

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 101**

[Docket No. 03N-0076]

RIN 0910-AC50

**Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fatty acids (*trans* fat); to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fatty acids (saturated fat) and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The agency is also requesting comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices. Elsewhere in this issue of the **Federal Register**, FDA is amending its regulations on nutrition labeling to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line under the line for the declaration of saturated fat.

**DATES:** Submit written or electronic comments by October 9, 2003.**ADDRESSES:** Submit written or electronic comments to the Division of Dockets Management (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:** Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2373.**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of November 17, 1999 (64 FR 62746) (the November 1999 proposal), FDA (we) proposed, among other things, to: (1) Amend our regulations on nutrition labeling to require that the amount of *trans* fat present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fat with a footnote indicating the amount of *trans* fat in a serving of the product when the product contains 0.5 or more grams (g) per (/) serving, (2) establish a nutrient content claim for "*trans* fat free," and (3) revise existing nutrient content and health claims that have limits on levels of saturated fat to include a criterion for *trans* fat. In that proposal, FDA concluded that dietary *trans* fat, like saturated fat, has adverse effects on blood cholesterol measures that are predictive of coronary heart disease (CHD) risk (64 FR 62746 at 62754).

Comments received in response to the November 1999 proposal were very diverse. Many comments strongly opposed the inclusion of *trans* fat as part of the amount and % DV for saturated fat (see "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (the *trans* fat final regulation) found elsewhere in this issue of the **Federal Register**) and supported the declaration of *trans* fat on a separate line immediately under that for saturated fat. Comments relating to claims were equally diverse and indicated strongly opposing views. Comments objecting to proposed definitions for nutrient content claims were based on scientific, legal, and economic arguments with some comments stating that the agency was acting in advance of scientific justification. Moreover, comments encouraged the agency to wait for the soon-to-be published report on macronutrients by the Institute of

Medicine of the National Academy of Sciences (IOM/NAS) before finalizing the proposal. The comments explained that the IOM/NAS was expected to review the available science on *trans* fat and might establish a dietary reference intake (DRI) level from which FDA could establish a daily reference value (DRV) that would assist it in providing other information on the nutrition label, such as a % DV for *trans* fat.

In September of 2002, the IOM/NAS issued the report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) and found that, similar to saturated fat, there is "a positive linear trend" between *trans* fat intake and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of CHD (Ref. 1). Although the IOM/NAS macronutrient report recommended that the intake of *trans* fat be as low as possible while maintaining a nutritionally balanced diet, it did not provide a DRI for *trans* fat or information that the agency needs to establish a DRV for nutrition labeling purposes.

Dietary guidance for the general population similar to that in the IOM/NAS macronutrient report was included in the *Dietary Guidelines for Americans* (2000, 5th ed.) (Ref. 2), which recommended cutting back on saturated and *trans* fats when reducing total fat intake. Moreover, the National Cholesterol Education Program's Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults recommended that individuals at high risk for CHD keep their intake of *trans* fat low (Ref. 3).

In light of recommendations in the IOM/NAS macronutrient report, the agency published in the **Federal Register** of November 15, 2002 (67 FR 69171) a document reopening the comment period of the November 1999 proposal (November 2002 reopening of the comment period) to solicit comments on a proposed footnote statement that would be used in place of a % DV for *trans* fat on the nutrition label. In that document, the agency recognized the importance of providing information on the *trans* fat content of foods on food labels and set forth its thinking that the proposed footnote statement would provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. Thus, in the absence of a basis on which to establish a DV, the agency proposed to require an asterisk (or other symbol) in the % DV column for *trans* fat, when it is listed,