Food Labeling; Notification Procedures for Statements on Dietary Supplements

OMB No. 0910-0331

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Dietary Supplement Health and Education Act (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(6) (21 U.S.C. 343(r)(6)), which provides for the notification of the Secretary (and by delegation the Food and Drug Administration (FDA)) no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling.

Section § 101.93 (21 CFR 101.93) establishes procedures for submitting the required information. Section 101.93 requires submission of a notification to FDA no later than 30 days after first marketing a dietary supplement that bears a statement of nutritional support. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

This information collection is necessary because the notification from the responsible firm is required by the act in order for the firm to be able to lawfully make a claim pursuant to 21 U.S.C. 343(r)(6) in its labeling.

We request the extension of OMB approval for the following collection of information requirement:

21 CFR 101.93 - Reporting

Requires submission of a notification to FDA no later than 30 days after first marketing a dietary supplement that bears a statement of nutritional support and that the notification be signed by a responsible individual who can certify the accuracy of the information presented.

2. Purpose and Use of the Information Collection

DSHEA requires the notifications that are the subject of this regulation. The notification alerts the FDA that a dietary supplement is being marketed that bears a nutritional support statement and provides to FDA the text of the nutritional support statement. FDA utilizes the information to ensure that statements of nutritional support made by dietary supplement manufacturers or distributors about their products comply with section 403(r)(6) of the act.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the act statements on

their labels or labeling. Respondents are from the private sector (for profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The agency is not equipped to receive these submissions electronically at this time. Therefore, this information collection will not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. FDA is working diligently to develop the necessary technology infrastructure to enable it to accept these submissions electronically in the future. The agency has made progress toward completion of a Public Key Infrastructure (PKI) capable system that we expect to enable us to accept these submissions electronically. Accordingly, FDA has carefully evaluated the nature and regulatory significance of the submission, in particular the significant legal consequences attendant to the signing and submitting of the notification, and request that the agency be authorized to continue this information collection activity in non-electronic format.

The notification must be signed by a responsible person, and in signing the notice, that person is certifying that the information is accurate and that the firm is in possession of substantiation that the claim that is the subject of the notification is truthful and not misleading. The signatory of the notification is, therefore, assuming potential liability under 18 U.S.C. 1001. Moreover, if the person who signs the notification is, in fact, not a responsible person authorized by the firm to certify that the firm is in compliance with all applicable requirements of the Act, then the submission of a noncompliant notification may also exposure the firm and/or its products to liability under the act.

The notification carries legal implications for the firm and the signatory. Therefore, these documents carry significant risk of repudiation. For this reason, FDA believes that the significant legal consequences attendant to the signature warrant a level of authentication and signer non-repudiation that only digital signatures in a PKI model can currently provide. Because CFSAN lacks that model, but is working with other FDA units toward putting it in place, the agency believes that other forms of electronic submission that the agency might be able to accept present unacceptable risks that provide a basis to not accept these submissions electronically until an acceptable infrastructure is in place.

FDA estimates that none of the respondents (0%) will use electronic means to submit the required information.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency that collects this information. There are no similar data that can be used or modified for this use. This notification is only given when a dietary supplement bearing a nutritional support statement on its label or in its labeling is marketed. Therefore, the information being submitted to the agency will be original for each submission.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately seventy-five percent (75%) of the respondents are small businesses. The reporting requirements of this regulation are mandated by DSHEA and the agency has concluded that they will not be a burden to small businesses. However, FDA aids small businesses in dealing with its requirements 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

Respondents will submit the required information on an occasional basis, associated with the marketing of their products, as required by section 403(r)(6) of the act. The information is only collected if a manufacturer of a dietary supplement is making a statement of nutritional support on its label or in its labeling. If the collection is not conducted or is conducted less frequently, the manufacturers of the dietary supplement making the statement of nutritional support will not be in compliance with section 403(r)(6) of the act.

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

There are no special circumstances associated with this collection of information.

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 June 2, 2009 (74 FR 26406). FDA received two letters in response, each containing one or more comments. One these letters was received several months after the close of the comment period. The comments that were timely filed were outside the scope of the comment request in the notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information collected is not confidential. The regulation does not specify confidentiality. However, all information received by FDA is subject to the agency's regulations concerning confidentiality in 21 CFR 20.61.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The total estimated hour burden associated with this collection is 1,650 hours annually. The agency believes that there will be minimal burden on industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary supplements. FDA is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. FDA estimates that listing the information

required by section 403 of the act, and presenting it in a format that will meet the procedures of §101.93, will require a burden of approximately 45 minutes (0.75 hour) per submission. FDA bases its estimate on its experience with similar notification programs. The agency estimates that the manufacturers, packers, or distributors will submit approximately 2,200 notifications a year. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	2,200	1	2,200	45/60	1,650

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $102,861. FDA estimates that this notification will be prepared by an employee making an average wage similar that of a Federal government employee at the GS-11/Step-3 rate for the Washington-Baltimore locality pay area for the year 2009, which is $31.17 per hour. To account for overhead, this cost is increased by 100 percent, which is $62.34 per hour. Thus, the annual wage cost for completion and submission of these notifications is approximately $102,861 (1,650 hours x $62.34 per hour).

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 information collection.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is approximately $17,326. FDA bases its estimate on the salary of one (1) full-time employee (FTE) at GS-13, Step 1, in the Washington-Baltimore Locality Pay Area for the year 2009 who spends an estimated 416 hours (416 hours x $41.65/hour = $17,326)

15. Explanation for Program Changes or Adjustments

The estimated burden has decreased from 1,875 hours to 1,650 hours. This adjustment is the result of a decrease in the estimated number of respondents from 2,500 to 2,200.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.