Premarket Notification for a New Dietary Ingredient

0910-0330

SUPPORTING STATEMENT

Terms of Clearance: None.

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 an 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 an 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 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 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 an NDI or a dietary supplement that contains an 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 an 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

At the present time, FDA is not able to accept NDI notifications electronically. Thus, the agency estimates that none (0%) of the notifications will be submitted electronically in the 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 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 the agency 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 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.

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 June 3, 2011 (76 FR 32214), FDA published a 60-day notice (the June 3, 2011, notice) requesting public comment on the proposed extension of this collection of information. FDA received five letters in response to the notice, each containing multiple comments. Several comments were generally supportive of FDA's information collection provisions in § 190.6. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments, and will not be discussed in this document.

(Comment 1) FDA received several comments on the utility of the premarket notification procedures. Some comments stated that the information collection is necessary for the performance of FDA's functions and that the information will be of great practical utility to FDA in carrying out its role of protecting consumers from the introduction of unsafe dietary supplements into interstate commerce.

(Response) FDA agrees. As noted, section 413(a) of the FD&C Act requires a manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, to submit 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 implements this statutory provision, and is essential to protecting consumers from unsafe dietary supplements.

(Comment 2) Several comments argued that FDA underestimated the burden hours associated with complying with the provisions of § 190.6. One comment argued that FDA's estimate of 20 hours per notification is too low and stated that firms filing notifications require 100 to 350 hours to generate data to meet the requirements of an NDI notification. The comment argued that FDA did not fully consider the time needed to acquire the required information.

(Response) FDA disagrees. FDA appreciates the data provided in the comment. However, the Agency stands by its estimate of the paperwork burden resulting from § 190.6. As noted in the June 3, 2011, notice, § 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. The Agency believes that there is minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the Agency 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 an NDI will reasonably be expected to be safe. Therefore, the Agency 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.

(Comment 3) One comment argued that FDA's estimate of 20 hours per notification is too low and stated that FDA should use burden hour data from "successful" notifications only, indicating that the number of hours spent on notifications to which FDA does not object more accurately reflect the burden on industry.

(Response) FDA disagrees that the estimate of 20 hours per notification is too low for the reasons stated in response to Comment 2. In addition, the Agency does not regularly collect from those submitting notifications under § 190.6 information about the number of hours they spent preparing the notifications, whether "successful" or "unsuccessful." FDA appreciates the suggestion provided in the comment, however, and will consider doing so when it prepares its next regular information collection request for this collection.

(Comment 4) One comment argued that FDA's estimate that it will receive 55 premarket notifications annually is inaccurate and "deeply flawed."

(Response) FDA disagrees that the estimate of 55 notifications annually is inaccurate. As stated in the June 3, 2011, notice, the estimated number of premarket notifications is an average based on the Agency's experience with notifications received during the last 3 years. FDA received 77 notifications in 2008, 39 notifications in 2009, and 48 notifications in 2010, for an average of 55 notifications. The sum of 77 + 39 + 48 equals 164. Dividing that sum by 3 yields an average of 54.66, which has been rounded up to 55.

(Comment 5) Several comments argued that FDA incorrectly estimated that there are no capital costs associated with submitting premarket notifications under § 190.6. Comments argued that FDA did not fully consider that notifiers invest significant capital resources in hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles and obtaining legal review of NDI notifications.

(Response) FDA disagrees. The comment mischaracterizes the significant costs associated with hiring consultants, obtaining reference materials, and securing legal review of a notification as capital costs. For purposes of information collection requests under the PRA, capital costs are costs for equipment, machinery, and construction that, if not for FDA's request or requirement, the respondent would not incur. This includes buying new software and new computer equipment; monitoring, sampling, drilling and testing equipment; record storage facilities; the cost of purchasing or contracting out information collection services; and, postage costs to mail in a report. Capital costs do not include costs to achieve regulatory compliance with requirements not associated with the information collection. Hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles and obtaining legal review of NDI notifications are costs associated with developing information that the manufacturer or distributor uses to satisfy itself that a dietary supplement containing an NDI is in full compliance with section 413(a) of the FD&C Act; thus, these costs are not a capital cost because they are costs associated with achieving regulatory compliance with requirements of the FD&C Act, not costs associated specifically with filing a notification under § 190.6. FDA notes that it has added a reference to these costs as "Costs to Respondent" in section 12(b) of the supporting statement component of the information collection request that it has submitted to OMB.

(Comment 6) Several comment letters noted that on July 5, 2011, FDA issued a draft guidance entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (available at

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm). Some comments argued that FDA underestimated the burden of the notification procedures under § 190.6 because it failed to take into account the provisions of the new draft guidance.

(Response) FDA disagrees that we underestimated the burden of the notification procedures under § 190.6. The collection of information analysis in the June 3, 2011, notice was limited to the sole collection of information contained in § 190.6; that is, the regulation itself and not the provisions of the new draft guidance. The notification requirements set forth in § 190.6 remain unchanged. The notice of availability for the new draft guidance (76 FR 39111, July 5, 2011) states that FDA will estimate the paperwork burden of the draft guidance document and submit it for OMB review under the PRA in a future issue of the *Federal Register*. Comments on the new draft guidance and any information collection provisions therein are outside the scope of the comment request in the June 3, 2011, notice, and will not be discussed in this document.

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.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

As previously discussed, the Agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the Agency 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 an NDI will reasonably be expected to be safe. Therefore, the Agency 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 an average based on the Agency's experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications. FDA received 77 notifications in 2008, 39 notifications in 2009, and 48 notifications in 2010, for an average of 55 notifications. Accordingly, 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 2011, 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). Several comment letters filed in response to the June 3, 2011 *Federal Register* notice noted that firms experience costs associated with hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles and obtaining legal review of NDI notifications. The comments did not provide data supporting specific burden hours or hourly wage rates associated with consultants or legal reviewers. As a result, the agency will analyze these costs for possible inclusion in its next information collection request for this collection.

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 2011 (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 (0.75 FTE x $119,238 = $89,429). Thus, the estimated cost to the Federal Government is approximately $694,853 ($605,424 + $89,429 = $694,424). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $1,388,848

15. Explanation for Program Changes or Adjustments

FDA estimates that the total annual burden has decreased from 1,420 hours to 1,100 hours (a reduction of 320 hours). This adjustment is the result of decreasing the estimated number of respondents from 71 to 55, to better reflect the average number of notifications received by FDA in the last three years. There was also a corresponding decrease (adjustment), in the total annual responses from 71 to 55, a decrease of 16.

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.