United States Food and Drug Administration

Food Labeling: Notification Procedures for Statements on Dietary Supplements

OMB Control No. 0910-0331

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports a Food and Drug Administration (FDA, agency, us or we) regulation and program. The Dietary Supplement Health and Education Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 403(r)(6) (21 U.S.C. 343(r)(6)), which requires notification to FDA (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 statement provided for in section 403(r)(6) of the FD&C Act 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 the CFSAN Online Submission Module (COSM), which is a component of the Food Application Regulatory Management system (FARM), as discussed in this supporting statement.

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. The electronic form and any optional elements prepared as attachments to the form (e.g., label) can be submitted in electronic format via COSM. Notification, whether electronic or paper, is required for all claims made pursuant to section 403(r)(6) of the FD&C Act.

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

2. Purpose and Use of the Information Collection

Notification to FDA is necessary for the review of statements made for dietary ingredients or dietary supplements on their label or in their labeling. We use this information to evaluate whether these statements are permissible under 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

Respondents may choose to submit information by either electronic or traditional (paper-based) means, however we encourage respondents to submit electronically via COSM. At the same time, respondents who prefer to submit a paper notification in a format of their own choosing have the option to do so. Since COSM allows for a more efficient way to submit information, we expect that more notifications will be submitted electronically over next three years, approaching 100%.

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 FD&C Act specific to dietary supplements.

5. Impact on Small Businesses or Other Small Entities

We assist small businesses in complying with regulatory requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. We do not believe the information collection poses undue burden on small business. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Respondents submit the required information on an as-needed 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 the first time a respondent makes a statement provided for in section 403(r)(6) on its label or in its labeling. If the collection is not conducted or is conducted less frequently, that respondent 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 December 2, 2021 (86 FR 68504). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is the name of the person who can certify the accuracy of the information submitted. FDA determined that, although PII is collected, it is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use the name or any other personal identifier to retrieve records from the information collected. Through appropriate instruction, FDA minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We believe that there is minimal burden on respondents to gather information to meet the requirements of section 403(r)(6) of the FD&C Act. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears a statement provided for in section 403(r)(6) on its label or in its labeling. We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity; Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.93; Statements for Dietary Supplements; Form FDA 3955	3,690	1	3,690	0.75 (45 minutes)	2,768

[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 $212,084.16. We estimate that notifications are prepared by employees making an average wage similar that of Federal government employees at the GS-11/Step-3 rate for the Washington-Baltimore locality pay area for the year 2022, which is $38.31 per hour. To account for overhead, this cost is increased by 100 percent, which is $76.62 per hour. Thus, the annual wage cost for completion and submission of notifications is $212,084.16 (2,768 hours x $76.62 per hour).

Table 2.--Estimated Annual Cost Burden

21 CFR Section; Activity; Form No.	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
101.93; Statements for Dietary Supplements; Form FDA 3955	2,768	$76.62	$212,084.16

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 $141,140. We base our estimate on the salary of FDA staff at GS-14/Step 6, in the Washington-Baltimore locality pay area for the year 2022 who spends an estimated 1,000 hours (1,000 hours x $70.57/hour = $70,570) reviewing notifications. To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $141,140.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our hourly burden estimate. However, burden costs were inadvertently entered into OMB's ROCIS digital platform for this collection during the last approval, and those costs have been revised from $196,825 to zero.

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.