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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 the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to *[insert date 30 days after date of publication in the Federal Register]*, the comment period for a proposed rule published in the **Federal Register** of November 17, 1999 (64 FR 62746), in which FDA proposed to amend its regulations on nutrition labeling to include the amount of *trans* fatty acids present in a food in the amount and percent Daily Value declared for saturated fatty acids. Since publication of the proposed rule, the National Academy of Sciences issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" that did not provide a dietary reference intake value for *trans* fat. In response to this report, FDA intends to take a more incremental approach and provide for mandatory declaration of *trans* fat content on a separate line within the Nutrition Facts panel. FDA is reopening the comment period to receive comment on a footnote statement that it is proposing be required on the label when *trans* fat is listed. Lastly, FDA is outlining conditions for when it would consider exercising

enforcement discretion for manufacturers who wish to begin labeling the *trans* fat content of food products prior to publication of a final rule.

DATES: Submit written or electronic comments on the proposed footnote by [*insert date 30 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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Joyce Saltsman, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1641.

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period

In the **Federal Register** of November 17, 1999 (64 FR 62746) (the November 1999 proposal), FDA (we) proposed to amend our regulations on nutrition labeling to require that the amount of *trans* fatty acids (*trans* fats) present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fatty acids. We also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure or disqualifying levels, the amount of *trans* fatty acids be limited as well. Finally, we proposed to define the nutrient content claim “*trans* fat free.” In that document, we requested comments on the proposal by February 15, 2000. In the **Federal Register** of February 16, 2000 (65 FR 7806), we reopened the comment period to April 17, 2000, in response to requests for more time to submit comments. In the **Federal Register**

of December 5, 2000 (65 FR 75887), we again reopened the comment period to January 19, 2001, in response to comments regarding nutrient content claims.

Subsequent to FDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) and found "a positive linear trend" between *trans* fatty acid intake and total and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of coronary heart disease (Ref. 1).

The report summarized that the scientific evidence would suggest a tolerable upper intake level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended "that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Likewise, the conclusions in the Dietary Guidelines for Americans, 2000 (Ref. 2) and recent guidelines from the National Cholesterol Education Program (NCEP) (Ref. 3) are similar with recommendations to limit *trans* fat intake in the diet.

The IOM/NAS report (Ref. 1) underscores the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasizes that consumers need to limit *trans* fat in their diets. FDA recognizes that, to accomplish this, information on the *trans* fat content of foods needs to be available on food labels. But the IOM/NAS report did not provide a dietary reference intake (DRI) value for *trans* fat or information that the agency believes

is sufficient to support its establishing a daily reference value (DRV) to assist the agency in providing other information on the label, such as a % DV for *trans* fat.

Comments to the November 1999 proposal stressed the importance of helping consumers understand the relevance of the quantitative amount of *trans* fat in relation to recommended dietary intake patterns. In addition, Section 2(b) of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535) states that the Secretary of Health and Human Services, and by delegation FDA, shall require the declaration of nutrients “be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” The % DV has been added to nutrition labeling for most nutrients to achieve this purpose. However, we do not have a basis on which to establish a DV for *trans* fat at this time. Therefore, in light of the public health recommendations to reduce *trans* fat intake in the American diet, FDA is proposing to require an asterisk (or other symbol) in the % DV column for *trans* fat when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box and that is followed by the statement “Intake of *trans* fat should be as low as possible.” In the absence of a % DV for *trans* fat, the footnote statement will provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. This statement is taken from the IOM/NAS macronutrient report and is consistent with the dietary guidance in the other recent scientific reports referenced in this document.

For interested parties who would like to submit comments on the proposed use of the footnote statement “Intake of *trans* fat should be as low

as possible,” we are reopening the comment period of the November 1999 proposal for a period of 30 days. Comments submitted during this period are to be limited to those that directly address the proposed use of the footnote. We are not requesting comments on any other issue, and we do not intend to consider such comments if submitted.

Following receipt of comments on this document, FDA intends to publish in early 2003 a final rule requiring mandatory declaration of *trans* fat content within the Nutrition Facts panel under the declaration for saturated fat, similar to the declarations of mono- and polyunsaturated fats. In response to interest expressed by manufacturers and trade associations to begin labeling the *trans* fat content of food products prior to publication of the final rule, we will consider the exercise of our enforcement discretion for such labeling as long as the footnote statement is also included in the Nutrition Facts panel. The agency cautions manufacturers that a final rule on this issue may differ from this proposal and that manufacturers would then be required to change their labels to conform to the final rule.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify all comments with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

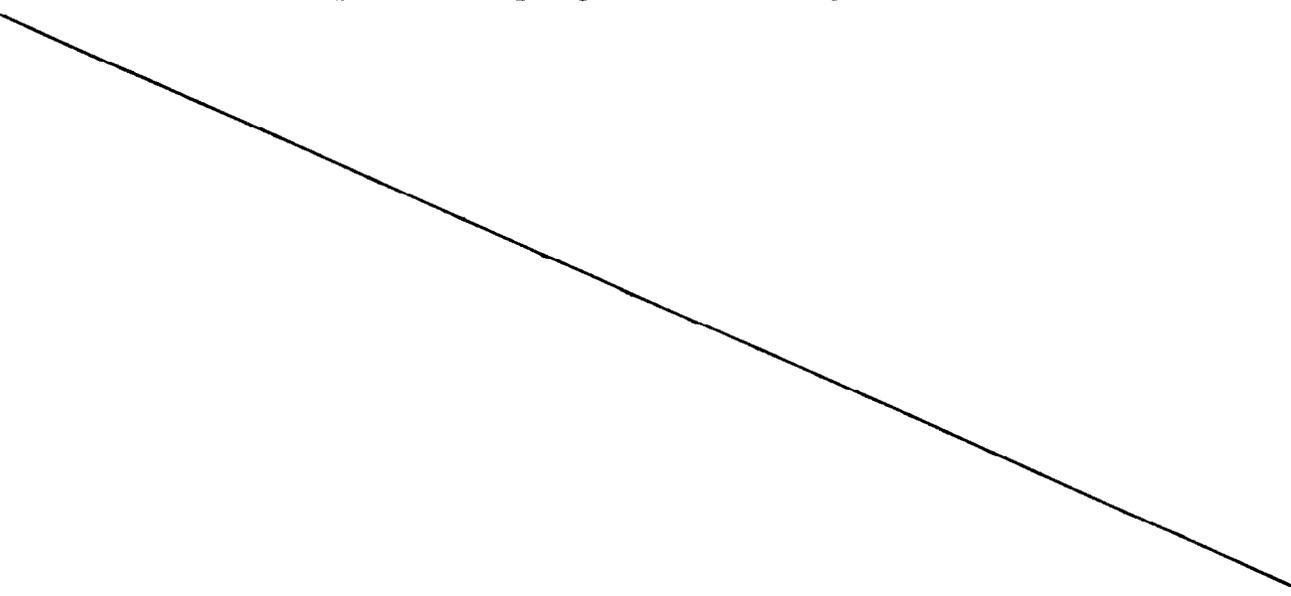
III. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the following three Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids," chapter 8, National Academy Press, Washington, DC, pp. 335–432, 2002 (Internet address: <http://www.nap.edu/books/0309085373/html/>).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans*, 5th ed. Washington, DC; Home and Garden Bulletin No. 232, pp. 27–31, 2000 (Internet address: <http://www.usda.gov/cnpp/Pubs/DG2000/Index.htm>).

3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Chapter II. "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL



Cholesterol and Reduce CHD Risk," 2001 (Internet address: <http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm>).

Dated: 11 | 8 | 02
November 8, 2002.



Margaret M. Dozel,
Associate Commissioner for Policy.

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