

hydrogenated” are not intended to describe the nutritional properties of the fat or oil. It explained that the purpose of the ingredient statement is to identify the ingredients in a food by listing the common or usual names of each ingredient (64 FR 62746 at 62762–62763).

Comments to the November 1999 proposal requested that the final rule define the nutrient content claim “reduced *trans* fat.” Other comments suggested a “reduced saturated fat” claim that would be defined as a reduction of saturated and *trans* fats combined. The agency considered these comments and determined that all interested parties should have an opportunity to comment on whether the final rule should define claims that address reduced levels of *trans* fat. Therefore, FDA reopened the comment period for the November 1999 proposal on December 5, 2000, for a period of 45 days (65 FR 75887) stating that it would consider only comments that addressed “reduced *trans* fat” and “reduced saturated and *trans* fat” claims.

Subsequent to FDA’s November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids” (the IOM/NAS macronutrient report) (Ref. 140) and found, similar to the effect of saturated fat, “a positive linear trend” between *trans* fatty acid intake and total and LDL-C concentrations, and therefore increased risk of CHD. Because *trans* fats are unavoidable in ordinary diets, the IOM/NAS report recommended that “*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.” Likewise, the conclusions in two other scientific reports, which became available subsequent to the November 1999 proposal, i.e., the Dietary Guidelines for Americans, 2000 (Ref. 88) and guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89), were similar with recommendations to limit *trans* fat intake in the diet. Although the IOM/NAS report (Ref. 140) underscored the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasized that consumers need to limit *trans* fat in their diets, it did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that FDA believes is sufficient to support the agency’s establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV, for *trans* fat.

In response to the recommendations of the new scientific reports to limit the intake of *trans* fat and to provide consumers with label information that may better assist them in understanding the quantitative declaration of *trans* fat in the context of a total daily diet, FDA reopened the comment period of the November 1999 proposal for a period of 30 days (67 FR 69171, November 15, 2002). In that document the agency proposed to require an asterisk (or other symbol) in the %DV column for *trans* fat, when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box that is followed by the statement “Intake of *trans* fat should be as low as possible.” The agency stated that the statement is taken from the IOM/NAS macronutrient report and is consistent with the dietary guidance in the other recent scientific reports identified in that document (67 FR 69171 at 69172).

In the November 15, 2002, **Federal Register** document to reopen the comment period the agency also stated that it would consider the exercise of its enforcement discretion for those manufacturers who wanted to begin labeling the *trans* fat content of food products prior to publication of the final rule (67 FR 69171 at 69172). The agency cautioned manufacturers that the *trans* fat final rule may differ from what was being proposed in the November 15, 2002, document to reopen the comment period and that manufacturers would then be required to change their labels to conform to the final rule.

### C. Comments

FDA received over 1,650 letters in response to the November 1999 proposal, over 45 letters in response to the December 5, 2000, notice reopening the comment period, and over 25 letters in response to the November 15, 2002, proposal and notice to reopen the comment period. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, academia, health care professionals, professional societies, city and State governments, other Federal agencies, and other countries. Some of the comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions and requested revisions. Some comments requested that the proposal be withdrawn or repropose. A few comments addressed issues outside the scope of the proposal and will not be discussed here. On September 18, 2001, the Office of Information and Regulatory Affairs

(OIRA), Office of Management and Budget, sent to the Secretary of the Health and Human Services (the Secretary) a letter requesting that the Secretary and FDA consider giving greater priority to the November 1999 proposal (Ref. 156) in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer’s risk of developing CHD. The estimated public health benefits from increased consumer awareness of *trans* fat content in foods that were described in FDA’s preliminary Regulatory Impact Analysis in the November 1999 proposal, and the subsequent evidence found in more recent studies, strongly support the interests of the Government to lower the incidence of and economic burden of CHD in the United States. This final rule summarizes the relevant comments that were received in response to the November 1999 proposal and provides the agency’s conclusions regarding the labeling of *trans* fat on the Nutrition Facts panel.

A summary of the relevant comments that pertain to nutrition labeling of *trans* fat, the agency’s responses to the comments, and a discussion of the agency’s conclusions follow.

## II. Highlights of the Final Rule

In this final rule and given the current state of scientific knowledge, FDA is requiring the mandatory declaration in the nutrition label of the amount of *trans* fatty acids present in foods, including dietary supplements. The declaration of this nutrient must be on a separate line immediately under the declaration for saturated fat but it will not include a %DV that is required for some of the other mandatory nutrients, such as saturated fat. In addition, the agency is withdrawing those sections of the proposed rule pertaining to the definition of nutrient content claims for “free” and for “reduced” levels of *trans* fatty acids, and 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. Further, the agency is withdrawing the proposed requirement to include a footnote stating: “Intake of *trans* fat should be as low as possible.”

The action the agency is taking in this final rule is based on its evaluation of comments received in response to the November 1999 proposal, the reopening of the comment period on November 15, 2002, and on scientific evidence that shows that consumption of *trans* fatty acids increases LDL-C, a primary risk factor for CHD. The scientific evidence includes current authoritative reports,