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Guidance for Industry and FDA

**Requesting an Extension to Use Existing
Label Stock after the *Trans* Fat Labeling
Effective Date of January 1, 2006**

Final Guidance

Additional copies are available from:
Office of Nutritional Products, Labeling and Dietary Supplements, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

For questions regarding this guidance, please contact Julie Moss at (301) 436-2373.

<http://www.cfsan.fda.gov/guidance.html>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Issued December 2005**

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See additional PRA statement in Section IV of this guidance

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Guidance for Industry and FDA¹

Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006

This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

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

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in agency guidance documents means that something is suggested or recommended, but not required.

II. Background

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) on the Nutrition Facts panel (<http://www.cfsan.fda.gov/~acrobot/fr03711a.pdf>). The *trans* fat final rule

¹ This guidance has been prepared by Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, at the Food and Drug Administration (FDA).

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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, manufacturers are encouraged to voluntarily label *trans* fat before January 1, 2006. Any product that is initially introduced into interstate commerce on or after January 1, 2006 must be labeled with *trans* fat. Sources of *trans* fat include partially hydrogenated oil and some animal-based foods.

The *trans* fat final rule will affect most, but not all, packaged, labeled food products sold in the United States. For example, products that qualify for and use the simplified format (21 CFR 101.9(f)) and are not required to use the additional footnote statement (21 CFR 101.9(f)(4)) will not have to list the amount or presence of *trans* fat on the food label. In addition, under 21 CFR 101.9(j)(1)(i) and 101.36(h)(1), retailers with annual gross sales of not more than \$500,000 or with annual gross sales of foods to consumers of not more than \$50,000 and who place no nutrition claims or other nutrition information on product labels, or in labeling or advertising, are exempt from *trans* fat labeling requirements and the retailers are not required to file a notice with FDA. Further, under 21 CFR 101.9(j)(18) and 21 CFR 101.36(h)(2), nutrition labeling exemptions for low-volume products apply under certain circumstances. For example, if the person claiming the exemption employs fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a preceding 12-month period the product would be eligible for a labeling exemption for any 12-month period. For these exemptions, a notice must be filed annually with FDA.

FDA understands that some businesses may experience hardship in meeting the compliance date for *trans* fat labeling. FDA received a request for a stay of administrative action related to the *trans* fat labeling requirements from the International Dairy Foods Association (IDFA) and the International Ice Cream Association (IICA) (Docket No. 1994P-0036/PSA1) due, in part, to stated economic hardship on certain small manufacturers of ice cream and frozen dessert products. IDFA and IICA claimed that approximately 30 of such small firms had a much larger number of label changes (23-500 shelf-keeping-units (SKUs) per company) which resulted in costs that were significantly greater than what FDA provided in cost estimates for small businesses in its economic analysis for the *trans* fat final rule. In addition, the petitioners stated that the businesses had to create an unofficial database on the predicted value of *trans* fat content in milk and have been limited in their capacity to obtain information on *trans* fat content from ingredient suppliers, who were themselves reformulating the ingredients supplied to reduce or eliminate *trans* fat. These types of concerns may not be limited to manufacturers of ice cream and frozen dessert products.

FDA believes that most businesses, including small businesses, should not have difficulty meeting the January 1, 2006 effective date, but there may be certain circumstances under which some businesses may want to request the agency to 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. Therefore, the agency is setting forth certain factors it

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intends to consider for such requests and the process businesses may use to request the agency's consideration for enforcement discretion on *trans* fat labeling requirements.

III. Discussion

Requests for FDA to consider enforcement discretion for the use of some or all existing labels that do not comply with the *trans* fat labeling requirements will be handled on a case-by-case basis and at FDA's discretion. Requests may be considered at any time before or after the January 1, 2006 effective date of the final rule. The agency anticipates the time period during which firms would use existing labels to be no longer than 12 months beginning from the date that the agency issues a letter back to the firm.

The following are factors that the agency intends to consider in any request from a firm for the agency's exercise of enforcement discretion. To expedite FDA review, you are encouraged to provide a complete but concise explanation covering all the factors noted below.

1. Whether the declared label value for *trans* fat is 0.5 gram (g) or less per serving for each type of product identified (e.g., candy, canned vegetables, etc.);
2. An explanation of why the request is being made;
3. The number of existing labels for each type of product identified that the firm is requesting to use *and* for the total number of existing labels for all products identified that the firm is requesting to use;
4. The dollar amount associated with the number of existing labels to be used for each type of product identified *and* for all products identified; and
5. The estimate of the amount of time needed, not exceeding 12 months, to exhaust the number of existing labels for all products identified that the firm is requesting to use.

Firms may send a written request by either mail or e-mail (Extension.Trans@fda.hhs.gov) to:

Ms. Felicia B. Billingslea
Food and Drug Administration
5100 Paint Branch Pkwy. (HFS-820)
College Park, MD 20740

FDA intends to use the information in the request to make decisions about whether to consider enforcement discretion for the *trans* fat labeling requirements. FDA is aware that allowing enforcement discretion to use existing labels that do not include a *trans* fat amount could delay the public health benefits of the *trans* fat final rule. Therefore, to mitigate this potential delay in public health benefit, FDA is including, as a factor to consider for the use of enforcement discretion, whether the declared label value for *trans* fat is 0.5 g or less per serving. The agency believes that the short-term inability for consumers to compare foods that have 0.5 g or less *trans* fat would have less impact on public health than the inability to compare foods that have higher amounts of *trans* fat.

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FDA will respond in writing to each request. Firms are encouraged to keep this letter for their records and should make such copy available for inspection to any officer or employee of FDA who requests it.

You may want to consider an alternate means of compliance with the *trans* fat labeling requirements, such as the use of a sticker label to declare *trans* fat in the Nutrition Facts panel. FDA does not object to the use of a sticker label to allow firms to correct their labels, provided that the sticker adheres to the package under the intended storage conditions.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

The time required to complete this information collection is estimated to average five hours per request for extension, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0571 (expires 01/31/2006).