

# 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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids. This action responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI). This rule is intended to provide information to assist consumers in maintaining healthy dietary practices. Those sections of the proposed rule pertaining to the definition of nutrient content claims for the "free" level of *trans* fatty acids and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels are being withdrawn. Further, the agency is withdrawing the proposed requirement to include a footnote stating: "Intake of *trans* fat should be as low as possible." Issues related to the possible use of a footnote statement in conjunction with the *trans* fat label declaration or in the context of certain nutrient content and health claims that contain messages about cholesterol-raising fats in the diet are now the subject of an advance notice of proposed rulemaking (ANPRM) which is published elsewhere in this issue of the **Federal Register**.

**DATES:** This rule is effective January 1, 2006.

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#### I. Background

##### A. Nutrition Labeling

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101-535) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide, among other things, that certain nutrients and food components be included in nutrition labeling. Section 403(q)(2)(A) and (q)(2)(B) (21 U.S.C. 343(q)(2)(A) and (q)(2)(B)) of the act state that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) can, by regulation, add or delete nutrients included in the food label or labeling if he or she finds such action

necessary to assist consumers in maintaining healthy dietary practices.

In response to these provisions, in the **Federal Register** of November 27, 1991 (56 FR 60366), FDA published a proposed rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." In that document, the agency proposed to require that foods bear nutrition labeling listing certain nutrients and the amount of those nutrients in a serving of the food. Given the scientific knowledge about *trans* fatty acids at the time, FDA did not propose to require that *trans* fatty acids be listed. However, FDA requested comments on whether the listing of *trans* fatty acids should be voluntary (56 FR 60366 at 60371). (Note: throughout this preamble, FDA has used the term "*trans* fatty acids" and "*trans* fat" interchangeably; likewise, for the terms "saturated fatty acids," and "saturated fat").

In the **Federal Register** of January 6, 1993 (58 FR 2079), FDA issued a final rule implementing the 1990 amendments entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" that prescribes how nutrition labeling is to be provided on foods that are regulated by the agency. In that document, the agency required the declaration of total fat and saturated fat in the nutrition label, with the declaration of both monounsaturated fat and polyunsaturated fat (both defined as the *cis* isomers only) required, when claims are made about fatty acids and cholesterol. Based on its review of the comments, the agency stated that it was premature to include *trans* fatty acids in nutrition labeling because of a lack of agreement on the dietary implications of *trans* fatty acid intake. However, the agency acknowledged that it might be necessary to revisit the labeling of *trans* fatty acids in the future (58 FR 2079 at 2090-2092).

FDA received a citizen petition, dated February 14, 1994, from CSPI (docket number 94P-0036/CP1) stating that an increasing body of evidence suggests that dietary *trans* fatty acids raise blood cholesterol levels, thereby increasing the risk of coronary heart disease (CHD). The petitioner argued that the 1993 final rules implementing the 1990 amendments do not adequately reflect the effect of dietary *trans* fatty acids on CHD and that label values for saturated fat underestimate the total amount of "heart-unhealthy" fats because *trans* fatty acids are not declared. CSPI requested that FDA amend the definition of saturated fat in