Food Labeling: Revision of the Nutrition Facts and Supplement Facts Label

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Following the passage of the Nutrition Labeling and Education Act of 1990, which added section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 343(q)), FDA issued various regulations related to nutrition information on food labels, including the declaration of nutrients, the format for nutrition labeling, reference values for use in declaring the nutrient content, and allowances for certain specified products to be exempt from nutrition labeling (21 CFR 101.9). In addition, following the passage of the Dietary Supplement Health and Education Act of 1994, FDA amended its food labeling regulations to establish requirements for nutrition labeling of dietary supplements (21 CFR 101.9(j)(6) and 21 CFR 101.36). Section 403(q) of the Federal Food, Drug, and Cosmetic Act 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. In the proposed rule "*Food Labeling: Revision of the Nutrition and Supplement Facts Labels*," FDA is proposing to revise its regulations to provide updated nutrition information on the label and improve how the nutrition information is presented to consumers, in light of current scientific evidence, dietary recommendations of most recent consensus reports, and public comments received in response to advance notices of proposed rulemaking.

This information collection is being requested to support FDA regulations at 21 CFR Part 101.

2. Purpose and Use of the Information Collection

Federal Government: Under the NFL proposed rule, FDA is requiring that manufacturers make and keep records to verify declarations in their food labeling regarding certain nutrients. We believe these requirements are necessary because analytical methods are not available that would allow us to verify labeling declarations and consumers rely on this information. The information collection requirements of the proposed rule allow the agency to determine whether products comply with FDA regulations.

Individuals/Households: The Nutrition Facts label contains nutrient content information on which consumers rely 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 provisions of the proposed rule (i) 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, (ii) 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 (iii) potentially prompts industry to reformulate products to maintain health and nutrient content claims.

3. Use of Improved Information Technology and Burden Reduction

While the proposed rule does not require the use of electronic reporting or recordkeeping, we encourage this approach. Records must be made available to FDA upon request. We expect most all facilities will utilize electronic means to satisfy the information collection requirements of the proposed rule.

4. Efforts to Identify Duplication and Use of Similar Information

Disclosure of information about the nutrient content of foods is mandated under the Nutrition Labeling and Education Act of 1990. We believe the information collection requirements under the proposed rule are consistent with this statutory authority and we are unaware of any duplicative collection requirements.

5. Impact on Small Businesses or Other Small Entities

We estimate the proposed rule will affect approximately 59,872 manufacturers, of which 98 percent are small businesses. The targeted exemption from labeling that currently exists for some small businesses will continue to be available under the proposed rule. 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. Currently, there are about 3,000 small businesses registered with FDA for a small business nutrition labeling exemption. On average we grant labeling exemptions to approximately 10,000 products per year.

6. Consequences of Collecting the Information Less Frequently

Under the proposed rule, we are requiring 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. Manufacturers would be required 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. In addition, we are proposing to require that such records 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.

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

A proposed rule entitled, "*Food Labeling: Revision of the Nutrition and Supplement Facts Labels*," was published in the Federal Register on March 3, 2014 (79 FR 11879).

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

Under the proposed rule, records required by part 101 will be protected from public disclosure to the extent allowable under 21 CFR part 20. Our general policies, procedures, and practices relating to the protection of confidential or otherwise protected information received from third parties would apply to information received under this rule.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

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

If the rule is finalized, the declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber would be mandatory and we estimate that all respondents would incur recordkeeping burden. We estimate 1 hour per recordkeeping provision, as shown in Table 1. We estimate that there are fewer than 20 isolated and synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen or health claim petition filed by a manufacturer related to a particular isolated and synthetic non-digestible carbohydrate is granted or denied, it applies to all food products that contain said non-digestible carbohydrate. Thus, we estimate that, at most, 20 manufacturers would incur a recordkeeping burden associated with filing a citizen or health claim petition related to an isolated and synthetic non-digestible

carbohydrate that does not meet the definition of dietary fiber and that the required recordkeeping would be 1 hour per manufacturer. 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 believe all estimated respondents would incur this recordkeeping burden.

Table 1 – Estimated Annual Recordkeeping Burden[1]

Type of Declaration; Proposed 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]	59,872	1	59,872	1	59,872
Dietary Fiber; 101.9(c)(6)(i)[2]	59,872	1	59,872	1	59,872
Soluble Fiber; 101.9(c)(6)(i)(A)[2]	59,872	1	59,872	1	59,872
Insoluble Fiber; 101.9(c)(6)(i)(B)[2]	59,872	1	59,872	1	59,872
Dietary Fiber; 101.9(c)(6)(i) (filing a claim)	20	1	20	1	20
Vitamin E ; 101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Folate/Folic Acid/101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Total					359,252

[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.

12b. Annualized Cost Burden Estimate

The mean hourly wage of an operations manager in the food manufacturing industry is $53.56 (Bureau of Labor Statistics. May 2012 National Industry-Specific Occupational Employment and Wage Estimates; NAICS 311000 - Food Manufacturing). We increase this cost by 50 percent to account for benefits and overhead, for a total of $80.34 (= $53.56*1.5). We therefore estimate the annualized cost incurred by respondents to be $28,862,305.68 (359,252 burden hours x $80.34/hr).

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. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation to be $16.33 to $55.46 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 2012. To account for overhead, this cost is increased by 50 percent, making the total cost $24.50 to $83.19 per hour. The midpoint of this range is $53.85 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $269.25 per review ($53.85/hour x 5 hours). FDA estimates that it will review records for an average of 500 inspections per year. Thus, FDA estimates that the total annual cost to the Federal Government for reviewing records during inspections would be $134,625 ($269.25 x 500 inspections) in 2012 dollars.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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.