FOOD LABELING; NOTIFICATION PROCEDURES FOR STATEMENTS ON DIETARY SUPPLEMENTS
0910-0331

21 CFR Part 101.93

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 403(r)(6) (21 U.S.C. 343(r)(6)), which provides for the notification of the Secretary (and by delegation the Food and Drug Administration (FDA)) no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling (Attachment A).

Section § 101.93 (21 CFR 101.93) establishes procedures for submitting the required information. Section 101.93 requires submission of a notification to FDA no later than 30 days after first marketing a dietary supplement that bears a statement of nutritional support. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented (Attachment B).

We request the extension of OMB approval for the following collection of information requirement:

21 CFR 101.93 - Reporting

Requires submission of a notification to FDA no later than 30 days after first marketing a dietary supplement that bears a statement of nutritional support and that the notification be signed by a responsible individual who can certify the accuracy of the information presented.

2. Purpose of Information Collection

DSHEA requires the notifications that are the subject of this regulation. The notification alerts the FDA that a dietary supplement is being marketed that bears a nutritional support statement and provides to FDA the text of the nutritional support statement. FDA utilizes the information to ensure that statements of nutritional support made by dietary supplement manufacturers or distributors about their products comply with

section 403(r)(6) of the act. Moreover, the submission from the responsible firm is required by the act in order for the firm to be able to lawfully make a claim pursuant to 21 U.S.C. 343(r)(6) in its labeling.

3. Use of Improved Information Technology

The agency is not equipped to receive these submissions electronically at this time. Therefore, this information collection will not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. FDA is working diligently to develop the necessary technology infrastructure to enable it to accept these submissions electronically in the future. The agency has made progress toward completion of a Public Key Infrastructure (PKI) capable system that we expect to enable us to accept these submissions electronically. Accordingly, FDA has carefully evaluated the nature and regulatory significance of the submission, in particular the significant legal consequences attendant to the signing and submitting of the notification, and request that the agency be authorized to continue this information collection activity in non-electronic format.

The notification must be signed by a responsible person, and in signing the notice, that person is certifying that the information is accurate and that the firm is in possession of substantiation that the claim that is the subject of the notification is truthful and not misleading. The signatory of the notification is, therefore, assuming potential liability under 18 U.S.C. 1001. Moreover, if the person who signs the notification is, in fact, not a responsible person authorized by the firm to certify that the firm is in compliance with all applicable requirements of the Act, then the submission of a noncompliant notification may also exposure the firm and/or its products to liability under the act.

The notification carries legal implications for the firm and the signatory. Therefore, these documents carry significant risk of repudiation. For this reason, FDA believes that the significant legal consequences attendant to the signature warrant a level of authentication and signer non-repudiation that only digital signatures in a PKI model can currently provide. Because CFSAN lacks that model, but is working with other FDA units toward putting it in place, the agency believes that other forms of electronic submission that the agency might be able to accept present unacceptable risks that provide a basis to not accept these submissions electronically until an acceptable infrastructure is in place.

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 a dietary supplement bearing a nutritional support statement on its label or in its labeling is marketed. Therefore, the information being submitted to the agency will be original for each submission.

5. Small Business

The reporting requirements of this regulation are mandated by DSHEA and the agency has concluded that they will not be a burden to small businesses. However, FDA aids small businesses in dealing with it 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 of a dietary supplement is making a statement of nutritional support on its label or in its labeling. If the collection is not conducted or is conducted less frequently, the manufacturers of the dietary supplement making the statement of nutritional support will not be in compliance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

7. Special Circumstance of Information Collection

There are no special circumstances associated with this information collection.

8. Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d), on July 24, 2006 (71 FR 41818), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No timely comments were received.

9. Payment of Gifts

This information collection does not involve any payment or gift to respondents.

10. Confidentiality Provided Respondents

The 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

The total estimated hour burden associated with this collection is 1,875 hours annually. The agency believes that there will be minimal burden on industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary

supplements. FDA is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. FDA estimates that listing the information required by section 403 of the act, and presenting it in a format that will meet the procedures of § 101.93, will require a burden of approximately .75 hour per submission. The agency estimates that the manufacturers, packers, or distributors will submit approximately 2,500 notifications a year. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
101.93	2,500	1	2,500	.75	1,875

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

Estimated Annualized Cost for the Burden Hours.

The total estimated annualized hour burden costs for this collection is $51,563. FDA estimates that this notification will be prepared by an employee making $27.50/hour or ($27.50/hr x 0.75 hours x 2,500 notifications = $51,563).

13. Cost to the Respondents

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

14. Cost to the Federal Government

The estimated cost to the federal government is approximately $15,417. This is based on the salary of one (1) full-time employee (FTE) at GS-13, Step 1, in the Washington-Baltimore Locality Pay Area who spends an estimated 416 hours (416 hours x $37.06/hour = $15,417).

15. Change in Burden

The total estimated annual reporting burden is unchanged from the previous request.

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. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.