

**SUPPORTING STATEMENT  
NOTIFICATIONS OF A HEALTH CLAIM  
OR NUTRIENT CONTENT CLAIM BASED ON AN  
AUTHORITATIVE STATEMENT OF A SCIENTIFIC BODY**

**A. JUSTIFICATION**

**1. Necessity of the Information Collection**

The Food and Drug Administration Modernization Act (FDAMA) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding sections 403(r)(2)(G) and 403(r)(3)(C) (21 U.S.C. 343(r)(2)(G) and 343(r)(3)(C)). Sections 403(r)(2)(G) and 403(r)(3)(C) of the act provide that a food producer may market a food product whose label bears a nutrient content claim or a health claim, respectively, that is based on an authoritative claim of certain scientific bodies of the Federal government or the National Academy of Sciences or any of its subdivisions.

Under these sections of the act, such a claim must be the subject of notification of intention to use the claim 120 days before a food producer begins marketing of a product bearing the claim.

FDA previously obtained OMB approval of emergency processing of the notification procedures described in FDA's Guidance for Industry for "Notifications of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" (Attachment 1) because the collection of information was needed prior to the expiration of the time periods established for obtaining OMB review and approval under 5 CFR part 1320 and the use of normal clearance procedures were reasonably likely to prevent or disrupt the collection of information provided by FDAMA. The provisions of sections 403(r)(2)(G) and 403(r)(3)(C) became effective on February 19, 1998. Because of the short period of time between passage of FDAMA and the date of its effectiveness, FDA had inadequate time to prepare regulations and guidance through

notice and comment rulemaking. This guidance provides industry with FDA's considerations on the information that should be in a notification of health claim or nutrient content claim based on an authoritative statement while the agency proceeds with notice and comment rulemaking in this matter. FDA is now seeking OMB approval of the extension of the guidance and information collection provisions, as follows:

**Guidance for Industry**

**Reporting**

Provides guidance to the industry on the preparation of notifications for submission to FDA 120 days prior to marketing of a food that bears a label containing a health claim or nutrient content claim based on an authoritative statement.

**2. How, by Whom, and for What Purpose Information is Used**

Sections 403(r)(2)(G) and 403(r)(3)(C) of the act require the reporting provisions that are the subject of this draft guidance as a condition for a firm to market a product whose label bears a nutrient content claim or health claim based on an authoritative statement. FDA will review the information contained in the notification to ensure that the claim complies with the requirements of sections 403(r)(2)(G) and 403(r)(3)(C) of the act. A claim that does not comply with these requirements may misbrand the food product bearing such claims. Receipt of the notification 120 days before a firm begins marketing of a product should provide FDA with sufficient time to be able to determine whether the claim is in compliance with the provisions of sections 403(r)(2)(G) and 403(r)(3)(C).

### **3. Use of Improved Information Technology**

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

### **4. Identification of Duplication and Similar Information Already Available**

No duplication of Federal regulations concerning the guidance on notifications is likely because of the clear Congressional authorization of FDA jurisdiction pertaining to notifications of claims based on authoritative statements as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

### **5. Small Businesses**

The reporting provisions discussed in the guidance for the notifications procedures are those mandated under sections 403(r)(2)(G) and 403(r)(3)(C) of the act. However, FDA aids small businesses in dealing with its requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs within the agency.

### **6. Consequences if Data Were Collected Less Frequently and Technical or Legal Obstacles**

There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. Under the provisions of sections 403(r)(2)(G) and 403(r)(3)(C) of the act, a food product would be misbranded and subject to regulatory action if its

label or labeling contained a nutrient content claim or health claim, based upon an authoritative statement that was not the subject of a notification submitted to FDA 120 days before marketing of the product.

## **7. Special Circumstances**

Not applicable.

## **8. Outside Consultation**

FDA is currently reviewing comments to 9 interim final rules (Attachment 2) published on June 22, 1998 (63 FR 34084-34117). These interim final rules were published in response to notifications submitted to the agency before the issuance of its guidance on notifications. The agency's conclusions concerning the objections will be addressed in any final rules coming from these rulemakings and the notice and comment rulemaking for an implementing regulation. The guidance will be revised accordingly.

In accordance with 5 CFR 1320.8(d), on Thursday, August 13, 1998, in Volume 63, No. 156, page 43400, a 60-day notice for public comment (Attachment 3) was published in the Federal Register.

One comment was submitted by a food industry association. This comment addressed several points, only some of which were relevant to the information collection provisions contained in the guidance. Most of the other points were relevant to a group of interim final rules the agency issued in June 1998 in response to a notification for nine claims based on authoritative statements; these points will be addressed in the rulemakings to which they pertain. The points in the comment that are relevant to the information collection provisions in the guidance are discussed in

the following paragraphs.

The comment first stated that the guidance goes further than provided by the statute in two respects: First, in the guidance's request that notifications include a "potentially burdensome" account or analysis of how the scientific literature relating to the relationship between a nutrient and a disease or health-related condition or to the nutrient level to which the claim refers either supports or fails to support the authoritative statement, and second, in the guidance's request that information on analytical methodology for the nutrient that is the subject of the claim be submitted. The comment expressed the opinion that, although the kind of information identified by the guidelines may be useful to FDA and could be submitted voluntarily, the information should not be a mandatory element of a notification; moreover, the lack of such information should not be the basis for prohibiting a health claim based on an authoritative statement. The comment stated that notifications should not impose any significant regulatory burden on manufacturers, adding that, as a general matter, it would object to any expansion of information required as part of a notification.

First, the agency notes that neither the account of the scientific literature relating to the claim nor the information about analytical methodology is described in the guidance as a mandatory element of a notification. In both cases, the agency uses the term "should" to convey its view that the inclusion of such information is desirable. Further, the guidance states explicitly, "An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both."

Second, the agency does not believe that providing the account of the relevant scientific information and the analytical methodology are overly burdensome. FDA believes that most

companies would prepare an account of the scientific literature that supports or fails to support a claim in the normal course of evaluating potential claims based on authoritative statements and making the business decision of whether to use such claims in the marketing of their products. Similarly, FDA believes that most companies would be knowledgeable about the analytical methodologies that might be used to determine the amount of a nutrient or other substance present in their products. The agency recognizes that including such information in a notification causes some burden. The agency provided an estimate of this burden in the August 13, 1998 notice. No comments were submitted addressing the accuracy of this estimate.

#### **9. Gifts or Payment to Respondents**

This information collection does not provide for gifts or payment to respondents.

#### **10. Confidentiality**

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, whether notifications will be placed in a public docket at FDA's Dockets Management Branch will be addressed in notice and comment rulemaking for an implementing regulation. Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

#### **11. Sensitive Questions**

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

## 12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

### Burden Hours

FDA estimates the total annual hour burden for this information collection to be 60 hours, as follows:

#### ESTIMATED ANNUAL REPORTING BURDEN

21 U.S.C. 343(r)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours
Draft Guidance for Notifications	12	5	60	1	60

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

FDA estimates that as many as 12 food producers may submit a notification of a health claim or nutrient content claim based on an authoritative statement. The agency further estimates that each producer would on average submit 5 such notifications. Because 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 the producers. FDA believes that analytical methodology for the nutrients that are the subject of such a claim as required under the guidance will be readily available and should take no longer than 1 hour on average to incorporate into a notification for submission to the agency. FDA is basing its estimates on its experience with other similar notification procedures that fall under its jurisdiction and its knowledge of health claims and nutrient content claims.

The hour burden estimates contained above are for the information collection provisions established by this draft guidance alone and do not include those that stem solely from the act or

the FDAMA.

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 \$3,000. This estimate is based on the base hourly rate of a GS-13 salary (\$25.00) plus overhead expenses as being equal to salary for a total hourly cost of \$50.00 (60 hours x \$50.00/hour = \$3,000).

**13. Annual Cost Burden to Respondent**

There are no capital costs or operating and maintenance costs associated with this collection beyond those related to the hour burden for submitting the notification.

**14. Annualized Cost to the Federal Government**

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

Estimated number of hours per year = 60 x 80 = 4800 hours; or

Estimated number of notifications = 60

Estimated number of hours for the review and evaluation of notifications = 80

Estimated cost for review and evaluation = \$259,200

Total time of 4800 hours x \$27.00/hour

for review and evaluation (salary) = \$129,600

Overhead = \$129,600

Total cost (Salary + Overhead) = \$259,200

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. Overhead is estimated as being equal to salary.

#### **15. Changes of Adjustments in Burden**

There are no changes or adjustments in burden..

#### **16. Statistical Analysis, Publication Plans, and Schedule**

Not Applicable

#### **17. Approval Not to Display Expiration Date**

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

#### **18. Exceptions to Certification Statement**

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.

### **B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

There are no plans to publish the information collected under the provisions of this

proposed regulation for statistical use. The collection of information required under the provisions of this proposed regulation do not employ statistical methods.