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

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

The agency believes 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. FDA intends to review the notifications the agency receives to ensure that they comply with the criteria established by the FD&C Act.

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).

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 August 3, 2011 (76 FR 46819). No comments were received.

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 FDA's 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, the agency estimates that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. FDA estimates that it will

receive one nutrient content claim notification and one health claim notification per year over the next three years.

Sections 403(r)(2)(G) and 403(r)(3)(C) of the FD&C Act require 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, FDA believes 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, FDA estimates that one respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, FDA estimates 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. FDA has determined that this information should be readily available to a respondent and, thus, the agency estimates that it will take a respondent 1 hour to incorporate the information into the notification. The agency expects there will be 2 respondents for a total of 2 hours.

12 b. Annualized Cost Burden Estimate

FDA estimates that the annualized cost to respondents for the hour burden associated with the preparation and submission of notifications to be $59,894.64. This estimate is based on the base hourly 2011 rate of a GS-13 salary ($42.66) plus overhead expenses as being equal to salary for a total hourly cost of $85.32 (702 hours x $85.32/hour = $59,894.64).

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

Estimated cost for review and evaluation	= $34,128
Total time of 400 hours x $42.66/hour for review and evaluation (salary)	= $17,064
Overhead	= $17,064
Total cost (Salary + Overhead)	= $34,128

Hourly cost for review and evaluation of the cost to the U.S. government is estimated as being equivalent to that of a GS-13 salary in Washington, DC in 2011. Overhead is estimated as being equal to salary.

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

As shown in Table 1, CFSAN has made slight adjustments in the burden table to update estimates for the number of respondents expected to submit notifications over the next 3 years. The changes in the 2011 estimates from the 2008 estimates can be described as follows.

In 2008, CFSAN estimated that there would be 2 respondents for health claim notifications per year over the next three years. CFSAN did not receive any notifications over that period of time and does not expect that to change over the next three years. To avoid estimating the number of respondents as zero, the agency estimates that there will be one or fewer respondents annually for health claim notifications. Thus, CFSAN changed the estimate from 2 respondents for health claim notifications to 1.

This adjustment also affected the number of respondents for the guidance. Since CFSAN's estimate for respondents was reduced by one, the estimate for the number of respondents for the guidance is reduced by one as well. Thus, CFSAN changed the estimate from 3 respondents for the guidance to 2.

The total hours for health claim notifications decreased from 900 to 450 hours. The total hours for the guidance decreased from 3 to 2 hours. The total hours for this information collection decreased from 1,153 to 702 hours.

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.