Premarket Notification for a New Dietary Ingredient

OMB Control No. 0910-0330

SUPPORTING STATEMENT

Terms of Clearance: Previous terms of clearance remain in effect (see below). OMB notes that FDA intends to submit a revision to this package to allow for electronic collection "within months." Therefore, this package is approved for a period of one year.

Previous 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 with Regard to Electronic Submission: With this request, FDA is seeking OMB approval of an electronic submission method for this collection. FDA has developed an electronic portal that interested persons will be able to use to electronically submit their new dietary ingredient notifications (NDINs) via FDA's Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Draft screenshots of Form FDA 3880 and the supplemental safety information form were made available for comment at http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm.

Response with Regard to Burden Estimates: While preparing its previous OMB approval request a year ago, FDA considered comments it received regarding its burden estimate for this collection, but made no adjustments because the agency believed that comments criticizing the estimate were based on incorrect methodology. It appeared that the commenters were including in their burden estimate the time it takes to *research* and *generate* safety data for a new dietary ingredient (NDI), which would be incorrect because the information required for the notification under § 190.6 should have already been developed by the respondent to meet the separate safety requirement in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(a)(2)) (see explanation in section 12a, "Annualized Burden Estimate"). Thus, the burden estimate for the NDIN requirement should reflect only the time necessary for *extract*ing and *summariz*ing that information.

During the comment period for this request, one comment asserted that we underestimated the reporting burden of the NDIN procedures under §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 2011 draft guidance) (available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm). FDA announced the availability of the 2011 draft guidance for comment in a notice published in the Federal Register of July 5, 2011 (76 FR 39111). 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 when we publish a revised draft guidance that will supersede the 2011 draft guidance (see discussion in section 8, "Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency").

The purpose of the current PRA proceeding is to seek comment on and obtain OMB approval for the NDIN collections of information in effect during the interim period when no guidance on NDINs is in effect, which are those found in the FDA's NDIN regulations at 21 CFR §190.6 and in the electronic NDIN submission forms that we have made available for comment. After publishing a revised draft guidance on NDINs and related issues, we intend to publish a 60-day notice inviting comment on the proposed collections of information associated with that document. At that time, we will carefully evaluate all comments we receive.

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 (ONLDS) 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, 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 a pre-market notification to be submitted to FDA at least 75 days before a NDI or a dietary supplement that contains a NDI is 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 manufacturers and distributors in the dietary supplement industry: specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

With this request, FDA is seeking OMB approval of an electronic submission method for this collection. FDA has developed an electronic portal that interested persons will be able to use to electronically submit their notifications to ONLDS via FDA's Unified Registration and Listing System (FURLS). Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Draft screenshots of Form FDA 3880 and the supplemental safety information form were made available for comment at http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm. 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 required 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 NDI not found in the food supply or a dietary supplement that contains such 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 (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 the Federal Register of November 14, 2014 (79 FR 68275), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. We received three comments in response to the notice. Two of the comments were unrelated to the PRA, and therefore we did not consider them.

The third comment asserted that we underestimated the reporting burden of the NDIN procedures under §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 2011 draft guidance) (available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm). FDA announced the availability of the 2011 draft guidance for comment in a notice published in the Federal Register of July 5, 2011 (76 FR 39111).

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 2011 draft guidance was published solely for the purpose of seeking comment, and it has not been made final. Moreover, FDA intends to publish a revised draft guidance for comment later this year, and the revised draft guidance will supersede the 2011 draft guidance. Although we expect the revised draft guidance to be followed by a final guidance, there will be an interim period where no guidance on NDINs is in effect. The purpose of the current PRA proceeding is to seek comment on and obtain OMB approval for the NDIN collections of information in effect during this interim period, which are those found in the FDA's NDIN regulations at 21 CFR §190.6 and in the electronic NDIN submission forms that we have made available for comment. After publishing a revised draft guidance on NDINs and related issues, we intend to publish a 60-day notice inviting comment on the proposed collections

of information associated with that document. 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 confidential 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 confidential commercial information. Trade secrets and confidential 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).

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 manufacturers and distributors in the dietary supplement industry: specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient.

We estimate 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 operating and maintenance costs associated with this collection of information.

We believe that the burden of the premarket notification requirement on industry is limited and 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 a new dietary ingredient is in compliance with the FD&C Act. In the past, commenters have suggested that our burden estimate is too low. We carefully considered the issue and believe that burden estimates of greater than 20 hours per notification likely include the burden associated with researching and generating safety data for a new dietary ingredient. Under section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2)), a dietary supplement that

contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA's regulation on NDINs, § 190.6(a), requires the manufacturer or distributor of the dietary supplement, or of the new dietary ingredient, to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient 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. 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. However, we sought comments on this estimate in both the 60-day and 30-day notices, and we encouraged comments offering alternative burden estimates to include documentation to support the alternative estimate.

We further estimate that 55 respondents will submit one premarket notification each. We base our estimate of the number of respondents on notifications received over the past 3 years, which averaged about 55 notifications per year.

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 NDIN 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 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

We seek OMB approval of the proposed electronic submission method for this collection; in all other respects, the collection remains unchanged. Because we expect that submitting an NDI notification electronically will take the same or less time than submitting a notification on paper, our burden estimate is also unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

For the first 90 days after receiving an NDI notification, FDA keeps the notification confidential as required by 21 U.S.C. 350b(a) and 21 CFR 190.6(e). After the 90th day, FDA places the notification on public display at FDA's Division of Dockets Management, after redacting any trade secrets and confidential commercial information.

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.