

UNITED STATES FOOD AND DRUG ADMINISTRATION

Premarket Notification for a New Dietary Ingredient

OMB Control Number 0910-0330

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations and associated forms. Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient (NDI), a manufacturer or distributor of a NDI, or of the dietary supplement that contains the NDI, is to submit to FDA (as delegate for the Secretary of Health and Human Services) the information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a NDI will reasonably be expected to be safe. Section 190.6 (21 CFR 190.6) implements this statutory provision. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit to the Office of Dietary Supplement Programs (ODSP) notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the NDI, (3) a description of the dietary supplement(s) that contain the NDI, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR 190.6 and Form FDA 3880.

2. Purpose and Use of the Information Collection

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of NDIs and dietary supplements that contain NDIs in order to protect consumers from ingredients and products whose safety is unknown. We use the information collected in NDI notifications to evaluate the safety of NDIs in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

Description of Respondents: The respondents to this collection of information are certain manufacturers and distributors in the dietary supplement industry. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

We developed an electronic portal that respondents may use to electronically submit their notifications to ODSP via the Center for Food Safety and Applied Nutrition (CFSAN) Online Submission Module (COSM). COSM was developed to assist industry partners when filing regulatory submissions and is specifically designed to aid users wishing to file submissions with CFSAN. COSM allows safety and other information to be uploaded and submitted online via Form FDA 3880. This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the NDI is reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as a description of the ingredient and other information. Firms that prefer to submit a paper notification in a format of their own choosing have the option to do so; however, Form FDA 3880 prompts a submitter to input the elements of an NDI notification in a standard format that we will be able to review efficiently. Form FDA 3880 may be accessed at <https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm>. We estimate that approximately 95% of respondents will submit the information electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. 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 required when the manufacturer or distributor is introducing or delivering for introduction into interstate commerce an NDI or a dietary supplement that contains an NDI. Therefore, the information being submitted to FDA will be original for each submission.

5. Impact on Small Businesses or Other Small Entities

We estimate that ten percent (10%) of respondents are small businesses. The reporting requirement of the regulation is mandated by the FD&C Act and there is no statutory exception for small businesses. The same information is requested from large and small firms and is the minimal amount needed. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. Assistance is 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. The information is only collected if a manufacturer or distributor is introducing or delivering for introduction into interstate commerce an NDI not found in the food supply or a dietary supplement that contains such an NDI. If the collection is not conducted or is conducted less frequently, manufacturers or distributors of the subject product will not be in compliance with section 413(a) of the FD&C Act (21 U.S.C. 350b(a)).

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), we published a 60-day notice requesting public comment on the proposed collection of information in the *Federal Register* of October 16, 2020 (85 FR 65830). We received twenty-one comments, fourteen of which were PRA-related. The other seven comments were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document. Of the fourteen PRA-related comments, twelve related to the necessity and practical utility of the information being collected, and two questioned the accuracy of our burden and cost estimates.

Comment: Several comments related to FDA’s necessity and practical utility of the information being collected. In other words, we received comments asking why this information is required to be submitted and how we use this information.

Response: Under section 413(a) of the FD&C Act, the manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, must submit a premarket notification to FDA at least 75 days before introducing the product into interstate commerce or delivering it for introduction into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement “have been present in the food supply as an article used for food in a form in which the food has not been chemically altered” (21 U.S.C. 350b(a)(1)). The notification must contain the information which provides the basis on which the manufacturer or distributor of the NDI or dietary supplement has concluded that the dietary supplement containing the NDI will reasonably be expected to be safe (21 U.S.C. 350b(a)(2)). FDA’s implementing regulation, § 190.6 (21 CFR 190.6), specifies the procedure for submitting a premarket NDI notification and the information the manufacturer or distributor must include in the notification.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of NDIs and dietary supplements that contain NDIs in order to protect consumers from ingredients and products whose safety is unknown. We use the information collected in NDI notifications to evaluate the safety of NDIs in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

One comment questioned the necessity of submitting the safety information recommended in the draft guidance referenced in the following response. As further explained in the following response, the recommendations found in this draft guidance are for comment only.

Comment: Two comments asserted that we underestimated the reporting burden and the cost associated with § 190.6 by failing to take into account the recommendations in the draft guidance entitled “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues” (the 2016 draft guidance) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues>) and erroneously cited a draft guidance that published in July 2011, which the 2016 draft guidance supersedes. We announced the availability of the 2016 draft guidance for comment in a notice published in the *Federal Register* of August 12, 2016 (81 FR 53486).

Response: Although we agree with the commenter that information collection recommendations in guidance are subject to the PRA, we intend to meet our PRA obligations in that regard separately at a later time. The 2016 draft guidance was published solely for the purpose of seeking comment, and it has not been made final. The purpose of the current PRA proceeding is to seek comment on and extend OMB approval for the premarket NDI notification information collections found in the regulations at 21 CFR § 190.6 and in the electronic NDI notification form that we have made available for comment. We intend to publish a 60-day notice inviting comment on the proposed collections of information associated with the 2016 draft guidance at a later date. At that time, we will carefully evaluate all comments we receive.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Under 21 U.S.C. 350b(a) and 21 CFR 190.6(e), FDA must keep NDI notifications private to the extent provided for by law for 90 days after receipt. After the 90th day, we place the notification on public display at FDA's Division of Dockets Management, except for any trade secrets or other private commercial information. Trade secrets and private commercial information are redacted from the notification and not otherwise disclosed to the public, as required by 21 U.S.C. 413(a) and 21 CFR 190.6(e).

Privacy Act

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) or other data of a personal nature. 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 via Form 3880, CFSAN Online Submission Module is name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business.

CFSAN Online Submission Module supports a Food and Drug Administration regulation and form. Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient (NDI), a manufacturer or distributor of an NDI, or of the dietary supplement that contains an NDI, is to submit to FDA (as delegate for the Secretary of Health and Human Services) the information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing an NDI will reasonably be expected to be safe. Section 190.6 (21 CFR 190.6) implements this statutory provision.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
21 CFR Section; Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
190.6; Submitting notification	55	1	55	20	1,100

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

Based on our experience with the information collection over the past 3 years, we estimate that 55 respondents will submit 1 premarket notification each. We estimate that extracting and summarizing the relevant information from what exists in the company's files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. We believe that the burden of the premarket notification requirement is reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing the NDI is in compliance with the FD&C Act. If the required premarket notification is not submitted to FDA, section 413(a) of the FD&C Act provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)). Even if the notification is submitted as required, the dietary supplement containing the NDI is adulterated under section 402(f) of the FD&C Act unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. This requirement is separate from and additional to the requirement to submit a premarket notification for the NDI.

FDA's regulation on NDI notifications, § 190.6(a), requires the manufacturer or distributor of the dietary supplement or of the NDI to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the NDI will reasonably be expected to be safe. Thus, § 190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately \$98,054 per year. We estimate that the average hourly wage for the employee preparing and submitting the NDI notification

would be equivalent to a GS-12/Step-3 level in the locality pay area of Washington-Baltimore in 2021, which is \$44.57/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be \$89.14/hour. Thus, the overall estimated cost incurred by the respondents is \$89,650 (1,100 burden hours x \$89.14/hr = \$98,054).

Table 2.--Annual Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Employees preparing & submitting the NDI notification	1,100	\$89.14	\$98,054

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 collection of information.

14. Annualized Cost to the Federal Government

We estimate the staffing burden necessary to review and respond to NDI notifications will be 9 full-time employees (FTEs) at an average salary of GS-13, Step 5, in the Washington-Baltimore Locality Pay Area for 2021 (9.0 FTEs x \$117,516 = \$1,057,644), and approximately half the time of two supervisory employees at an average salary of GS-14, Step 5 (\$138,866). Thus, the estimated cost to the Federal Government is approximately \$1,196,510 (\$1,057,644 + \$138,866). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government \$2,393,020.

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 burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

For the first 90 days after receiving an NDI notification, we keep the notification secure as to the fullest extent allowed by law as required by 21 U.S.C. 350b(a) and 21 CFR 190.6(e). After the 90th day, we place the notification on public display at FDA’s Dockets Management Staff, after redacting any trade secrets and confidential commercial information.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.