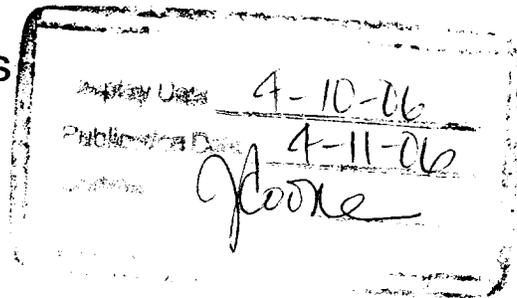


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0130]



**Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Trans Fatty Acids in Nutrition Labeling**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements of FDA's regulations requiring that trans fatty acids be declared in the Nutrition Facts panel of conventional foods and dietary supplements on a separate line without a percent Daily Value (%DV).

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Labeling; Trans Fatty Acids in Nutrition Labeling—21 CFR 101.9(c)(2)(ii) and 101.36(b)(2) (OMB Control Number 0910-0515)—Extension**

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)) establishes the requirements for nutrition labeling of foods. In particular, section 403(q)(1)(A) and (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 section 403(q)(1) 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)) that require information on the amounts of fat and certain fatty acids in food products to be disclosed in the Nutrition Facts panel. Similarly, FDA issued regulations in § 101.36(b) (21 CFR 101.36(b)) 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.

*Description of Respondents:* Persons and businesses, including small businesses.

FDA estimates the burden of 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	Total Operating Costs
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	\$155,200
101.36(b)(2)	910	32	29,500	2	59,000	\$16,500
Totals					615,200	\$171,700

<sup>1</sup>There are no capital costs or maintenance costs associated with this collection of information.

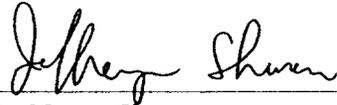
FDA believes that the burden associated with the disclosure of trans fatty acid information on labels or in labeling food and dietary supplement products is largely a one-time burden created by the need for firms to revise the labels for those existing products that contain trans fatty acids.

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 percent 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.

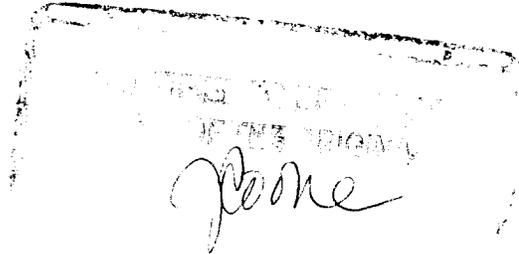
Multiplying the total number of responses by the hours per response gives the total hours. FDA estimated operating costs by combining testing and relabeling costs (\$44.9 million + \$126.8 million). This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expected that, with a compliance period of over 2 years, 75 percent of firms will

coordinate labeling revisions required by the trans fat final rule with other planned labeling changes for their products.

Dated: APR 03 2006  
April 3, 2006.



Jeffrey Shuren,  
Assistant Commissioner for Policy.



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