 1 hour per product, for an annual recurring recordkeeping burden of 216 hours (216 × 1), 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 burden hours and annual records.

Reporting

Table 2 – Estimated Annual Reporting Burden[1]

Filing of citizen petition Regarding to a particular isolated or synthetic non-digestible carbohydrate	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. 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.

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 a recordkeeping 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 reported in Table 2.

Third-Party Disclosure

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Labeling Modifications of …	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs (in billions of 2014$)
NFL/SSL	31,283	26	813,358	2	1,626,716	$2.47
Serving Size	13,452	25	336,300	2	672,600	$1.00
New Products	500	1	500	2	1,000	$0.01
TOTAL			1,150,158		2,300,316	$3.48

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

We calculate a third-party burden associated with the Nutrition Facts Label rule to account for the need by food manufacturers to revise their nutrition labels. We estimate 2 hours per disclosure for a total burden of 1,626,716 hours. The incremental time burden for reviewing labels to assess how to bring them into compliance with the requirements of the Nutrition Facts label is estimated to be 1 hour per label. These requirements reflect a one-time burden attributed to revision of the label because establishments must already print packaging for food products as part of normal business practices, and must disclose required nutrition information under food labeling regulations. Upon implementation of the rule we expect this burden to have been realized. We calculate each label redesign would require 1 additional hour, making the total 2 burden hours per UPC. We estimate 31,283 manufacturers representing 813,358 UPCs, with an average disclosure of 26 labels annually (813,358/31,283), would be covered under the Nutrition Facts label rule. Based on the RIA, we have estimated the capital cost to be $2.47 billion (2014$). This information is reflected in Table 3, row 1.

Under §§ 101.9 and 101.12, some manufacturers of retail food products will need to 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. Additionally, some manufacturers will need to change product labels to add a second column of nutrition information per package or per discrete unit as part of the Nutrition Facts label. The third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. This burden is reflected in Table 3, row 2. Based upon our knowledge of food labeling, we estimate that the affected manufacturers would require 2 hours per product to modify the label's Nutrition Facts panel. We estimate that it will take an affected manufacturer 1 hour to review a label to assess how to bring it into compliance with the new requirements. We estimate each label redesign will require 1 additional hour per UPC, for a total of 2 hours per UPC. We estimate 13,452 manufacturers will initially be affected by the rulemaking and that 336,300 products will initially be required to be relabeled, for an average of 25 (336,300/13,452) products annually per respondent. Based on the RIA, we estimate the initial capital cost to be $1 billion (2014$). These calculations are reflected in Table 3, row 2.

Finally, the rulemaking generates recurring burdens related to the requirement that some manufacturers undertake an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims, and also to the requirement that some manufacturers undertake a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required. We estimate that about 500 new products will be affected by these requirements each year, and that associated the disclosure burden is 2 hours per product, for an annual burden of 1,000 hours. Based on the RIA, we estimate the annual recurring capital cost to be approximately $0.01 billion (2014$). These calculations are reflected in Table 3, row 3.

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

There are no capital costs associated with the 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. Based on internal data, we estimate the current cost of labeling enforcement efforts to be roughly $1.3 million per year (2014$), and we do not expect a significant increase in such efforts as a result of the rulemaking.

15. Explanation for Program Changes or Adjustments

While this is a new information collection, upon implementation of the rulemaking we expect to consolidate the burden under OMB Control No. 0910-0381 (Food Labeling Regulations).

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 for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.