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Display Date	2-14-00
Publication Date	2-16-00
Certifier	JMU/UC/27

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P-0036]

RIN 0910-AB66

Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for the submission of comments and other related information regarding the proposed rule on *trans* fatty acids in nutrition labeling, nutrient content claims, and health claims. This proposed rule was announced in the **Federal Register** of November 17, 1999 (64 FR 62746). This action is being taken in response to requests for more time to submit comments to FDA.

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

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5587.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 1999 (64 FR 62746), FDA proposed to amend its regulations on nutrition labeling to require that the amount of *trans*

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fatty acids present in a food, including dietary supplements, be included in the amount and percent Daily Value declared for saturated fatty acids. FDA proposed that when *trans* fatty acids are present, the declaration of saturated fatty acids shall bear a symbol that refers to a footnote at the bottom of the nutrition label that states the number of grams (g) of *trans* fatty acids present in a serving of the product. FDA also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels, the amount of *trans* fatty acids be limited as well. In addition, the agency proposed to define the nutrient content claim “*trans* fat free.” The proposal responded, in part, to a citizen petition on *trans* fatty acids in food labeling from the Center for Science in the Public Interest. This action was taken to prevent misleading claims and to provide information to assist consumers in maintaining healthy dietary practices. Interested persons were given until February 15, 2000, to comment on the proposed rule.

The agency has received requests to reopen the comment period for the November 17, 1999, proposal to allow additional time for interested persons to comment.

National trade associations representing manufacturers, processors, retailers, and other industry groups assert that the complexity of the issue requires a thorough and thoughtful analysis to prepare meaningful comments. They believe that the comment deadline of February 15, 2000, does not provide the time necessary to accomplish this task. Also, industry reported that the comment period covered several major holidays and the critical Y2K period, in which many people had limited time or simply were not available to work on this important issue. The trade associations indicate they are currently gathering comments and surveying their members on the effect of the proposal and that many members are small businesses that do not have the resources to respond quickly. The trade associations assert that they and their members need time to: (1) Test their products to determine whether they contain 0.5 g *trans* fat per serving; (2) investigate appropriate analytical methods; (3) evaluate options such as product reformulation with alternative fat and oil sources; (4) review data bases and food product formulations; (5) review scientific evidence included and

omitted from the proposal; (6) review labeling options and the costs of label changes; (7) establish economic models and evaluate them; and (8) assess the implementation costs relative to the length of the implementation period.

Additionally, the trade associations believe that they need to determine the number of food products affected because they think that FDA's estimate is low. Also, they note that the agency's estimate of zero for discarding label and package inventory is based on a 2-year compliance period. They point out the compliance period could be closer to 1 year. Also, they state that trade associations must have time to resolve member differences to present a consensus position for the industry.

In its proposal, FDA tentatively concluded that the proposed action, if finalized, will have a significant impact on consumers ability to use the food label to maintain healthy dietary practices. The agency also acknowledged that the proposed rule is economically significant under Executive Order 12866 and would have a major economic impact under the Small Business Regulatory Enforcement and Fairness Act (Public Law 104-121). In addition, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that the proposed rule would be a major rule for the purpose of congressional review. It is therefore important that adequate time be allowed to appropriately address the many issues involved in this proposed rulemaking. Accordingly, the agency has decided to reopen the comment period on the November 17, 1999, proposal for 60 days in response to the requests.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by *[insert date 60 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit

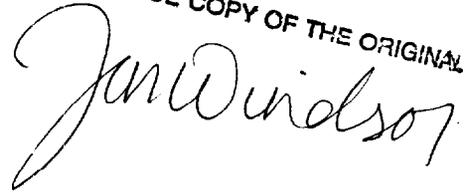
one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 2000



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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