PREMARKET NOTIFICATION FOR A NEW DIETARY INGREDIENT

OMB No. 0910-0330

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the 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, a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit to FDA (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. Part 190 (21 CFR part 190) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, 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 new dietary ingredient, (3) a description of the dietary supplements that contain the new dietary ingredient, 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 a new dietary ingredient or a dietary supplement that contains a new dietary ingredient 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 new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology by firms. Companies are free to use whatever forms of information technology may best assist them in developing the notification.

4. Efforts to Identify Duplication and Use of Similar Information

The 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 new dietary ingredient or a dietary supplement containing such new dietary ingredient. Therefore, the information being submitted to the agency will be original for each submission.

5. Impact on Small Businesses or Other Small Entities

The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by this regulation. To exempt a small business would only hurt that business since it could not market a dietary ingredient or a dietary supplement containing such new dietary ingredient. The agency, however, does have an office of Small Manufacturers Assistance which may be contacted if help is needed.

6. Consequences of Collecting the Information Less Frequently

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 new dietary ingredient. 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 act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

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 March 26, 2008 (73 FR 16020). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Pursuant to the provisions of §190.6(e), FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date. After the 90th day, all the information in the notification will be placed on public display in docket number 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 of a sensitive nature.

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours		
190.6	71	1	71	20	1,420		

12. Estimates of Annualized Burden Hours and Costs

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

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

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 to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, 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 of the act 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 three years (i.e., 2005, 2006 and 2007), and information from firms that have submitted recent premarket notifications.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized cost to respondents for the hour burden associated with the requirements of this regulation to be approximately $50,637.20. This estimate is based upon an industry employee making a salary equivalent to a GS-12 step 3 level in the locality pay area of Washington-Baltimore at $35.66/hour in 2008 ($35.66/hr x 20 hrs x 71 respondents = $50,637.20).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

FDA estimates the staffing burden necessary to review and respond to the current volume of received notifications for new dietary ingredients to be 4.5 full-time employees (FTEs) at an average salary of GS-13, Step 5, in the Washington-Baltimore Locality Pay Area for 2008 (4.5 FTEs x $94,025 = $423,112.50), and approximately half the time of one supervisory employee at an average salary of GS-14, Step 5 (0.5 FTE x $111,104 = $55,552). Thus, the estimated cost to the Federal Government is approximately $478,664.50 ($423,112.50 + $55,552 = $478,664.50). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the Federal Government $957,329.

15. Explanation for Program Changes or Adjustments

There was no change in the burden estimate..

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection. Pursuant to the provisions of §190.6(e), FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date. After the 90th day, all the information in the notification will be placed on public display in docket number 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

No exceptions are requested.