

FDA disagrees with the comments that stated that mandatory labeling of *trans* fat is not warranted because average *trans* fat intake is minimal or because *trans* fat consumption is not a matter of public health risk at ordinary levels of intake. As described in section IV of this document, subjects in intervention studies showing that *trans* fat intake raises LDL-C levels had a wide range of *trans* fat intake levels, including levels that overlap the range of intake estimates for the U.S. population. The findings from intervention studies are supported by findings of a positive association between *trans* fat intake and increased CHD risk in the prospective observational studies, among free-living subjects consuming ordinary diets. Taken together, these studies demonstrate that *trans* fat consumption in the United States is a matter of public health concern at ordinary levels of intake.

FDA disagrees with the comments that suggested that the nutrition label would not be misleading if grams of *trans* fat were not listed, except where claims about fatty acids or cholesterol were made, monounsaturated fats and polyunsaturated fats were declared, or where *trans* fats were present at less than 2 g, 1g or 0.5 g per serving. The agency believes that the absence of information of the amount of *trans* fat in a product, when labeling of *trans* fat as a mandatory nutrient is required, even where *trans* fat is present at less than 0.5 g, would be misleading. The presence or absence of *trans* fat in a product is a material fact as to the consequences that may result from the use of the product. Consumers need to know when a product contains less than 0.5 g *trans* fat just as much as they need to know when a product contains 1, 2, or more grams of *trans* fat in order to understand how each product impacts their overall dietary intake of *trans* fat. Such need is not based solely on the presence or absence of claims, levels of other fats, or declaration of other fats on the label. Consumers need to understand how each product contributes to their overall intake of *trans* fat in order to maintain healthy dietary practices which call for reducing *trans* fat intake as low as possible while consuming a nutritionally adequate diet. Consumption of several foods, each with 0.5 to 1 g *trans* fat per serving, over the course of a day may result in a significant overall *trans* fat intake for the day. The association between the intake of *trans* fat over a range of intakes and the risk of CHD are discussed in section IV of this document. Because

low levels of *trans* fats may have significant impacts on increased CHD risk, there are important public health reasons for excluding foods high in *trans* fat intake and for including foods lower in *trans* fat intake. Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act. Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, is consistent with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of other information on the label. FDA also disagrees with the comments that stated that *trans* fat declaration would assist consumers in maintaining healthy dietary practices only under certain circumstances, such as when certain claims are made, when monounsaturated and polyunsaturated fats are declared on the label, when *trans* fat is present at greater than 0.5 g, 1 or 2 g per serving or when the food is not "low" in total fat (i.e., more than 3 g fat/reference amount). As described previously, consumers need information on both saturated and *trans* fats in individual food products so that they can follow current dietary recommendations and maintain optimal LDL levels. It is the provision of *trans* fat information on foods consumed throughout the day that can assist consumers in maintaining healthy dietary practices, and the usefulness of this information is not limited to foods with certain nutritional characteristics. In addition, the consumption of several foods with 0.5 or 1 g of *trans* fat per day that may provide a total of 8 g of *trans* fat to the diet would be expected to have the same effect on LDL-C levels as consumption of one food with 8 g *trans* fat. Requiring *trans* fat to be declared only when present at a specified level would be inconsistent with statutory

directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of the amount present.

Similarly, tying mandatory declaration of *trans* fat to the declaration of monounsaturated and polyunsaturated fats overlooks the difference in health effects of these fatty acids and the basic premise of section 403(q) of the act that requires the listing of nutrient information necessary to assist consumers in maintaining healthy dietary practices. Unlike information on *trans* fat, FDA has not determined that information on monounsaturated and polyunsaturated fat is necessary to assist consumers in maintaining healthy dietary practices. Accordingly, the declaration of those fatty acids is not mandatory. Rather, unless claims are made about fatty acids or cholesterol, the agency provides that their listing is voluntary (§ 101.9(c)(2)(ii), (c)(2)(iii), and (c)(3)), consistent with the authority in section 2(b)(1)(C) of the 1990 amendments that stipulates that regulations shall "permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section * * *."

Regarding the comment that consumers prefer simplicity and clarity in labels, FDA does not agree that providing a listing of the amount of *trans* fat on a label is not simple or clear nor did the comment provide any rationale for its assertion. Further, FDA does not agree that *trans* fat listing on a label would be "added verbiage" about an unfamiliar nutrient that likely will not benefit consumers. The comment presented no information to support its assertion. The addition of *trans* fat as a mandatory nutrient on a separate line will not significantly change the appearance of the nutrition information that consumers are already familiar with. Having consistent information about *trans* fat present on all food labels will facilitate consumer education efforts about *trans* fat, as discussed later in this document (see Comment 28).

FDA is not persuaded by the comment that it is not necessary to make *trans* fat labeling mandatory because, after an initial disclosure of *trans* fat by certain foods, additional foods would disclose *trans* fat due to competitive pressure (unfolding principle). Although some disclosure of *trans* fat under competitive pressure might occur, the overall extent of such voluntary disclosure is not certain. Before the 1990 amendments