

## Supporting Statement

### Guidance for Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006 0910-0571

#### A. Justification

##### 1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) issued a final rule on July 11, 2003 (68 FR 41434) to require food labels to bear the gram 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 amended 21 CFR 101.9 Nutrition Labeling of Food at § 101.9(c)(2). The effective date for the *trans* fat labeling final rule is January 1, 2006. However, FDA has been advised by some businesses that they may experience hardship in revising their labels in time to meet the compliance date for *trans* fat labeling. Therefore, the agency believes that it would be appropriate to consider, on a case-by-case basis, whether to exercise enforcement discretion with respect to the January 1, 2006 effective date for *trans* fat labeling for some businesses, so that these businesses would have the option of using some or all of their existing label stock that does not comply with the final rule upon an appropriate showing.

FDA intends to notify the public, in a level one guidance document issued pursuant to the Good Guidance Practices regulation, 21 CFR 10.115, of the factors it intends to consider in granting or denying such requests and the process businesses may use to request the agency's consideration for enforcement discretion on *trans* fat labeling requirements.

##### 2. How, by Whom, Purpose of Collection

After receiving OMB clearance under the Paperwork Reduction Act (PRA), FDA will announce the availability of a guidance entitled, "Guidance for Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006." The guidance will provide voluntary recommendations on the process for firms that wish to request an extension to use existing label stock after the effective date of the *trans* fat labeling final rule. This is a new information collection.

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 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.

Factors that the agency intends to consider in any request from a firm for the agency's exercise of enforcement discretion include:

- Whether products contain 0.5 gram 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. 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.

### **3. Consideration Given to Information Technology**

Companies are free to use whatever forms of information technology may best assist them in developing requests as proposed in this guide.

### **4. Identification of Duplicative Information**

As this is a guidance document, no firm is required by regulation to submit a request. There should be no duplicative information collection as a result of this guidance.

### **5. Small Businesses**

This guidance document is specifically tailored to help small businesses comply with the *trans* fat labeling rule in the most cost effective way.

### **6. Less Frequent Information Collection**

This guidance will only be used by those businesses that would experience financial hardship if they have to comply with the *trans* fat labeling final rule by January 1, 2006.

### **7. Information Collection Circumstances**

There are no special circumstances associated with this information collection.

### **8. Consultations with Persons Outside FDA**

FDA considered requests from businesses before the issuance of this guidance. The Federal Register Emergency Notice will solicit comments on this information collection.

9. **Payment or Gift**

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

10. **Confidentiality Provisions**

This information collection will only be used to assist businesses in complying with the *trans* fat labeling final rule.

11. **Privacy**

No information of a personally sensitive nature is expected to be received in any request from a firm.

12. **Burden of Information Collection**

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

Table 1--Estimated Annual Reporting Burden <sup>1</sup>					
Activity	No. of Requests	Annual Frequency of Requests	Total Annual Records	Hours per Record	Total Hours
Written requests to FDA in year 1	56	1	56	5	280
Written requests to FDA in year 2	28	1	28	5	140
One time burden hours for years one and two					420

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

FDA estimates a two year time period during which these requests will be made following the issuance of the guidance. Beyond two years time, FDA expects businesses to fully comply with the *trans* fat labeling 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 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 label on their products as a result of the *trans* fat final rule. Given that only 3 businesses have submitted requests to FDA thus far, FDA estimates that, in the first year following the issuance of this 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 four hours to put together a request to FDA and approximately one 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 five 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 is 280 hours.

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 five hours to complete each request, the total burden hours for year two will be 140 hours.

### **13. Cost to Respondents**

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

### **14. Annualized Cost to the Federal Government**

There are no annualized costs to the Federal Government as a result of this guidance.

### **15. Reason for Change**

This is a new collection.

### **16. Statistical Reporting**

The agency has no plans for publication of information from this information collection.

### **17. Display of OMB Approval Date**

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

### **18. Exceptions to “Certification for Paperwork Reduction Act Submissions”, of OMB Form 83-I**

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