

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Starting Date	11-21-05
Publication Date	11-22-05
Author	J. Coome

[Docket No. 2005N-0343]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 proposed collection of information associated with the guidance document entitled "Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006." Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the Office of Management and Budget (OMB's) approval of this collection of information (OMB control number 0910-0571). Since this was an emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing this notice.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from 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.

Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006 (OMB Control Number 0910-0571)—Extension

This policy provides guidance to FDA and the food industry about when and how businesses may request the agency to consider enforcement discretion for the use of some or all existing label stock, that does not declare *trans* fat labeling in compliance with the final rule, on products introduced into interstate commerce on or after the January 1, 2006, effective date.

Industry Compliance With the *Trans* Fat Final Rule

FDA issued a final rule (the *trans* fat final rule) on July 11, 2003, (68 FR 41434) to require food labels to bear the gram (g) amount of *trans* fat without a percent Daily Value (% DV) directly under the saturated fat line on the Nutrition Facts panel (<http://www.cfsan.fda.gov/~acrobat/fr03711a.pdf>). The *trans* fat final rule affects almost all manufacturers of packaged, labeled food sold in the United States. FDA believes that most businesses, including small businesses, should not have difficulty meeting the January 1, 2006, effective date of the *trans* fat final rule. However, under certain circumstances some businesses may want to request that the agency consider an extension of time to use current labels that are not in compliance with the *trans* fat final rule. Therefore, the agency believes that it would be appropriate to consider, on a

case-by-case basis, whether to exercise enforcement discretion on the January 1, 2006, effective date for *trans* fat labeling for some businesses that can make an appropriate showing.

The agency intends to consider the following factors in any request from a firm for the agency's exercise of enforcement discretion:

- Whether products contain 0.5 g or less *trans* fat;
- The explanation of why the request is being made;
- The number of existing labels that the firm is requesting to use;
- The dollar amount associated with the number of existing labels to be used; and
- The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels the firm is requesting to use.

Requests may be considered at any time before or after the January 1, 2006, effective date of the *trans* fat final rule. Firms may submit their requests in writing to FDA's Center for Food Safety and Applied Nutrition. Firms are encouraged to keep this letter of request for their records and should make a copy available for inspection to any FDA officer or employee of who requests it. FDA intends to use the information in the letter to make decisions about whether a firm's product is subject to FDA's enforcement discretion for the *trans* fat labeling requirements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written requests to FDA in year one	56	1	56	5	280
Written requests to FDA in year two	28	1	28	5	140
Onetime burden hours for years one and two					420

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

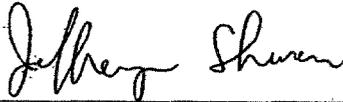
FDA estimates a 2-year time period during which these requests will be made following the issuance of this guidance. Beyond 2 years, FDA expects businesses to fully comply with the *trans* fat final rule, as it is unlikely that there will still be old labeling stock left to use.

FDA expects that, although all sizes of business are eligible, small businesses and very small businesses are the firms most likely to be able to demonstrate a need to request an extension to the *trans* fat labeling deadline. The agency has already received three requests from businesses regarding the *trans* fat labeling compliance date of January 1, 2006. Because small businesses are more likely to submit requests for extensions, and most of the affected businesses are small, we use the number of small businesses as the base to calculate the reporting burden. The regulatory flexibility analysis of the *trans* fat final rule estimated that 11,180 small businesses will have to revise the labels on their products as a result of the *trans* fat final rule. Given that only three businesses have submitted requests to FDA so far, FDA estimates that, in the first year following the issuance of the guidance, the total number of businesses that will request a labeling compliance extension from FDA can be estimated as approximately 0.5 percent of the number of small businesses, which equals 56.

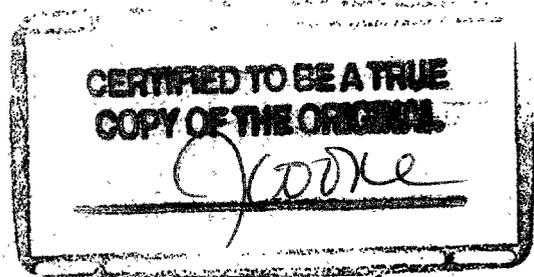
FDA estimates that it will take one employee approximately 4 hours to put together a request to FDA and approximately 1 hour for a supervisor to look over the request before submitting it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: **NOV 14 2005**
November 14, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S