Food Labeling; Notification Procedures for Statements on Dietary Supplements

0910-0331

SUPPORTING STATEMENT

Terms of Clearance: None.

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 FD&C 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 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 FD&C 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 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 FD&C 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 FD&C 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

With this request, FDA is seeking OMB approval of an electronic submission method for this collection. FDA has developed an electronic portal that interested persons will be able to use to electronically submit their notifications to CFSAN's Office of Dietary Supplement Programs via FDA's Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Draft screenshots of Form FDA 3955 were made available for comment at *http://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm*. Upon implementation of the electronic form, FDA estimates that initially seventy-five percent (75%) of the notifications will be submitted electronically, increasing to one hundred percent (100%) over next three years.

4. Efforts to Identify Duplication and Use of Similar Information

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. 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. 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 FD&C 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 FD&C 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 March 11, 2016 (81 FR 12910). FDA received one letter with three comments in response to the notice. The first comment generally agreed with the proposed collection of information. The second comment suggested that electronic submission could potentially decrease burden on respondents. FDA agrees. The third comment suggested that FDA consider whether there might be changes to the number of submissions or other considerations that might affect the burden on respondents. FDA considers available data to determine the number of submissions it expects to receive and, subsequently, the burden hours created by the information collection.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts 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

12a. 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 FD&C Act in submitting information regarding nutritional support 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 FD&C 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	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.93	2,200	1	2,200	0.75 (45 minutes)	1,650

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $109,032. 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 2016, which is $33.04 per hour. To account for overhead, this cost is increased by 100 percent, which is $66.08 per hour. Thus, the annual wage cost for completion and submission of these notifications is approximately $109,032 (1,650 hours x $66.08 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 $36,732.80. 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 2016 who spends an estimated 416 hours (416 hours x $44.15/hour = $18,366.40). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $36,732.80.

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

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.