SUPPORTING STATEMENT

PREMARKET NOTIFICATION FOR A NEW DIETARY INGREDIENT

21 CFR Section 190.6
0910-0330

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)). Section 413(a) of the act (Attachment A) provides that a manufacturer or distributor must notify the Secretary (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a new dietary ingredient or a dietary supplement containing it. This notification must include an explanation of the manufacturer's or distributor's basis for concluding that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe.

FDA established Federal regulations at 21 CFR §190.6 (Attachment B) that provide the details of the administrative procedures associated with a new dietary ingredient premarket notification. These regulations identify the type of information that must be submitted in a written notification in order to meet the requirements of section 413 of the act. This documentation must include copies of any published articles or other information the manufacturer or distributor cited in support of the determination that the new dietary ingredient or a dietary supplement containing it will reasonable be expected to be safe.

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.

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 March 19, 2002, in Volume 67, Number 53, page 12570, a 60-day notice for public comment (Attachment C) was published in the *Federal Register*. No comments were received.

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 premarket 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.

During the past three fiscal years, from October 1, 1999 through September 30, 2001, FDA received an average of 23 notifications per year from an average of 1 notification per submitting manufacture or distributor. In comparison, during the previous three fiscal years, from October 1, 1996 through September 30, 1998, FDA received an average of 11 notifications per year from an average of 1 notification per submitter. The annual average number of notifications FDA received during fiscal years 1999-2001 increased by 12 year (23 - 11 = 12). Because the premarket notification program for new dietary ingredients is relatively new, the agency anticipates that this upward trend in receiving more notifications will continue over the next three fiscal years, from October 1, 2001 through September 30, 2004. Therefore, FDA estimates that it will receive an annual average of 35 notifications (23 + 12 = 35) from an annual average of 1 notification per submitter during fiscal years 2002-2004.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Response	Hours per Response	Total Hours
190.6	35	1	35	20	700

Estimated Annualized Cost for the Burden Hours

The total estimated annualized hour burden costs for the collection of an annual average of 23 notifications over the last three fiscal years 1999-2001 was $11,500. This increased cost was due to a doubling of the total annual average number notifications industry submitted to FDA compared to the previous three fiscal years 1996-1998 (i.e., increased from 11 to 23). Therefore, the cost to industry to prepare the notifications during fiscal years 1999-2001 approximately doubled as well compared to the three earlier fiscal years 1996-1998 (i.e., increased from $5,500 to $11,500). The estimated costs during fiscal years 1996-1998 were 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 $25.00/hr in 1999 ($25.00/hr x 20 hrs x 23 respondents = $11,500).

The total estimated annualized hour burden costs for the collection of an anticipated annual average of 35 notifications over the next three fiscal years 2002-2004 is $19,929. 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 $28.47/hour in 2002 ($28.47/hr x 20 hrs x 35 respondents = $19,929).

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 $ 75,699/yr ($60, 046/yr + $15, 653/yr = $ 75,699/yr). This is based on the 2002 salaries of two (2) staff at the GS-13 step 5 level, one of whom spends an estimated 0.50 man-years and another who spends an estimated 0.30 man-years (0.50 FTE + 0.30 FTE = 0.80 FTE x $75,058/yr = $60, 046/yr) for a total burden of 1164 hrs/yr (2080 hrs/yr x 0.80 FTE = 1164hrs/yr); and two (2) staff at the GS-14 step 1 level, each of whom spends an estimated 0.10 man-years (0.10 FTE + 0.10 FTE = 0.20 FTE x $78, 265/yr = $15, 653/yr) for a total burden of 416 hrs/yr (2080 hrs/yr x 0.20 FTE = 416 hrs/yr).

An increase in the number of FDA staff involved with notifications is mainly due to two factors: an increase in the number of notifications the agency has received in the past and will likely receive in the next three fiscal years and an increase in the diversity of the types of new dietary ingredient substances that are the subject of premarket notifications. During the last three fiscal years, the notifications FDA received addressed more novel ingredients compared to earlier years. FDA anticipates that this trend will continue in fiscal years 2002-2004, and will include staff with specialized expertise to assist in the review of safety data submitted in the notifications. Typically, FDA=s review of a notification will involve staff from several disciplines, as appropriate, e.g., nutrition, pharmacy, chemistry, toxicology, medicine, microbiology, and botany.

15. Change in Burden

The total hourly burden for manufacturers or distributors increased from 220 during fiscal years 1996-1998 to 460 during fiscal years 1999-2001 due to a doubling of the number of notifications industry submitted to FDA. FDA estimates that the total hourly burden for manufactures or distributors over the next three fiscal years 2002-2004 will increase from 460 to 700, following a similar upward trend in the number of notifications industry is anticipated to submit to FDA.

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 830-I

No exception is requested to the certification statement identified in ITEM 19, "Certification for Paperwork Reduction Act Submissions" of OMB Form 830-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.