

SUPPORTING STATEMENT

PRE-MARKET NOTIFICATION FOR A NEW DIETARY INGREDIENT

21 CFR Part 190.6

A. JUSTIFICATION

1. Circumstances That Make Collection of Information Necessary.

The Dietary Supplement Health and Education Act (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 413(a) (21 U.S.C. 350b(a)), which provides for the notification of the Secretary (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient (Attachment A). Section 413(a) of the act requires that this notification include any citation to published articles, which is the basis on which the manufacturer or distributor of the dietary supplement containing a new dietary ingredient, or of a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably to expected to be safe

FDA established § 190.6 (21 CFR 190.6) which provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413 of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or of a dietary supplement that contains a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonable be expected to be safe. (Attachment B).

We request the extension of the OMB approval for information collections contained in the following citation:

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 of Information Collection

The DSHEA required the reporting requirements that are the subject of this regulation. This information is used by the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient to inform FDA of the basis on which it has concluded that the dietary supplement containing such dietary

ingredient will reasonably be expected to be safe. FDA uses this information to determine whether there is any basis for concern about the marketing of the dietary supplement containing the new dietary ingredient.

3. Use of Improved Information Technology

The agency is not equipped to receive these submissions electronically, therefore, this reporting requirement will not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

4. Duplication

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. Small Business

The reporting requirements of this regulation are those mandated by the DSHEA and the agency has tentatively concluded that they will not be a burden to small businesses. However, FDA aids small businesses in dealing with its requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs within the agency.

6. Frequency of Reporting

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 Federal Food, Drug, and Cosmetic Act.

7. Special Circumstance of Information Collection

There are no special circumstances that would cause an information collection.

8. Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d), on Tuesday, February 9, 1999, in Volume 64, No.

26, page 6364, a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

9. Payment of Gifts

There has been no decision to provide any payment or gift to respondents.

10. Confidentiality Provided Respondents

The proposed regulation does not specify confidentiality. However, all information received by FDA is subject to the agency's regulations concerning confidentiality in 21 CFR 20.61.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Estimate of Burden

Burden Hours

FDA believes that there will be minimal burden on the industry to generate data to meet the requirements on the pre-market notification program, because FDA is requesting only that information that the manufacturer or distributor should already be developing to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, 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 of the act, will require a burden of approximately 20 hours of work per submission. The agency estimates the manufacturer or distributor will submit approximately 11 new premarket notification on new dietary ingredients a year. This estimate is based on the average number of pre-market notifications received by the agency in 1996, 1997, and 1998.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
190.6	11	1	11	20	220

Estimated Annualized Cost for the Burden Hours

The total estimated annualized hour burden costs for this collection is \$5,500. FDA

estimates that this pre-market notification will be prepared by an employee making \$25.00/hour or ($\$25.00/\text{hr} \times 20 \text{ hours} \times 11 \text{ respondents} = \$5,500$).

13. Cost to the Respondents

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

14. Cost to the Federal Government

The estimated cost to the federal government is approximately \$6343. This is based on the salaries of two (2) FTE's at GS-13-5 who spend an estimate of 0.05 man-years each or a total burden of 208 hours ($2 \text{ FTE} \times 63,431 \times 0.05\text{m-yr/FTE} = \6343).

15. Change in Burden

The total hour burden is increase from 120 to 220. This increase is due to an increase in the number of notifications being received by the agency. Based on the number of notifications received in 1995-1996, the agency estimated an average of 6 notifications per year. However, this total hour burden is being increased to 220 because the agency is estimating an average of 11 notifications per year based on the average number of notifications received during 1996, 1997 and 1998.

The estimated annualized cost for the burden hours was calculated in the previous supporting statement to be \$3,000 ($\$25.00/\text{hour} \times 20 \text{ hour} \times 6 \text{ notifications} = \$3,000$). Since the estimated number of notifications per year has been increased to 11, the estimated annualized cost for the burden hours is increased to \$5,500 ($\$25/\text{hr} \times 20 \text{ hour} \times 11 \text{ notifications} = \$5,500$).

16. Publication of Collected Information

The information from this collection will not be published.

17. Approval for Not displaying Expiration Date

No approval requested.

18. Exception to the Certification Statement; Item 19, OMB Form 83-I

No exception is requested to the certification statement identified in ITEM 19, "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-1.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.