

label space for the proposed footnote statement. One comment stated that the Nutrition Facts panel would no longer be simple and uncluttered and, as a result, consumers would be discouraged from reading the label. Other comments complained that the 30-day comment period for the November 2002 proposal was inadequate to address footnote issues and to conduct needed consumer research.

Many of the comments stated that FDA did not carry its burden under the first amendment. The comments argued that the proposed footnote statement fails to serve a substantial government interest in alleviating a genuine public harm, does not directly advance that interest and is not narrowly tailored. Several comments stated that the footnote statement is tantamount to a warning statement and is misleading.

Some comments stated that the use of the footnote statement would be establishing a new precedent by providing guidance, not just quantitative information on the Nutrition Facts panel. They argued that there were no consumer data to show that the footnote will help consumers understand the information. Comments stated that the agency had such data when it decided on the Nutrition Facts panel labeling format that only included quantitative information and should have consumer data here, where a new precedent is being considered.

Lastly, a few comments opposed FDA's offer to consider exercising our enforcement discretion to allow products to begin declaring *trans* fat and include the proposed footnote statement prior to publication of the final rule. One comment stated that the agency should publish a "clarification notice" to stop companies that are changing their labels now.

The agency is persuaded by comments that the statement it proposed may have unintended consequences. It was not FDA's intent to distract consumers from dietary guidance to minimize intake of saturated fat, but rather, in the absence of a DV for *trans* fat, to inform consumers of recommendations concerning its consumption.

While the online survey was small, its results support concerns expressed by the food industry that some consumers would interpret the footnote as a de facto DV of zero or as a warning statement that they should avoid all *trans* fat. The agency agrees with comments that this interpretation is inconsistent with dietary guidance given in the IOM/NAS report to keep intake of *trans* fat "as low as possible while consuming a nutritionally

adequate diet" (Ref. 140), as well as guidance in the Dietary Guidelines 2000 to cut back on saturated and *trans* fats when reducing total fat intake (Ref. 87) or in the 2001 NCEP report to keep the intake of *trans* fatty acids low (Ref. 89). FDA also agrees that these scientific reviews have similar dietary recommendations for the intake of saturated fat and cholesterol that are important for consumers to take into consideration when making decisions about heart-healthy dietary choices. The agency addressed only *trans* fat in the footnote statement, not because saturated fat or cholesterol had different recommendations or were less important, but because they have established DVs from which to determine the % DV for nutrition labeling purposes.

The agency agrees with comments that support consumer testing to ensure that information on the food label provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. FDA concludes, therefore, that based on arguments presented in the comments, that while the footnote would provide guidance on dietary recommendations for *trans* fat, it is premature to require the use of the proposed footnote statement in the nutrition label without further research. Consumer research would likely need to provide information on the impact of the statement in a footnote on consumers' food selections.

Accordingly, as a result of concerns expressed in the comments, asserting that consumers may place undue emphasis on *trans* fat information relative to other heart-unhealthy fats from the presence of the *trans* fat proposed footnote, the agency is not proceeding at this time to incorporate a requirement for a footnote statement in this final rule. Instead, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research on the use of a footnote and the language that may be used in a footnote to better reflect the dietary recommendations given in the previously-mentioned scientific reviews. The ANPRM will also solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and to establish disclosure and disqualifying criteria for *trans* fat.

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 consumer's understanding about cholesterol-raising lipids. In light of the need for consumer research to evaluate consumers' understanding of the totality of dietary recommendations that address the selection of foods for a heart-healthy diet, the agency notes in the ANPRM that it intends to conduct such research and looks forward to receiving additional research from other interested parties.

In the meantime, as noted in the preceding comment, FDA is issuing this final rule to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. To help consumers understand more about this heart-unhealthy fat, the agency plans to initiate consumer education programs about this final rule following publication (see Comment 28). As noted earlier, most comments that opposed the proposed footnote stated a belief that even in the absence of a DV, consumers can still find quantitative information useful, and pointed to current labeling of mono- and polyunsaturated fats. In light of previous research that shows that consumers often use information on the Nutrition Facts panel to compare levels of nutrients in two or more foods, FDA concludes that it is important to proceed to list the quantitative information on *trans* fat at this time so that consumers will have information to use in comparing products and making dietary selections to reduce their intake of *trans* fat. The agency believes a footnote or other labeling approach about saturated fat, cholesterol, and *trans* fat may provide additional assistance to convey the relative importance of each of these fats to consumers in a manner which enables them to understand their relative significance, to each other and in the context of a total daily diet. However, because of the public health impact of CHD in the United States and the additional time it will take to conduct the necessary consumer research, the agency concludes that it is essential to proceed at this time to mandate the listing of the quantitative information on *trans* fat so that consumers will be able to use that information to help maintain healthy dietary practices and to address an added footnote statement at a later time.

FDA acknowledges concerns, expressed in response to the November