

OMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier G. Crowley

Food and Drug Administration

[Docket No. 2003N-0314]

**Agency Information Collection Activities; Submission for the Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910-0331)—Extension**

Section 403(r)(6) of the Federal Food, Drugs, and Cosmetics Act (the act) (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes the following: (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) the signature of a responsible individual who can certify the accuracy of the information presented, who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

*Description of Respondents:* Businesses or other forprofit organizations.

In the **Federal Register** of July 23, 2003 (68 FR 43533), FDA published a 60-day notice requesting public comment on the information collection provisions. One firm submitted a comment stating that it believed that the burden of making the required submission could be slightly reduced by enabling the electronic submission of the required information, perhaps submitted through the Agency's Web site. The comment also suggested that FDA consider amending its information requirements to provide that an electronic submission include a notifier-assigned reference number.

The Center for Food Safety and Applied Nutrition (CFSAN) is working with other FDA units toward developing the necessary technology infrastructure, namely a public key infrastructure (PKI)-capable system, to enable it to accept these submissions electronically in the future. The requirement for a PKI-capable system for these notifications derives, in part, from the certification requirement in § 101.93(a)(3) and the significant legal consequences attendant to it. CFSAN lacks a PKI-capable system, but is working with other FDA units toward putting it in place. In the meantime, 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.

With respect to the comment's request that FDA provide for the notifier to include a reference number in its submission, as we develop and implement an electronic submission system, we intend to consider what changes, if any, in the information required to be submitted is needed to ensure that the notification requirements and process meet the agency's needs and those of the regulated industry.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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

<sup>1</sup>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 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. The agency 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. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

Dated: OCT - 6 2003  
October 6, 2003.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

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*Blaine Lunley*