UNITED STATES FOOD & DRUG ADMINISTRATION

Food Labeling: Notification Procedures for Statements on Dietary Supplements

OMB Control No. 0910-0331

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of the Dietary Supplement Health and Education Act (DSHEA). The 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 requires the notification to the Food and Drug Administration (FDA, the agency, us or we) (by delegation of the Secretary of the Department of Health and Human Services) 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. This requirement is codified in our food labeling regulations at 21 CFR 101, subpart F.

Specifically, section 101.93 (21 CFR 101.93) establishes procedures for submitting required information and 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, and that the notifying firm has substantiation that the statement is truthful and not misleading.

To assist respondents with the required reporting, we developed Form FDA 3955. Form FDA 3955 allows interested persons to electronically submit notifications via an electronic system. We are revising the information collection by upgrading the current electronic system (FURLS) to the Food Applications Regulatory Management (FARM) system; however, FARM requests no new or different information. Rather, it improves our operational efficiency by its ability to interface with other agency systems. Screen shots of the FARM system have been made available for comment through our website at: https://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm.

Respondents who prefer to submit a paper notification in a format of their own choosing still have the option to do so. However, Form FDA 3955 prompts a respondent to include certain elements in their notification described in § 101.93 in a standard format electronically and helps the respondent organize their notification to include only the information needed for our review of the claim. Notification, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act.

We therefore request OMB approval of the information collection provisions found in 21 CFR 101.93, as well as the associated upgraded collection system FARM, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Notification to FDA is necessary for the review of nutrition claims made pursuant to 21 U.S.C. 343(r)(6). Food that is not compliant with labeling requirements of the FD&C Act may be determined to be misbranded and subject to enforcement to protect consumers.

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

Respondents may choose to submit information by either electronic or traditional (paper-based) means, however we encourage the use of FARM. FARM is an upgraded collection system that interfaces with other agency databases. At the same time, respondents who prefer to submit a paper notification in a format of their own choosing still have the option to do so. Since the electronic portal has allowed for a more efficient way to submit information, we estimate that one-hundred percent (100%) of the notifications will be submitted electronically over next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While other collections support food labeling provisions found in FDA regulations, this information collection supports the notification requirement established under section 403(r)(6) of the act specific to dietary supplements.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately seventy-five percent (75%) of the respondents are small businesses, however we do not believe the information collection poses undue burden on these entities. However, we aid small businesses in complying with regulatory requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. We also provide resources, including a Small Business Guide, on our website at www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Respondents 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 for 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 February 7, 2019 (84 FR 2528). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

Information collected is not confidential. However, regulations concerning confidentiality in 21 CFR 20.61 apply to all information received. In consultation with our Privacy Office, we have concluded that, although the name and address of the manufacturer, packer, or distributor of the dietary supplement product is included in the submission, it does not request any personally identifiable information. Therefore, under 5 U.S.C. § 552a(e)(3) we have determined that a Privacy Act Statement is not required.

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 2,767.5 hours annually. We believe that there is minimal burden on respondents to gather 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. We are 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. We estimate that listing the information required by section 403 of the FD&C Act and presenting it in a format that will meet the procedures listed in § 101.93, requires a

burden of approximately 45 minutes (0.75 hour) per submission. We base our estimate on our experience with similar notification programs. We estimate that the manufacturers, packers, or distributors will submit approximately 3,690 notifications a year. This estimate is based on the average number of notification submissions received in the preceding 12 months.

Table 1.--Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.93	3,690	1	3,690	0.75 (45 mins.)	2,767.5

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

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately $196,824.60. We estimate 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 2019, which is $35.56 per hour. To account for overhead, this cost is increased by 100 percent, which is $71.12 per hour. Thus, the annual wage cost for completion and submission of these notifications is $196,824.60 (2,767.5 hours x $71.12 per hour).

Table 2. --Estimated Annual Burden Cost			
Activity and CFR cite	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
101.93	2,767.5	$71.12	$196,824.60

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 $39,536.64. We base our 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 2019 who spends an estimated 416 hours (416 hours x $47.52/hour = $19,768.32) reviewing the notifications. To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $39,536.64.

15. Explanation for Program Changes or Adjustments

The information collection reflects a revision to the collection mechanism. Specifically, we are implementing an updated IT system, FARM, that improves our operational efficiency by interfacing with other agency systems. As explained in Question 1, no new information is collected, however we characterize the change as a revision. We have also adjusted our estimates to reflect an increase in submissions. Specifically, our estimated burden for the information collection reflects an overall increase of 1,117.5 hours (from 1650 to 2767.5 hours) and a corresponding increase of 1,490 responses (from 2,200 to 3,690 responses).

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. We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.