Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

OMB Control No. 0910-0374

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997 (FDAMA), provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences. Under this section of the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the *Federal Register* of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body." The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in the notification. The guidance can be found at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm056975.htm.

FDA is requesting extension of OMB approval of these notification procedures and the provisions contained in the guidance entitled, "Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body."

2. Purpose and Use of the Information Collection

We believe that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. We intend to review the notifications we receive to ensure that they comply with the criteria established by the FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

Firms may submit notifications by e-mail at label.claims@cfsan.fda.gov. The agency estimates that fifty percent (50%) of notifications will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency with the authority to receive notifications of claims based on authoritative statements. There is no likelihood of Federal duplication of effort because of the clear Congressional authorization of FDA jurisdiction pertaining to notifications of claims based on authoritative statements, as distinguished from the jurisdictions of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by this regulation. However, FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The information is only collected if a firm is preparing to market a product that bears a label containing a nutrient content claim or health claim based on an authoritative statement of a scientific body. If the information is not collected or is collected less frequently, and the health or nutrient content claim is not otherwise authorized, the product bearing the claim will not be in compliance with section 403(r) of the FD&C Act and would, therefore, be misbranded.

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

This collection of information does not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other proprietary information. The collection fully complies with 5 CFR 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of November 12, 2014 (79 FR 69494). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Sections 403(r)(2)(G) and 403(r)(3)(C) do not provide that information in a notification based on an authoritative statement will be kept confidential. However, all information received by FDA is subject to the agency's regulations concerning confidentiality in 21 CFR 20.61. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: The respondents include businesses that market food products whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences. Respondents are from the private sector (for-profit businesses).

FDA estimates the burden of this collection of information as follows:

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

Section of the FD&C Act	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for Notifications	2	1	2	1	2
TOTAL					702

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

These estimates are based on our experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, we estimate that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. We estimate that we will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of

the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or the National Academy of Sciences, we believe that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, we estimate that one respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, we estimate that one respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. We have determined that this information should be readily available to a respondent and, thus, we estimate that it will take a respondent 1 hour to incorporate the information into each notification. We expect there will be two respondents for a total of 2 hours.

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized cost to respondents for the hour burden associated with the preparation and submission of notifications to be $61,102.08. We estimate that the average hourly wage for an employee to prepare and submit the notification would be equivalent to a GS-13/Step 1 level in the locality pay area of Washington-Baltimore in 2015, which is $43.52 per hour. Total annual burden hours (702) multiplied by $$43.52 per hour equals $30,551.04. To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents $61,102.08.

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 collection.

14. Annualized Cost to the Federal Government

The annualized cost to the Federal government for the review and evaluation of notifications is estimated as follows:

Estimated number of hours per year = 2 x 200 = 400 hours; or
Estimated number of notifications = 2
Estimated number of hours for the review and evaluation of notifications = 200

We estimate that the average hourly wage for an employee to review and evaluate a notification would be equivalent to a GS-13/Step 1 level in the locality pay area of Washington-Baltimore in 2015, which is $43.52 per hour. We estimate overhead as being equal to salary.

Estimated cost for review and evaluation	= $34,816
Total time of 400 hours x $43.52/hour for review and evaluation (salary)	= $17,408
Overhead	= $17,408
Total cost (Salary + Overhead)	= $34,816

Note: Should the notification be determined by the agency to be unsatisfactory and an acceptable resolution between the notifier and the agency is not reached, the agency will have the additional burden of conducting notice and comment rulemaking. This would result in a substantial increased burden to the agency of approximately 2,000 hours for each unacceptable notification.

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.