NOTIFICATION OF A HEALTH CLAIM OR NUTRIENT CONTENT CLAIM BASED ON AN AUTHORITATIVE STATEMENT OF A SCIENTIFIC BODY

OMB No. 0910-0374

SUPPORTING STATEMENT

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 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 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.

FDA is requesting extension of OMB approval of these notification procedures.

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 act. In addition to the information specifically required by the 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 act.

3. Use of Improved Information Technology and Burden Reduction

The guidance does not discuss the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology by firms. Companies are free to use whatever forms of information technology may best assist them in developing the notification.

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

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 dealing with the requirements of the act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

6. Consequences of Collecting the Information Less Frequently

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 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 May 7, 2008 (73 FR 25749). No comments were received.

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

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 of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Persons that 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.

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

Section of the Act/Basis of Burden	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	2	1	2	450	900
Guidance for Notifications	3	1	3	1	3
Total					1,153

[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. FDA estimates that it will receive 1 nutrient content claim notification and 2 health claim notifications per year.

Sections 403(r)(2)(G) and 403(r)(3)(C) of the 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 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 Federal government or the National Academy of Sciences, FDA believes that the information that is required by the 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 it will take a respondent 250 hours to collect and assemble the information required by the statute for nutrient content claim notifications and 450 hours to collect and assemble the information required by the statute for health claim notifications.

Pursuant to 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. This 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.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the annualized cost to respondents for the hour burden associated with the preparation and submission of notifications to be $91,663.50. This estimate is based on the base hourly 2008 rate of a GS-13 salary ($39.75) plus overhead expenses as being equal to salary for a total hourly cost of $79.50 (1153 hours x $79.50/hour = $91,663.50).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to 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 = 3 x 200 = 600 hours; or
Estimated number of notifications = 3
Estimated number of hours for the review and evaluation of notifications = 200

Estimated cost for review and evaluation = $47,700
Total time of 600 hours x $39.75/hour

for review and evaluation (salary) = $23,850
Overhead = $23,850
Total cost (Salary + Overhead) = $47,700
Hourly cost for review and evaluation of the cost to the Federal government is estimated as being equivalent to that of a GS-13 salary in Washington, DC in 2008. 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

There is no change in the estimated number of burden hours (1,153 hours).

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the information collected under the provisions of this guidance for statistical use.

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

Not applicable.