

nutrient that is the subject of the claim. In proposing nutrient content claims, the agency stated that "With the exception of the term "sugar free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs" (56 FR 60421 at 60429, November 27, 1991). The approach of having an appropriate reference value for daily consumption provides a consistent and quantitative basis for defining claims. As stated in section V of this document, in the absence of the type of quantitative information from authoritative scientific groups on which the agency could support the establishment of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a %DV. The agency does not believe that the current level of scientific evidence supports the establishment of such a value for *trans* fat at this time. Many comments supported this position. As a result of the absence of an appropriate reference value for *trans* fat, the agency has been hampered in developing an integrated approach that responds to the issues raised in the comments.

Accordingly, the agency is withdrawing those sections of the November 1999 proposal pertaining to the establishment of a definition for "*trans* fat free," consideration of "reduced *trans* fat" and "reduced saturated and *trans* fat" claims and limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. FDA plans to continue to evaluate the evolving science and, when the science has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims, it will proceed to do so through a new rulemaking. FDA will seek to ensure that it acts consistent with its obligations under the first amendment to allow truthful and nonmisleading speech.

As discussed under comment 17, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment 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.

VII. Other Issues

(Comment 26) Several comments requested that FDA defer rulemaking on *trans* fat labeling until both FDA and USDA are able to concurrently take this action.

FDA consulted with USDA and both agencies agree that it is important that nutrition labeling rules for both agencies be consistent and that labeling of *trans* fat is necessary to assist consumers in maintaining healthy dietary practices. USDA is considering a similar policy for *trans* fat labeling based on the view that the approach to nutrition labeling should be consistent, but currently does not have a rulemaking on *trans* fat labeling on its regulatory agenda. Because *trans* fat levels are expected to be higher in foods regulated by FDA, as compared to foods under USDA jurisdiction, and because FDA has a citizen petition on the labeling of *trans* fat, FDA has determined that it is necessary to proceed with this final rule based on the public health interest. FDA notes that it is committed to cooperating with USDA, as needed, on *trans* fat labeling in any future action that USDA may consider.

(Comment 27) Some comments requested that *trans* fat not be used in restaurant food or its use be reduced.

These comments are outside the scope of this rule on the nutritional labeling of *trans* fat. This rulemaking is about *trans* fat labeling and not about whether or not *trans* fat is used in food generally or in particular food products. Although restaurant foods are not required to provide full nutrition labeling, they are required under § 101.10 (21 CFR 101.10), "Nutrition Labeling of Restaurant Foods," to provide information on nutrients that are relevant to any nutrient content claims made. Further guidance on labeling of restaurant foods may be found in "Questions and Answers Volume II, A Guide for Restaurants and Other Retail Establishments" (Ref. 111).

(Comment 28) A number of comments to the November 1999 proposal and the November 2002 notice reopening the comment period of the November 1999 proposal stated that there is a great need for consumer education about *trans* fatty acids and the nutrition label.

FDA agrees that consumer education will be needed as a result of this final rule so that consumers are better able to utilize the new *trans* fat labeling information to assist them in maintaining healthy dietary practices. Since the first edition of "Dietary Guidelines for Americans" in 1980 (Ref. 112), Americans have been advised to avoid too much saturated fat to reduce

the risk of heart disease. This message has also been a major factor in the National Cholesterol Education Program, which has been in existence since 1985 (<http://www.nhlbi.nih.gov/about/ncpe/index.htm>) that focuses on individuals at higher risk for CHD. Some success of these educational programs was demonstrated by the third National Health and Nutrition Examination Survey (Ref. 89) conducted during 1988–94, that showed that the public's intake of saturated fat has declined since the previous survey conducted from 1976–80 (Ref. 113). Also, the 1994–96 CSFII showed a decline in the public's intake of saturated fat since a previous survey conducted in 1989–91 (Ref. 142). Therefore, in introducing new messages about *trans* fatty acids, FDA intends to work with existing public health programs to build upon the extensive work done by them to educate consumers about saturated fatty acids and cholesterol and their relationship to heart health.

The agency also plans to initiate a variety of outreach and consumer education programs about this final rule following publication. Electronic dissemination of this information will be provided at FDA's Web site and briefings will be provided to representatives of a variety of health professionals, government agencies, industry representatives, trade associations, and press and consumer groups so that they can communicate *trans* fat information to their constituencies. To assist in this effort, education and press materials will be developed to facilitate communication to consumers about changes they will see as *trans* fat is added to the nutrition label and how they can use that information in their efforts to maintain a healthy diet.

(Comment 29) A few comments suggested using color coding to help consumers quickly recognize unhealthy products, including those containing *trans* fat. One of the comments mentioned applying this technique to ingredient listing and another comment said that a graphic could show the proportion of saturated, *trans*, polyunsaturated, and monounsaturated fats. The latter comment noted that horizontal color bars were used quite successfully in the introduction of canola oil in the United States.

These comments are outside the scope of this final rule on the nutrition labeling of *trans* fatty acids. The agency notes that manufacturers are free to use color bars on the product label outside of the Nutrition Facts panel (i.e., the box), to illustrate the kinds of fatty acids