Premarket Notification for a New Dietary Ingredient

OMB Control No. 0910-0330

SUPPORTING STATEMENT

Terms of Clearance: In accordance with the terms of 5 CFR 1320, OMB approves this collection of information for a period of two years. OMB notes that FDA has not provided a means for respondents to submit this information electronically. FDA should make such electronic response available when this collection is resubmitted for approval.

Further, OMB notes that FDA received multiple comments indicating that the true burden of this collection is higher than FDA has estimated. FDA should conduct outreach to the affected community and prepare a full response to these comments - and a re-estimation of the burden, if appropriate - before resubmitting this ICR for approval.

Response: FDA continues to work on the development of an electronic form for submitting notifications. A draft of the form has undergone inner-agency review generating certain revisions and modifications, which FDA is currently undertaking. Upon its completion, the agency will submit the form for OMB review and approval, and expects to do so within the next few months.

FDA deliberated over comments it received regarding its estimated burden for this collection, but made no adjustments. FDA believes commenters may have included in their burden estimate the time it takes to *research* and *generate* safety data for a new dietary ingredient. FDA believes, however, that the information being requested under § 190.6 should have already been established by the respondent, as required under section 413 of the FD&C Act, and thus the burden should reflect only the time necessary for *extract*ing and *summariz*ing that information. At the same time, FDA has communicated with the trade industry that we would like more detailed information on the specific burden associated with this collection and that we will continue to reevaluate our estimate accordingly.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 a NDI, or of a NDI, to submit to the Office of

Nutrition, Labeling, and Dietary Supplements 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 supplements that contain the NDI, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

We request an extension of OMB approval for the following information collection requirements contained in §190.6:

21 CFR 190.6 - Reporting

Requires submission of a pre-market notification at least 75 days before a NDI or a dietary supplement that contains a NDI can be introduced or delivered for introduction into interstate commerce.

2. Purpose and Use of the Information Collection

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of NDIs and dietary supplements that contain NDIs, in order to protect consumers from the introduction of unsafe dietary supplements into interstate commerce. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a NDI is in full compliance with the FD&C Act.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FDA continues to work on the development of an electronic form for submitting notifications. A draft of the form has undergone inner-agency review generating certain revisions and modifications, which FDA is currently undertaking. Upon its completion, the agency will submit the form for OMB review and approval and expects to do so within the next few months. Upon implementation of the electronic form, FDA estimates that approximately 50% of respondents will submit the information electronically.

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 the manufacturer or distributor is introducing or delivering for introduction into interstate commerce a NDI or a dietary supplement that contains a NDI. Therefore, the information being submitted to FDA will be original for each submission.

5. Impact on Small Businesses or Other Small Entities

FDA estimates 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. 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. The information is only collected if a manufacturer or distributor is introducing or delivering for introduction into interstate commerce a dietary supplement that contains a 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.

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 the Federal Register of August 26, 2013 (78 FR 52773), FDA published a 60-day notice (the August 26, 2013 notice) requesting public comment on the proposed extension of this collection of information. FDA received two letters in response to the notice, with one containing multiple comments. Some comments were outside the scope of the four collection of information topics on which the notice solicits comments and are therefore not discussed in this document.

One comment suggested providing drop-down menus to facilitate data entry. FDA appreciates this suggestion and will continue to consider various configurations for submitting information in electronic form that are most effective and efficient for respondents. Another comment stated that FDA's estimate of 20 hours per notification is not accurate. The comment indicated that 40-60 hours were required to extract and summarize relevant information from the

firm's files, and that an additional 20-40 hours was needed to format the information to meet NDI requirements. FDA deliberated over this comment, but believes that collecting and compiling data under applicable regulatory requirements for the premarket notification program places a minimal burden on respondents. As noted both in our August 26, 2013 notice and below in this document, §190.6(a) requires each manufacturer or distributor of an NDI, or dietary supplement containing an NDI, to submit notification of the basis for their conclusion that the supplement or ingredient will reasonably be expected to be safe. Because we are requesting only that information that the manufacturer or distributor should have already developed, we believe that 20 hours per submission is an appropriate burden estimate.

Both letters note that in the Federal Register of July 5, 2011 (76 FR 39111), FDA issued a draft guidance entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm) and suggested that FDA underestimated the reporting burden of the notification procedures under §190.6 because we failed to take into account the provisions of the draft guidance. FDA considered this response but submits that the notification procedure requirements set forth in its regulations at 21 CFR §190.6 remain unchanged. The collection of information in this instant analysis is exclusive of the draft guidance and pertains only to the subject regulations. However, as stated in the notice of availability for the draft guidance FDA does intend to publish a 60-day notice inviting comment on the information collection burden associated with that document and will carefully evaluate all comments it receives.

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

Pursuant to the provisions of §190.6(e) (21 CFR 190.6(e)), FDA will not disclose the existence of, or the information contained in, the NDI notification for 90 days after the filing date. After the 90th day, all the information in the notification will be placed on public display at FDA's Division of Dockets Management. However, any information that is trade secret or otherwise confidential commercial information will not be disclosed to the public. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

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 Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers. Respondents are from the private sector (for-profit businesses).

FDA estimates the burden of this collection of information as follows:

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 (in Hours)	Total Hours
190.6	55	1	55	20	1,100

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

As previously discussed, FDA believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because FDA is requesting only that information that the manufacturer or distributor should already have developed as the basis for its conclusion that a dietary supplement containing a NDI will reasonably be expected to be safe. Therefore, FDA estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413(a) of the FD&C Act and § 190.6 will require a burden of approximately 20 hours of work per submission.

The estimated number of premarket notifications and hours per response is based on FDA's experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications. We estimate that 55 respondents will submit 1 premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $84,194 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the request for certification would be equivalent to a GS-12/Step-3 level in the locality pay area of Washington-Baltimore in 2013, approximately $38.27/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $76.54/hour. Thus, the overall estimated cost incurred by the respondents is $84,194 (1,100 burden hours x $76.54/hr = $84,194).

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 collection.

14. Annualized Cost to the Federal Government

FDA estimates the staffing burden necessary to review and respond to the current volume of received NDI notifications to be 6 full-time employees (FTEs) at an average salary of GS-13, Step 5, in the Washington-Baltimore Locality Pay Area for 2013 (6.0 FTEs x $100,904 = $605,424), and approximately half the time of one supervisory employee at an average salary of GS-14, Step 5 (0.5 FTE x $119,238 = $59,619). Thus, the estimated cost to the Federal Government is approximately $694,853 ($605,424 + $59,619 = $665,043). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $1,330,086.

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

Pursuant to the provisions of §190.6(e), FDA will not disclose the existence of, or the information contained in, the NDI notification for 90 days after the filing date. After the 90th day, all the information in the notification will be placed on public display at FDA's Division of Dockets Management.

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

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.