

SUPPORTING STATEMENT

Food Labeling; *Trans* Fatty Acids in Nutrition Labeling

OMB Number 0910-0515

A. JUSTIFICATION

1. Necessity of the Information Collection

Section 403(q) (21 U.S.C. 343 (q)) of the Federal Food, Drug, and Cosmetic Act (the act) (Attachment A) establishes the requirements for nutrition labeling of foods. In particular, §§ 403(q)(1)(A) and 403(q)(1)(B) require that the label or labeling of a food bear nutrition information on the amount of nutrients present in a product. Section 403(q)(2) of the act permits FDA to require information about nutrients not specified in § 403(q)(1) of the act if that additional information will assist consumers in maintaining healthy dietary practices. Section 403(q)(5)(F) of the act specifies the nutrition information that must be on the label or labeling of dietary supplements. Under these provisions of the act, FDA issued regulations in §101.9(c)(2) (21 CFR 101.9(c)(2)) (Attachment B) that require information on the amounts of fat and certain fatty acids in food product to be disclosed in the Nutrition Facts panel. Similarly, FDA issued regulations in §101.36(b) (21 CFR 101.36(b)) (Attachment C) that specify the nutrition information that must be on the label or labeling of dietary supplements. In particular, §§ 101.9(c)(2)(ii) and 101.36(b)(2) require that the amount of *trans* fatty acids present in a food, including dietary supplements, must be declared on the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

We request OMB approval for the following information collection requirements contained in §101.9 and §101.36:

21 CFR 101.9(c)(2)(ii) Third Party Disclosure

Requires the disclosure on the label or labeling of conventional food products of the amount of *trans* fatty acids contained in the product.

21 CFR 101.36(b)(2) Third Party Disclosure

Requires the disclosure on the label or labeling of dietary supplement products of the amount of *trans* fatty acids contained in the product.

2. How, by Whom, and for What Purpose Information is Used

The information relating to *trans* fatty acid content is used by the consumer to assist him/her in constructing a diet consistent with dietary guidelines for limiting saturated fat intake.

Scientific data links intake of *trans* fatty acids and saturated fats to cardiovascular disease.

3. Use of Improved Information Technology

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in determining the amount of *trans* fatty acids contained in the product and required to be disclosed on the product's label or labeling.

4. Identification of Duplication and Similar Information Already Available

No duplication of Federal regulations concerning the requirements for the labeling of food products is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to the labeling of foods as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

5. Small Business

The disclosure requirements of §§ 101.9 and 101.36 took effect on January 1, 2006 in accordance with the agency's announcement concerning the uniform compliance date for food labeling requirements. The time period between issuance of the final rule (July 11, 2003) and the effective date of the final rule (January 1, 2006) provided firms with lead time to revise their labeling and to dispose of their inventory of old labels. However, FDA understands that some businesses, including small businesses, may experience hardship in meeting the compliance date for *trans* fat labeling. The agency set forth certain factors it intends to consider, on a case-by-case basis, to exercise enforcement discretion on the January 1, 2006 effective date for *trans* fat labeling and the process businesses may use to request the agency's consideration for enforcement discretion on *trans* fat labeling requirements. Thus, the agency issued a guidance document for industry and FDA entitled, "Guidance for Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006" (<http://www.cfsan.fda.gov/~dms/transgu3.html>). Additionally, under §§101.9(j)(18) and 101.36(h)(2), small businesses may claim exemption from the requirements for all nutrition labeling, including the disclosure of information relating to *trans* fatty acids.

6. Consequences if Data Were Collected Less Frequently

There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. However, failure of a firm to comply with the requirements for disclosure of the information on labels or in the labeling of its food products may result in those products being misbranded under section 403 of the act, and the firm or products would be subject to regulatory action.

7. Special Circumstances

Not applicable.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on April 11, 2006 (71 FR 18338), a 60-day notice for public comment (Attachment C) was published in the Federal Register. One comment was received but was unrelated to the information collection.

9. Gifts

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

10. Confidentiality

Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

Burden Hours

FDA estimated the total annual hour burden for this collection to be 615,200, as follows:

ESTIMATED REPORTING BURDEN¹

21 CFR Section	Number of Respondents	Responses per Respondent	Total No. of Responses	Hours per Response	Total Hours	Operating Costs
101.9(c)(2)(ii) ²	10,490	27	278,100	2	556,200	\$155,200,000
101.36(b)(2) ²	910	32	29,500	2	59,000	\$16,500,000
Totals					615,200	\$171,700,000

¹ There are no capital or maintenance costs associated with this collection of information.

² The number of responses per respondent for this section varies greatly depending upon the size of the firm and the numbers and types of products marketed by the firm.

FDA believes that the burden associated with the disclosure of *trans* fatty acid information on labels or in labeling food and dietary supplement products is largely a one-time burden created by the need for firms to revise the labels for those existing products that contain *trans* fatty acids.

FDA estimated that there were approximately 10,490 firms producing food products and 910 firms producing dietary supplement products that, because they contain *trans* fatty acids, were affected by §§ 101.9 and 101.36 . The agency estimated that these firms needed to revise approximately 278,100 food labels and 29,500 dietary supplement labels, although only about 25% of these label changes would have to be made earlier than the firms planned. Because these firms were already disclosing information on total fat, saturated fat, and other significant nutrients on their product labels, based upon its knowledge of food and dietary supplement labeling, FDA estimated that firms would require less than 2 hours per product to comply with the nutrition labeling requirements of §§ 101.9 and 101.36 .

Estimated Annualized Cost for the Burden Hours

FDA estimated the approximate annualized cost to respondents for the hour burden associated with this regulation to be:

§101.9(c)(2)(ii)	\$ 155,200,000
§101.36(b)(2)	\$ 16,500,000
Total burden costs	\$ 171,700,000

13. Annual Cost Burden to Respondent

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

Under the provisions of §101.9(c)(2)(ii), FDA estimated operating costs for food products by combining the approximate cost of analysis (\$291 per product) and the approximate cost of revising labels earlier than planned for affected products (\$1,520 per label). The cost of changing labels varied across product groups because the type of package and label varies. This estimate was based on combining the costs estimated for changing product labels for different kinds of products. Based on these assumptions, the agency estimated the cost to respondents for the hour burden associated with changing food product label to be approximately \$155,200,000.

Under the provisions of §101.36(b)(2), FDA estimated operating costs for dietary supplement products by combining the approximate cost of analysis to determine the level of *trans* fatty acids in the affected products (\$291 per product) and the approximate cost of revising labels earlier than planned for those products (\$2,480 per label). Based on these assumptions, the agency estimated the cost to respondents for the hour burden associated with changing dietary supplement labels to be approximately \$16,500,000.

Combining these costs for foods and dietary supplements, FDA found that the requirements of this final rule resulted in total one-time operating costs of \$171,700,000. The agency expected that, within the two-year compliance date, firms were able to coordinate required labeling revisions for *trans* fatty acid disclosure with other planned labeling changes for their products.

FDA estimated that most labels required to include information relating to *trans* fatty acid would be revised within two years after the final rule was published, including the time needed for product reformulation to modify the *trans* fatty acid content. The agency expected that, after this initial revision, respondents were unlikely to make significant changes in labeling for *trans* fatty acids. Thus, in succeeding years, there would be a significant decrease in the number of respondents and product labels requiring revision with a corresponding decrease in annual burden hour cost.

14. Annualized Cost to the Federal Government

FDA estimated that the annualized cost to the Federal Government would be minimal. Any costs due to this labeling change would be absorbed by the agency as part of the overall cost of its programs for ensuring compliance with the requirements for nutrition labeling.

15. Changes of Adjustments in Burden

This is an extension of a previous collection. The estimated number of burden hours did not change.

16. Statistical Analysis, Publication Plans, and Schedule

Not Applicable

17. Approval Not to Display Expiration Date

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.