

June 25, 2003

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6-25-03

INSERTS TO THE TRANS FAT FINAL RULE
Other changes are noted in the document

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On September 18, 2001, the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, sent the Secretary of the Health and Human Services a letter requesting the Secretary and FDA to 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 supports 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.

(The Secretary)

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FDA is issuing an advance notice of proposed rulemaking (ANPRM) elsewhere in this issue of the Federal Register that will solicit comment and additional consumer research that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in certain nutrient content claims and health claims, and to establish disclosure and disqualifying criteria for *trans* fat. In addition, the ANPRM is soliciting comment 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.

def. in summary

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Consumers would have information on the amount of *trans* fat in a product, along with other information about the amount of saturated fat and cholesterol. Consumers could use information about all three fats, not just saturated fat and cholesterol, to incorporate nutrition education information about recommended contributions for all three fats to the diet when making healthier food choices.

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That said, mandating the disclosure of this information does not require FDA to find that *trans* fatty acids actually cause CHD. In mandating the disclosure of this

information, FDA need not meet the standard of proof required to establish causation in a private tort action (*Glastetter v. Novartis Pharmaceutical Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

“The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it is unfair to require an individual to pay for another’s tragedy unless it is shown that it is more likely than not that he caused it***.”

In re “Agent Orange” Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y.) 1984), *aff’d* 818 F. 2d 145 (2d. Cir. 1987). In making its decision, the agency follows “the preventive perspective that [] agencies adopt in order to reduce public exposure to harmful substances.” *Glastetter*, 252 F. 3d at 991, quoting *Hollander v. Sandoz Pharmaceuticals Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000). Accordingly, so long as we conclude that the consumer would reasonably expect this information to be disclosed and that it is scientifically justifiable to require its disclosure, we are justified in taking this action.

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Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information **that the agency can use to establish** an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence...

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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 above 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 ~~on possible footnote statements~~ 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. As noted above, 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.

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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} ~~above~~, **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.** 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. **INSERT 123-1 goes here.**

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FDA will seek to ensure that it acts consistent with its obligations under the first amendment to allow truthful and non-misleading speech. ✓

INSERT: p. 123-2 (new paragraph)

As discussed
✓ 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. ^

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However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. As described in the November 1999 proposal (64 FR 62746 at 62753), estimates of nutrient intakes based on food frequency data may be subject to systematic bias toward either over- or underestimation of intake, depending on the design of the food frequency questionnaire (Ref. 27). Available estimates of *trans* fat intake from food frequency questionnaires in observational studies are lower than estimates of *trans* fat intake from a national food consumption survey (Ref. 26), as summarized in the November 1999 proposal (64 FR 62746 at 62752 to 62753) and in Section IV of this document. Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S. population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in Section IV, food intake is generally under-reported in consumption surveys (Ref. 26). Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. **However, intake of *trans* fat from national consumption survey data is likely to underestimate actual intake to a lesser extent than does the lower reported intake of *trans* fat from food frequencies done in observation studies.** Additionally, intake of

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trans fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

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The additional 0.0019 percent of energy represents 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation (1.964 percent - 0.0359 percent = 1.928 percent; 0.1 percent x 1.928 percent = 0.0019 percent).

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of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at \$14.73 per hour) and delivery charges for one two-pound package delivered overnight (at \$26.30). **The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible.** The model reports a range of testing costs for *trans* fat given in table 4.

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In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of \$30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. **Based on information in the model, three-quarters of the labels normally will be scheduled to be changed during the 30 month compliance period.** FDA estimates that **about 78,000 (25 percent) of the almost 308,000 SKUs will have to be changed earlier than would have been planned without this rule.** Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing

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and engraving, and the lost value of discarded labels. Across product categories, the average low relabeling cost per SKU is about **\$1,100** and the average high relabeling cost per SKU is **\$2,600**. The reported estimated costs

of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows **the total SKUs changed earlier than planned and** the total estimated costs of relabeling per product category and for the entire industry.

TABLE 5. RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	12,500	\$10,941,000	\$16,137,000	\$27,231,000
Baking Ingredients	1,700	\$1,615,000	\$2,380,000	\$3,899,000
Baby Foods	200	\$164,000	\$249,000	\$404,000
Selected Beverages	9,000	\$11,871,000	\$16,659,000	\$25,437,000
Breakfast Foods	1,000	\$801,000	\$1,237,000	\$2,044,000
Selected Candy	4,100	\$4,801,000	\$6,974,000	\$10,846,000
Selected Condiments, Dips and Spreads	3,700	\$4,026,000	\$5,970,000	\$9,283,000
Dairy Foods	8,700	\$10,744,000	\$16,025,000	\$25,032,000
Desserts	3,500	\$2,762,000	\$4,263,000	\$7,042,000
Dietary Supplements	8,100	\$13,449,000	\$20,110,000	\$34,041,000
Selected Dressings and Sauces	2,800	\$2,908,000	\$4,352,000	\$6,757,000
Eggs	2,400	\$1,983,000	\$2,896,000	\$5,086,000
Entrees	2,400	\$2,012,000	\$3,078,000	\$5,032,000
Fats and Oils	800	\$759,000	\$1,160,000	\$1,848,000
Fruits and Vegetables	7,500	\$7,426,000	\$10,915,000	\$17,882,000
Seafood	1,400	\$1,732,000	\$2,541,000	\$3,786,000
Side Dishes and Starches	4,100	\$3,361,000	\$5,124,000	\$8,494,000
Snack Foods	3,600	\$3,604,000	\$5,288,000	\$8,499,000
Soups	700	\$809,000	\$1,194,000	\$1,854,000
Weight Control Foods	200	\$196,000	\$283,000	\$489,000
Total	78,400	\$85,964,000	\$126,835,000	\$204,986,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are

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As mentioned previously, based on comments, FDA estimates that 15 percent of margarine products have already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are

already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of trans fat. The different ingredients used in the products appear to have had no impact on the cost of production. As greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. **However, given that increases in costs of inputs, if any, have not been passed on with a change in 15 percent of margarine products, it seems quite reasonable that an additional smaller change (10 percent) will not result in significant increases in ingredient costs.**

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Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that the products that will be reformulated contain average amounts of *trans* fat, so the fraction of margarine products reformulated will equal the fraction of *trans* fat removed from margarine. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule, [start p. 166] FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only 300 margarine products. **The new data ^{was} used to estimate that 30** margarine products ~~that~~ will reformulate as the result of this rule (10 percent of 300). Table 6 shows the cost of margarine reformulation.

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TABLE 6.—COST OF MARGARINE REFORMULATION

Cost of Reformulating per Product	\$440,000
Products Reformulating	30
Total Cost	\$13,200,000

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Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	\$40,298,000	\$44,930,000	\$59,282,000

Relabeling	\$85,964,000	\$126,835,000	\$204,986,000
Reformulation	\$13,200,000	\$13,200,000	\$13,200,000
Total	\$139,000,000	\$185,000,000	\$275,000,000

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because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits. **The rule may generate other benefits, but we do not quantify them. For example, consumers who are aware of the risks associated with *trans* fat will more readily find information on the *trans* fat content of various foods. The value of the reduction in search time for those consumers is an additional benefit of this final rule.**

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Insert for Page 170, preceding the paragraph before table 8:

As described in the November 1999 proposal (64 FR 62746 at 62768 and 62769), the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) were based on 5 intervention studies that made, in total, 6 dietary comparisons between consumption of *trans* fat and cis-unsaturated fat (Refs. 7, 8, and 11 through 13). The regression equation for LDL-C showed that each additional percent of energy from *trans* fat was predicted to increase LDL-C by 1.5 mg/deciliter (dL) (0.040 millimol/liter) ($R^2 = 0.86$, $p = 0.0028$) when substituted for the same percent of energy from cis-monounsaturated fat, holding total energy intake constant. The regression equation for HDL-C showed that each additional percent of energy from *trans* fat was predicted to decrease HDL-C by 0.4 mg/dL (0.013 millimol/liter) ($R^2 = 0.88$, $p = 0.0019$), when substituted for the same percent of energy from cis-monounsaturated fat. The regression lines were forced through the origin because a zero change in intake will produce a zero change in lipoprotein concentrations (Refs. 62, 69, and 154). In carrying out the regression, differences between diets in fatty acids other

than *trans* fat and cis-monounsaturated fat were adjusted for by using regression coefficients from a previous meta-analysis of 27 intervention studies (Ref. 65).

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Revision for Page 170, rewording and expanding the last paragraph on P 170, the paragraph before table 8:

Sample calculations using Method 1 and Method 2 are summarized in Table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk. **To estimate the change in CHD risk with change in *trans* fat intake, for each type of serum lipid, LDL-C and HDL-C, we multiplied the change in *trans* fat intake by three factors, representing 1) the change in serum lipid with change in *trans* fat intake, 2) the change in CHD risk with change in serum lipid, and 3) an adjustment for regression dilution. Table 8 shows that, for Method 1, based on changes in LDL-C, replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-monounsaturated fat would decrease CHD risk by 0.147 percent (-0.1 percent of energy from *trans* fat x 1.5 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.147 percent change in CHD risk). Based on changes in HDL-C, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.140 percent (-0.1 percent of energy from *trans* fat x -0.4 mg HDL-C/dL per percent of energy from *trans* fat x -2.5 percent change in CHD risk per mg HDL-C/dL x 1.4 adjustment factor for regression dilution = -0.140 change in CHD risk based on changes in HDL-C). For Method 2, based on changes in both LDL-C and HDL-C, the decrease in CHD risk would be 0.287 percent (-0.147 percent based on LDL-C plus -0.140 percent based on HDL-C = -0.287 percent based on LDL-C + HDL-C). FDA used these estimation methods to project the decrease in CHD risk in the November 1999 proposal (64 FR 62746 at 62767).**

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Revision and expansion of Table 9 and accompanying revisions for text on Page 171, paragraph between Table 8 and Table 9.

The first four columns of data show the factors for substitution of *trans* fat for 100 percent of individual types of fatty acids or carbohydrate. We project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. By combining the factors in the first four data columns, we obtained the factors for substitution of *trans* fat for combinations of different fatty acids and carbohydrate, shown in the last three data columns.

We generated the factors in Table 9 by combining the results of two sets of

metaanalyses. Table 9 shows the result of linking 1) the regression equation coefficients of Katan et al (Ref. 62) and Zock et al (Ref. 69), for substitution of *trans* fat for cis-monounsaturated fat and 2) the regression equation coefficients of Mensink and Katan (Ref. 65), for substitution of saturated and cis-unsaturated fat for carbohydrate. The regression equations of Mensink and Katan (Ref. 65) were based on 27 intervention studies that made dietary comparisons for consumption of carbohydrate, saturated fat, cis-polyunsaturated fat and cis-monounsaturated fat. The regression equation for LDL-C included 57 dietary comparison data points from 24 studies, and showed that, holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase LDL-C by 1.28 mg/dL (0.033 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to lower LDL-C by 0.24 mg/dL (0.006 millimol/liter) ($p = 0.114$) and each additional percent of energy from cis-polyunsaturated fat was predicted to lower LDL-C by 0.55 mg/dL (0.014 millimol/liter) ($p = 0.002$). The regression equation for HDL-C included 59 dietary comparison data points from 25 studies, and showed that holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase HDL-C by 0.47 mg/dL (0.012 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to increase HDL-C by 0.34 mg/dL (0.009 millimol/liter) ($p < 0.001$) and each additional percent of energy from cis-polyunsaturated fat was predicted to increase HDL-C by 0.28 mg/dL (0.007 millimol/liter) ($p = 0.002$).

Comparison with the observed data showed that the predicted regression lines explained 64 percent of the variation in changes in LDL-C and 88 percent of the variation in changes in HDL-C. The coefficients of Mensink and Katan (Ref. 65) are expressed as substitution of each type of macronutrient for carbohydrate, but the coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) are expressed as substitution of *trans* fat for cis-monounsaturated fat. For comparability with the coefficients for *trans* fat, we expressed the coefficients of Mensink and Katan in terms of substitution of each type of macronutrient for cis-monounsaturated fat. As stated in the November 1999 proposal (64 FR 62746 at 62769), when substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised LDL-C by 1.52 mg/dL, cis-polyunsaturated fat lowered LDL-C by 0.31 mg/dL, and carbohydrate raised LDL-C by 0.24 mg/dL. When substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised HDL-C by 0.13 mg/dL, cis-polyunsaturated fat lowered HDL-C by 0.06 mg/dL, and carbohydrate lowered HDL-C by 0.34 mg/dL. We then combined these coefficients with the coefficients for *trans* fat, to obtain the changes in lipoprotein levels with *trans* fat substituted for different macronutrients, as shown in Table 9.

Table 9 also gives examples of changes in CHD risk with replacement of 0.1 percent of energy from *trans* fat by different macronutrients and combinations of macronutrients. Table 8 shows the general method and illustrates the calculation of estimated changes in CHD risk with replacement of *trans* fat by cis-monounsaturated fat. To account for each type of macronutrient substitution, we used the corresponding factors from Table 9 for

changes in serum lipids. For example, for cis-polyunsaturated fat, Table 9 gives the factor, 1.81 mg LDL-C/dL, for replacement of 1 percent of energy from cis-polyunsaturated fat by *trans* fat. For Method 1, based on changes in LDL-C, the replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-polyunsaturated fat would decrease CHD risk by 0.177 percent (-0.1 percent of energy from *trans* fat x 1.81 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.177 percent change in CHD risk). As noted above, we project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. The changes in CHD risk associated with specific combinations of fatty acids or carbohydrate are shown in the last three data columns. The first four data columns show the change in CHD risk associated with each individual type of fatty acid and carbohydrate. The column showing *trans* fat replaced by 100 percent saturated fat is included in Table 9 for completeness in illustrating the data and methods we used to estimate changes in CHD risk with different macronutrient substitutions. The inclusion of this column does not indicate that FDA projects that *trans* fat will be replaced by 100 percent saturated fat, or that FDA would encourage such an inappropriate substitution. Rather, the substitutions for *trans* fat that FDA considers most likely are shown later, in Table 10.

As mentioned earlier, and in the November 1999 proposal (64 FR 62746 at 62769), the economic analysis used changes in both LDL-C and HDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C. To allow readers to reproduce all of our estimated changes in CHD risk, Table 9 shows changes in CHD risk based on Method 2, LDL-C and HDL-C, as well as Method 1, LDL-C. In addition, the column that shows a decrease in CHD due to a 100 percent replacement of *trans* fat for saturated fat represents the relationship between HDL-C and CHD, a relationship that is more uncertain than the causal relationship between LDL-C and CHD. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771-62773).

INSERT: p. 172-1 (table 9)

Table 9. Summary of changes in serum lipids and CHD risk with different macronutrient substitutions

A. Change in serum lipids with substitution of *trans* fatty acids for different types of fatty acids or carbohydrate

Macronutrient	<i>cis</i> -Monounsaturated fatty acid	<i>cis</i> -Polyunsaturated fatty acid	Saturated fatty acid	Carbohydrate	Half <i>cis</i> -monounsaturated and half <i>cis</i> -polyunsaturated	Half <i>cis</i> -monounsaturated and half saturated	Half <i>cis</i> -monounsaturated and half carbohydrate
Change in serum lipid when replaced by <i>trans</i> fat	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. Change in CHD risk with replacement of *trans* fatty acids by different types of fatty acids or carbohydrate

Macronutrient	<i>cis</i> -Monounsaturated fatty acid	<i>cis</i> -Polyunsaturated fatty acid	Saturated fatty acid	Carbohydrate	Half <i>cis</i> -monounsaturated and half <i>cis</i> -polyunsaturated	Half <i>cis</i> -monounsaturated and half saturated	Half <i>cis</i> -monounsaturated and half carbohydrate
Change in CHD risk with replacement of <i>trans</i> fat	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy
Method 1, LDL	-0.147	-0.177	0.002	-0.123	-0.162	-0.073	-0.135
HDL	-0.140	-0.119	-0.186	-0.021	-0.130	-0.163	-0.081
Method 2, LDL + HDL	-0.287	-0.296	-0.184	-0.144	-0.292	-0.235	-0.216

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A meta-analysis of the relative risk of CHD associated with *trans* fat intake was recently published (Ref. 102). The meta-analysis used the results of prospective observational studies in four cohorts: women in the U.S., men in the U.S., men in Finland, and men in the Netherlands. The results showed a pooled variance-weighted relative risk of 1.25 (95 percent confidence interval 1.11 to 1.40) for CHD associated with 2 percent of energy intake from *trans* fat. For 0.1 percent of energy intake from *trans* fat, the meta-analysis results would predict a relative risk of 1.0112 (confidence interval 1.0052 to 1.0170). That is, for 0.1 percent of energy intake from *trans* fat, the increase in CHD risk would be 1.12 percent (confidence interval 0.52 to 1.70 percent). In comparison, the largest change in CHD risk shown in Table 9, associated with 0.1 percent of energy intake from *trans* fat, is 0.162 percent using Method 1 and 0.292 percent using Method 2. Thus, the increase in CHD risk for 0.1 percent of energy intake from *trans* fat based on a meta-analysis of prospective studies is larger than the associated CHD risk estimated using either Method 1, LDL-C or Method 2, LDL-C and HDL-C. (The calculation of relative risk at different levels of *trans* fat intake is based on taking the natural logarithm. For 2 percent of energy intake from *trans* fat, the estimated relative risk was 1.25. The coefficient in the logistic regression is the natural logarithm of 1.25 = 0.223; $0.223/2 = 0.1116$, the coefficient for 1 percent of energy from *trans* fat; $0.1116 \times 0.1 = 0.0112$, the coefficient for 0.1 percent of energy from *trans* fat; the antilogarithm of 0.0112 = 1.0112, the relative risk associated with 0.1 percent of energy from *trans* fat.)

Thus, FDA disagrees with the comment about relative risk in the prospective studies, and maintains that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL-C and HDL-C, by which *trans* fat contributes to CHD risk....

INSERT: p.191-1 (includes text taken from 192 and 193)

✓ As shown in Table 2, a 0.0378 percent of energy decrease in *trans* fat intake is expected to occur by the effective date of the rule. Approximately three years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows the decreases in CHD risk that would be expected, three years after the effective date, for different examples of macronutrient substitutions for *trans* fat. The three specific substitutions shown in Table 10 are those that FDA used to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent cis-monounsaturated fat, (2) a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat, or (3) a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat (Ref. 73). Table 10 shows that, using one of these three substitutions, the predicted decrease in CHD risk would range from 0.027% to 0.061% for Method 1 and from 0.090% to 0.110% for Method 2.

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits from the reformulation of margarine FDA used a probabilistic model with a distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge. (The formal distribution we used was a BetaPERT, which uses three points: a minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent cis-monounsaturated fat as intermediate, and the change for a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.)

As shown in Table 10, the probabilistic model of substitutions for *trans* fat predicted a decrease in CHD risk of 0.052 percent using Method 1 and 0.106 percent using Method 2.

(Table 10)

INSERT: p. 195-1

Revision for page 195 at the end of section a.:

For nonfatal cases, FDA estimated the cost to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event is about \$22,700 and the total annual costs are \$51.1 billion (Ref. 75). If 1.1 million cases lead to \$22,700 per case, then all these cases cost about \$25 billion. The remaining 13.9 million cases average about \$1,900 per year ((\$51.1 billion - \$25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality- adjusted life years multiplied by \$100,000 per life year plus the medical costs of \$22,700 plus \$1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about \$282,000 ((0.29 x \$100,000 x 8.4) + (\$1,900 x 8.4) + \$22,700).

[page 195] b. *Value of CHD morbidity and mortality prevented.* In the proposed analysis, the per case valuations of morbidity and mortality prevented were estimated. **The annual benefits of the final rule equal the number of deaths prevented multiplied by the cost per death, plus the number of nonfatal cases prevented multiplied by the costs per nonfatal case.** The average cost per fatal case of CHD was estimated at about \$836,000. The average cost per nonfatal case was estimated at about \$281,000. These estimates were based on published research using \$100,000 as the value of a discounted statistical life year (VSLY). This estimate was close to the estimate used in the economic analysis of the regulations implementing the 1990 amendments. We received no comments on these estimates. However, the Office of Management and Budget has suggested using a higher value as a best estimate of the VSLY. Therefore, taking \$6.5 million as the often used current estimate of the value of a statistical life (VSL) we can calculate by discounting a higher VSLY for 35 years. Guidance from OMB also suggests estimating benefits based on both a 3 and 7 percent discount rate. Therefore, Table 11 shows the estimated benefits for different interest rates and VSLs.

TABLE 11.— BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSLY	Number of Discounted Years	Average Cost per Fatal Case	Average Cost per Nonfatal Case	Benefits Estimated by Method 1 in year 3 and annually after the effective date	Benefits Estimated by Method 2 in year 3 and annually after the effective date
\$100,000	not applicable	\$836,000	\$281,000	\$234 million	\$477 million
\$300,000 (VSL=\$6.5 million, discount rate=3%)	22	\$3,190,000	\$968,000	\$968 million	\$1,973 million
\$500,000 (VSL=\$6.5 million, discount rate=7%)	13	\$4,179,000	\$1,250,000	\$1,127 million	\$2,295 million

F. *Summary of Benefits and Costs*

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. **The benefits reported in Table 12 are based on a VSLY of \$300,000 and a discount rate of 3%.** The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted [start page 196] at 3 percent), the medium cost estimate in **Table 12** comes to about \$12 million per year. With Method 1, the cost per life year saved would be **about \$6,000 (\$12 million/2,000 life years)**. These ratios would be even lower if we included the

quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

		Effective date							
Years after publication		2	3	4	5	6	7	...	20
Costs									
	Low	\$139	none	none	none	none	none	...	\$139
	Medium	\$185	none	none	none	none	none	...	\$185
	High	\$275	none	none	none	none	none	...	\$275
Benefits									
Method 1	Annual	none	none	none	\$968	\$940	\$913	...	\$603
	Cumulative total				\$968	\$1,908	\$2,821	...	\$13,130
Method 2	Annual	none	none	none	\$1,973	\$1,916	\$1,860	...	\$1,230
	Cumulative total				\$1,973	\$3,889	\$5,748	...	\$26,757

INSERT: p. 200-201

[start page 200] proportion of SKUs from small businesses as a whole equaled the proportion in the EED (73 percent). Across product categories the average low relabeling cost per SKU is about **\$1,100** and the average high relabeling cost per SKU is **\$2,600**. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 15 shows the total estimated costs of relabeling per product category and for all small businesses affected.

TABLE 15.—RANGE OF RELABELING COSTS FOR SMALL BUSINESSES BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	9,100	\$7,987,000	\$11,780,000	\$19,879,000
Baking Ingredients	1,200	\$1,179,000	\$1,737,000	\$2,846,000
Baby Foods	100	\$120,000	\$182,000	\$295,000
Selected Beverages	6,600	\$8,666,000	\$12,161,000	\$18,569,000
Breakfast Foods	700	\$585,000	\$903,000	\$1,492,000
Selected Candy	3,000	\$3,505,000	\$5,091,000	\$7,918,000
Selected Condiments, Dips and Spreads	2,700	\$2,939,000	\$4,358,000	\$6,777,000
Dairy Foods	6,400	\$7,843,000	\$11,698,000	\$18,273,000
Desserts	2,600	\$2,016,000	\$3,112,000	\$5,141,000
Dietary Supplements	5,900	\$9,818,000	\$14,680,000	\$24,850,000
Selected Dressings and Sauces	2,000	\$2,123,000	\$3,177,000	\$4,933,000
Eggs	1,800	\$1,448,000	\$2,114,000	\$3,713,000
Entrees	1,800	\$1,469,000	\$2,247,000	\$3,673,000
Fats and Oils	600	\$554,000	\$847,000	\$1,349,000
Fruits and Vegetables	5,500	\$5,421,000	\$7,968,000	\$13,054,000
Seafood	1,000	\$1,264,000	\$1,855,000	\$2,764,000
Side Dishes and Starches	3,000	\$2,454,000	\$3,741,000	\$6,201,000
Snack Foods	2,600	\$2,631,000	\$3,860,000	\$6,204,000
Soups	500	\$591,000	\$872,000	\$1,353,000
Weight Control Foods	100	\$143,000	\$207,000	\$357,000
Total	57,200	\$62,754,000	\$92,590,000	\$149,640,000

Table 16 of this document shows the total costs to small businesses of the final rule. The adjusted total costs of the final rule equal the unadjusted total minus 1.8 percent of the total cost of the rule to all businesses (see 58 FR 2927 at 2928, January 6, 1993). The average cost per small business is about **\$12,000.** ✓

TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	\$34,713,000	\$38,703,000	\$49,343,000
Relabeling	\$62,754,000	\$92,590,000	\$137,891,000
Total	\$97,467,000	\$131,293,000	\$187,234,000
Adjustment for Exemption	-\$1,754,000	-\$2,363,000	-\$3,370,000
Adjusted Total	\$96,000,000	\$129,000,000	\$195,000,000

FDA has attempted to place the burden that these costs will place on small businesses in the context of the entire environment in which small businesses exist. Eastern Research Group under contract with FDA has developed a model for estimating the impact of regulatory costs on the survival of small businesses. (Reference: Eastern Research Group, "Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and Its Applications to Four FDA-Regulated Industries," 2002.) This model does not cover the entire range of products covered by this final rule, so it is not possible to estimate the burden of this rule. However, Table 16a gives a sense of the impact that this rule may have on three industry categories that have many small businesses. The model estimates the additional number of small businesses that will have negative cash flow as a result of the costs of complying with a regulation. These estimates are likely to be larger than the actual effects because the model is not able to take into account the exemption from nutrition labeling that is available to some small businesses, nor can it take into account the compliance period of over 2 years which allows small businesses to budget and plan ahead for the expense of the label change.

TABLE 16a.—ILLUSTRATIONS OF IMPACTS ON SMALL BUSINESSES

Product Category	NAICS Code	Total Number of Small Businesses	Average Number SKUs Changed Early per Firm	Range of Costs per Firm	Standard Number of Small Businesses Lost Regardless of Regulation	Additional Small Businesses Lost Due to Compliance Costs of This Rule
Nonchocolate Confectionery Products	311340	590	6	\$8,700 - \$18,100	30 - 80	0 - 30
Cheese	311513	520	6	\$7,500 - \$16,300	40 - 90	0 - 20
Commercial Bakery Products	311812	2,760	4	\$4,200 - \$9,800	560	10 - 60

C. Regulatory Options

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities.

1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the final rule would provide regulatory relief. Table 16 of this document shows that small businesses are expected to bear total costs of about \$130 million as a result of the final rule, an average of \$12,000 per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of \$12,000 per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by the Small Business Administration, if small businesses are exempted, most of the potential benefits from the final rule would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the final label in any case. In addition, under section 403(q)(5)(E) of the act and implementing regulations, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Nutritional Products, Labeling, and Dietary Supplements; (2) make very low volume products (fewer than 100,000 units annually); and (3)

INSERT: p. 203 and 204

rule does not affect nutrient content or health claims, no small businesses will have to change the principal display panels or marketing of their products, which could be very costly.

With small businesses producing 85 percent of the products and 73 percent of the SKUs, extending the compliance period for small businesses to the uniform effective date after January 1, 2006, would leave most labels not listing *trans* fat for almost 5 years after publication. This could result in significant confusion for consumers looking for *trans* fat content on labels and would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would be contrary to the intent of the 1990 amendments. It also would undermine the policy goal of providing consistent nutrition information to consumers. Also, extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

3. Exemptions for Small Entities

FDA has chosen not to exempt small entities because consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat, and thus, not contain a level of *trans* fat that would contribute to CHD risk, does not prevent the absence of that fact on the label to no longer be considered a “material fact” for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day’s consumption of a heart unhealthy fat is important for consumers “to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet” (section 2(b)(1)(A) of Public Law 101–535).

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and strong consensus among the scientific community for reducing *trans* fat intake.

Survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled about a food’s basic characteristics.

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. Not requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, would be inconsistent with statutory directives for nutrition labeling in

section 403(q) of the act.

Furthermore, the benefits of covering products made by small businesses exceed the costs that would be saved by exempting them. The medium estimated cost of covering small businesses is a one time cost of \$129 million dollars (table 16). If we assume no benefits from small businesses reformulating, then the benefits associated only with changing labels on all food products is \$48 million per year using Method 1 (\$99 million using Method 2). If small businesses produce at least 22% of food consumed annually, then benefits of covering products made by small businesses will exceed the costs that would be saved by exempting them after 20 years discounted at 3%. Using Method 2 for calculating benefits, small businesses would only need to account for production of at least 11% of food consumed. Since the Small Business Administration definition of small business includes the vast majority of food firms, products and SKUs, even the 22% amount is quite plausible.

D. Recordkeeping and Reporting Requirements

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this final rule. This final rule does not require the preparation of a report or a record.

E. Summary

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this final rule will have a significant economic impact on a substantial number of small entities. Approximately 10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between \$96 and \$184 million, or about \$9,300 to \$17,900 per entity.

INSERT: p. 208

The regulations set forth in this final rule require that *trans* fat 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 fat.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 17.—ESTIMATED REPORTING BURDEN ¹

21 CFR Section	Number of Respondents	Responses per Respondent	Total Number of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	\$155,200
101.36 (b)(2)	910	32	29,500	2	59,000	\$16,500
Totals					615,200	\$171,700

¹There are no capital costs and or maintenance costs associated with this collection of information

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. **This 2 hour per SKU estimate is based on assumptions about the amount of time required per SKU to test a product for *trans* fat, to redesign the label as needed, and to order the change for the label. FDA received no comments objecting to this estimate.**

INSERT: p. 209 -210

XIV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the Act (21 U.S.C. 343-1) is an express preemption provision. That section provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” certain food labeling requirements, unless an exemption is provided by the Secretary (and, by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is “any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * *” (Act § 403A(a)(4), 21 U.S.C. 343-1(a)(4)). Prior to the effective date of this rule, this provision operated to preempt States from imposing nutrition labeling requirements concerning *trans* fat because no such requirements had been imposed by FDA under section 403(q). Once this rule becomes effective, States will be preempted from imposing

any nutritional labeling requirements for *trans* fat that are not identical to those required by this rule.

Section 403A(a)(4) (21 U.S.C. 343-1(a)(4)) displaces both state legislative requirements and state common-law duties. *Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548-49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements that are not identical to the *trans* fat labeling required by this final rule, including state tort-law imposed requirements, this preemptive effect is consistent with what Congress set forth in section 403(A) of the Act.

Section 4(c) of the Executive Order further requires that any “regulatory preemption of State law shall be restricted to the minimum level necessary” to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the Act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency regulatory objective. Further, section 4(e) of the Executive Order provides that “when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA sought input from all stakeholders through publication of the proposed rule in the Federal Register. Eight comments from State and local governmental entities were received; all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed

footnote.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

Updated: ~~6-20~~ 6-25

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" and for ~~"reduced"~~ levels 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 a *trans* fat label declaration 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.

FOR FURTHER INFORMATION CONTACT: ~~Susan Thompson~~ ^{Julie Schrimpf}, Center for Food Safety and Applied Nutrition (HFS-832), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-~~1784~~ ²³⁷³.

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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

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 %DV₁ 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

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. ^{insert 12-1} 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, requiring} FDA is ~~authorizing~~ 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, such as Dietary Guidelines 2000 (Ref. 87), that recommend that Americans cut back on *trans* fats when reducing fat intake. The agency concludes that the declaration of this nutrient on a separate line, will help consumers understand that *trans* fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices. The agency intends to promote consumer awareness and understanding of the health effects of *trans* fat as part of an educational program.

↑ (Insert 13-1)

III. Legal Authority

General Comments

FDA received a number of comments from trade associations and others in industry asserting that FDA did not meet its burden under the first amendment in proposing to mandate nutrition labeling of *trans* fat. Further, the comments asserted that FDA did not meet its first amendment burden for establishing restrictions on specific claims by virtue of how FDA defined nutrient content claims or established disqualifying and disclosure levels, including the effects that those actions would have on restricting certain health claims on food. In addition, comments raised questions about whether the agency's proposed action was consistent with the Administrative Procedure Act (APA) and whether the agency was acting consistent with its authority under the act.

As stated in section VI of this document, FDA is withdrawing those sections of the rule pertaining to the definition for nutrient content claims that were proposed, 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. Further, the agency is withdrawing the proposed requirement to include a footnote stating "Intake of *trans* fat

should be as low as possible.” The agency provides an overview of comments received on these withdrawn sections in section VI of this document, and therefore, is not addressing those comments here. Thus, the agency is addressing only those comments that pertain to legal issues about the agency’s action to require mandatory *trans* fat labeling.

A. Statutory Authority

Several comments question whether the agency’s proposed requirement for mandatory *trans* fat labeling would prevent consumer deception or would assist consumers in maintaining healthy dietary practices. The comments suggest that the data do not support mandatory *trans* fat labeling, unless the label contains a nutrient content or health claim related to fat or cholesterol or unless polyunsaturated fat or monounsaturated fat is voluntarily declared on the label. Specifically, the comments assert that mandatory *trans* fat labeling in the absence of claims, or statements about other fats, would not assist consumers in following healthy dietary practices or would not prevent consumer deception.

A few comments suggest that there was no basis for concluding any health benefit can be expected from disclosure of *trans* fat levels on foods when present in amounts that have not been clinically shown to have a material impact on human health or disclosure on foods with a trivial contribution of fat.

Another comment ^{argues} ~~states~~ that the agency could only require mandatory labeling of *trans* fat under the statute where the absence of such labeling constitutes the omission of a material fact under section 201(n) of the act (21 U.S.C. 321(n)), such as when nutrient content claims are made about cholesterol or fatty acids, or when polyunsaturated and monounsaturated fats

are voluntary listed. A related comment suggests that *trans* fat labeling would be appropriate where the declaration of “total fat” and “saturated fat,” that did not explicitly include *trans* fat, were established as misleading under section 201(n) of the act (without *trans* fat listed). The comment seems to suggest that the declaration of “total fat” and “saturated fat” in that situation would be misleading if the actual nutrition contribution from *trans* fat that such products make to the diet was greater in comparison to other products. In addition, one comment suggests that mandatory nutrition labeling of *trans* fat can only be “material” where there is sufficient *trans* fat present in the food to significantly impact the overall fatty acid contribution that the food makes to the diet, such that only having total fat and saturated fat on the label would misrepresent the nutritional value of the product in a material way.

FDA believes it has adequate authority to adopt this rule. FDA’s authority under the act to require *trans* fat labeling includes sections 201(n), 403(a)(1) and (q), and 701(a) of the act (21 U.S.C. 371(a)). FDA has authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA can require labeling of certain facts that are material in light of representations made in the labeling or with respect to consequences which may result from the use of the article in order for a product not to be misbranded under sections 201(n) and 403(a) of the act. Further, under section 403(q)(2)(A) of the act, the Secretary (and FDA, by delegation) may require that information relating to a nutrient be in the labeling of food for the purpose of “providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.”

The agency believes that the data in the record supports mandatory *trans* fat labeling to ensure that consumers are not misled. and are adequately informed about the product's attributes Accordingly, FDA

products that states, in part, that very low calorie protein diets may cause serious illness or death. Another example of required information is the use of the term "milk derivative" following the ingredient declaration of sodium caseinate when used in a product labeled "non dairy" (21 CFR 101.4(d)).¹

Consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

that the reasonable consumer ~~know~~ should know -

Consumers must know ^{and the agency believes is material information} the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat, ^{is still a "material fact" for that food,} ~~and thus, not contain a level of *trans* fat that would contribute to CHD risk, does not prevent the absence of that~~

¹ FDA's regulation regarding the failure to reveal material facts (§ 1.21) states that "affirmative disclosure of material facts * * * may be required, among other appropriate regulatory procedures, by * * * regulations in this chapter promulgated pursuant to section 701(a) of the act; or direct court enforcement action (emphasis added)." Thus, establishing a requirement for mandatory *trans* fat labeling is consistent with § 1.21.

~~fact on the label to no longer be considered a "material fact" for that food.~~

In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers "to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet" (section 2(b)(1)(A) of Public Law 101-535). Further, foods in which *trans* fat has replaced saturated fat would appear to be heart healthy based on the saturated fat grams listed on the nutrition facts panel, when, in fact, such foods may not be heart healthy due to the large contribution of *trans* fat to the total fat content. Consumers would be misled without having *trans* fat information available on the label. Thus, for the reasons set forth previously, FDA concludes that it is acting within its statutory authority under the act to require *trans* fat labeling.

Moreover, Congress provided the agency with the express authority to add to the list of nutrients on the label under section 403(q)(2)(A) of the act. As stated in section V.A of this document, section 403(q)(2)(A) gives FDA the authority to require that information on additional nutrients be included in nutrition labels if FDA determines that providing such information will assist consumers to maintain healthy dietary practices. Section IV of this document provides ample evidence of the heart unhealthy effects from consumption of

~~information the agency believes the reasonable consumer would want to know~~ ^{is material information that} ~~trans fat over a range of intakes.~~ When scientific evidence supports such ~~trans fat~~ ^{know}

labeling, the agency has discretion to determine whether to require the addition of a particular nutrient to the label of food products. Thus, the agency is well within its statutory authority for requiring mandatory labeling of *trans*

fat and is not limited to requiring such information only when certain claims are made or only when other fats are listed on the label.

Further, the agency disagrees with the comments that assert that mandatory *trans* fat labeling would not assist consumers to maintain healthy dietary practices, unless the label also carries a nutrient content or health claim or information about other fats. The agency also disagrees with comments suggesting that there is no basis for concluding any health benefit can be expected from disclosure of *trans* fat if foods contain a trivial amount of *trans* fat or if *trans* fat is not present in amounts that have not been clinically shown to adversely affect human health.

The agency is exercising the discretion that Congress gave it in the 1990 amendments to include *trans* fat as a mandatory nutrient in food labeling, based on the state of the scientific evidence on the increased LDL-C levels from intake of *trans* fat. ^(see section IV) The scheme that Congress established would require all mandatory nutrients be listed on the food label, including those that the agency determines are necessary under section 403(q)(2)(A) of the act. Congress wanted one uniform statutory scheme for food labeling and discussed the importance of maintaining consistency in the format and content of the food label to “help all consumers to better understand and improve their eating habits by providing uniform information in a coherent and understandable format.” (136 Cong. Rec. S 16607 at 16609 (statement of Senator Metzenbaum)). The statute does not require other mandatory nutrients to be listed, for example, saturated fat, only when monounsaturated and polyunsaturated fat are voluntarily listed. Mandatory nutrients are listed for each food that bears a nutrition facts panel. Food that bears a nutrition label must contain certain required nutrients as part of that label to not be misbranded.

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and strong consensus among the scientific community for reducing *trans* fat intake. Thus, the agency believes it is ~~well~~ within the bounds of its statutory authority under section 403(q)(2)(A) of the act to require the listing of *trans* fat on the food label, which listing is not dependent on the presence of claims or other voluntary fat information.

B. The First Amendment

Several general comments were received asserting that the agency's action to mandate labeling is subject to review under the first amendment. The comments assert that mandatory labeling of *trans* fat is commercial speech, and thus, such speech is entitled to the full range of first amendment protections as all commercial speech (citing to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). The comments further assert that "compelled speech" is entitled to the same protections as speech "bans," (citing to *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 477 U.S. 557^{at} 566 (1980)). One comment explained that the court in *Pearson* emphasized that

Under the first prong of Central Hudson, commercial speech must be related to lawful activity²³ and not be misleading.

that the label is not false or misleading. Speech that is false or misleading is not protected and may be prohibited (*Central Hudson*, 447 U.S. 557 at 563–564).²

Given this determination, arguably the agency need not address the other three parts of the *Central Hudson* test at all. Nonetheless, and particularly in light of FDA's showing that such information is important to ensuring that consumers are adequately informed about the products they are buying, the proposed requirement satisfies the next three prongs. Turning to the second prong, the asserted governmental interest must be substantial, FDA's interest is clearly substantial, for at least two reasons. As noted previously, the FDA has a substantial interest in protecting and promoting public health and in preventing consumer deception by ensuring the accuracy and completeness of *trans* fat information in labeling. (See *Pearson*, 164 F.3d at 656.) The food labeling regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, and not misleading. (58 Fed. Reg. 2478, 2526 (1993)). Consumers have a first amendment interest in obtaining information on which to base a decision, particularly one that has health consequences, regarding whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." (*National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 162 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978)).

Moreover, FDA has a substantial governmental interest in assisting consumers to maintain healthy dietary practices. Such interest is consistent with the purpose of section 403(q)(2)(A) of the act; to provide information to consumers on nutrients (*trans* fat content of food) when such information is

²The agency does not need to address the comments that asserted that proposing to treat *trans* fat the same as saturated fat in the November 1999 proposal would be the same as requiring false labeling. Since the agency is requiring separate line labeling in this final rule, those comments are moot.

Under the third prong of *Central Hudson*, the regulation must directly advance the government's interest asserted. *Central Hudson* 447 U.S. 557 at 566.
24

of public health importance. The government is not confined to asserting a substantial government interest in preventing consumer deception for a regulation before that regulation can sustain a first amendment review (*Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484-85 (1995) (finding that the protection of the health, safety, and welfare of citizens is a substantial government interest)). In fact, FDA's interest in this rule includes an interest in ^{ensuring} assisting consumers ^{have information they need to help them} to maintain healthy dietary practices by providing complete, factual information to consumers on food labels so that they can reduce CHD risk.

Third, ^{of} requiring mandatory *trans* fat labeling on food products directly advances the government interest. As ^{analyses of} previously stated in section V.A of this document, survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. The most frequently reported label use and the one that increased the most following the implementation of the 1990 amendments was to see how high the food was in nutrients such as fat. Mandatory *trans* fat labeling would ^{assist} help consumers to maintain healthy dietary practices because it would provide needed information about the amount of *trans* fat in a given product so that consumers could plan a daily diet in a way that would reduce their intake of *trans* fat. Further, as stated in section V.A of this document, consumers need ^{be able to see} to understand the *trans* fat content of all foods subject to mandatory labeling so that they can ^{compare} understand the relative contribution of *trans* fat from each and make purchasing decisions accordingly.

Finally, ^{under the fourth prong of *Central Hudson*,} the regulation must be no more extensive than necessary to serve the government interest. ^{Id. (same cite as)} That is the case here. Given, as stated ^{earlier} in section V.A, that consumers need to understand the relative contribution of *trans* fat from all foods subject to mandatory labeling to make choices among

products that will reduce their intake of *trans* fat, there are not “numerous and obvious less-burdensome alternatives” (*Cincinnati v. Discovery Network*, 507 U.S. 410, 418 n.13 (1993)) than the requirement imposed here. Imparting truthful, factual, noncontroversial information about the presence or absence and amount of *trans* fat in food products on the label will provide consumers with the information ^{or} ~~they need~~ ^{to help them} to reduce their risk of CHD. Thus, the agency’s action to require factual information be imparted to consumers about *trans* fat content of foods by requiring such information in labeling is sufficiently narrowly tailored to meet the fourth prong of *Central Hudson*. The “government is not required to employ the least restrictive means conceivable” rather it is required to have “a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served” (*Greater New Orleans Broadcasting Ass’n, Inc. v. U.S.*, 527 U.S. 173 at 177 (citing *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989))). Requiring disclosure of *trans* fat content would assist consumers to maintain healthy dietary practices, provide complete, factual information ^{to help them} ~~that they need~~ on a food label ^{to help them to} ~~to~~ reduce *trans* fat intake and thereby reduce their risk of CHD. Further, it would prevent them from being misled by providing information on *trans* fat that ^{help them make} ~~they can use in making~~ product comparisons and choose products that are heart healthy.

The agency disagrees with the suggestion that narrow tailoring under the fourth prong of *Central Hudson* requires that *trans* fat content be included in the figure for total fat content. Such an approach would not provide consumers with labeling information on the amount of *trans* fat in a product. To provide consumers with a way to calculate the amount of *trans* fat in a product, all

other fats (including monounsaturated and polyunsaturated fats) would be required to be on the label. The comment provided no basis for why monounsaturated fat and polyunsaturated fat should be made mandatory, why it would make sense for consumers to have to calculate the value for *trans* fat content from each label under the statutory scheme in section 403(q)(2)(A) of the act, and why such an approach would be less burdensome under the fourth prong of *Central Hudson* to support its assertion.

Moreover, there is a substantial argument ~~to be made~~ that the agency need not satisfy the *Central Hudson* test because that test applies to prohibitions on speech, and not compelled commercial speech, which is at issue here. Although consumer curiosity alone is an insufficient interest to compel factual speech (*International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2nd Cir. 1996)), the government can compel manufacturers to disclose information that bears on a reasonable concern for human health or safety or some other sufficiently substantial government concern." Id. FDA's rule to require mandatory *trans* fat labeling is one that would require manufacturers to disclose such information.

Further, ^{the U.S. Court of Appeals for} the second circuit upheld a regulation compelling speech where the goal of the statute was to reduce the amount of mercury released into the environment; a goal that was "inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products" (*National Electrical Manufacturer's Ass'n v. Sorrell*, 272 F. 3d 104, 115 (2d Cir. 2001)). FDA is providing information that will assist consumers to maintain healthy dietary practices and prevent consumers from being misled if incomplete nutrition information on *trans* fat were provided on the food label, i.e., information that did not include the presence or amount of *trans*

fat in foods. Similar to the goal the State of Vermont has in increasing awareness of consumers to prevent the harmful consequences of mercury containing products entering the environment, FDA wants to prevent the harmful consequences (increased risk of CHD) to consumers from *trans* fats. Thus, the agency's action to require *trans* fat labeling in this rule comports with similar actions in other compelled commercial speech cases which have been upheld under the first amendment.

For all of the foregoing reasons, the agency believes it has complied with its burdens under the first amendment to support mandatory disclosure of the amount of *trans* fat in food labeling. The information that FDA is requiring in food labeling for *trans* fat, i.e., the amount of *trans* fat listed in grams or an optional footnote stating "Not a significant source of *trans* fat" if zero grams ^{are} present, is purely factual and uncontroversial information. FDA's action to compel *trans* fat labeling does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." Rather, it simply provides for purely factual and uncontroversial information that can be supported if such labeling is reasonably related to FDA's government interests (*Zauderer*, 471 U.S. at 650-51 (distinguishing between the level of review necessary under the first amendment where factual and uncontroversial information is required and recognizing that the constitutionally protected interest in not providing such information is minimal); see also *Glickman v. Wileman Brothers & Elliott, Inc.*, 521 U.S. 457, 472 (1997) (distinguishing compelled financial contributions that promote speech to encourage consumer purchases from speech in which the content of the message focuses on political or ideological differences). FDA's interests in requiring mandatory *trans* fat labeling is to protect the public

health by providing consumers with information that will assist them in maintaining healthy dietary practices and by preventing misleading labeling by providing factual, truthful, and noncontroversial information.

Providing information to consumers about the *trans* fat content of foods on food labeling is reasonably related to the agency's interest of assisting consumers to maintain healthy dietary practices. As explained in section IV of this document, there is a relationship between the level of *trans* fat in the diet and risk of CHD. To reduce this risk, consumers need information about the level of *trans* fat in food products. The agency has evidence that consumers refer to product labels when purchasing food products and use labels to determine how much fat is in a product (Ref. 96). Thus, by requiring that *trans* fat information be on a food label, the agency will be assisting consumers in making food purchasing decisions that can result in a reduction in *trans* fat intake so that they can reduce their risk of CHD. Moreover, because the presence or absence of *trans* fat is a material fact under section 201(n) of the act, as explained earlier, mandatory labeling that provides information about the presence or absence of *trans* fat, and if present, at what levels, is a reasonable means for imparting full, factual information to consumers so that they will not be misled in purchasing decisions because they have no information about *trans* fat content and may not even be able to calculate it based on information on other fats on the label.

The agency has carefully considered the limitations imposed by the first amendment to avoid unjustified burdens and costs of food labeling where there is no genuine public health benefit from the rule that does not alleviate a harm of potential consumer deception. The agency did carefully calculate the costs and benefits of food labeling (see Section 18) of this document and determined that the scope of mandatory *trans*

evidence did not establish a genuine "harm" from *trans* fat consumed at ordinary intake levels from foods that would be subject to the mandatory labeling requirements.

To the extent that comments were raising concerns about the agency going to a final rule based on including *trans* fat in the amount and % DV for saturated fat and that doing so would be the same as requiring false information on labels, those comments are now moot since the agency is requiring a separate line for labeling *trans* fat. FDA disagrees with the comment that suggests that FDA did not account for legal and policy considerations necessary to construct an appropriate *trans* fat regulatory framework, and that the rulemaking record does not support the scope of this rule. As stated previously, the agency is using the statutory framework that Congress provided in section 403(q)(2)(A) of the act to require mandatory *trans* fat labeling.

Further, the agency has explained its rationale, based on the science, for why it believes that it is necessary for consumers to have information on the *trans* fat content of foods to maintain healthy dietary practices. To the extent that the comments assert that the body of scientific evidence did not establish a "harm" from *trans* fat consumed at ordinary intake levels from foods, and thus, would preclude the agency from requiring mandatory *trans* fat labeling under the APA, the agency disagrees. ~~As it stated earlier,~~ ^{As stated earlier,} the science supports adverse health effects from consumption of *trans* fat among a range of intakes that includes intakes at average intake levels among the U.S. population. ^(see section IV.9 of this document) ^{INSERT 30-1 ✓} The agency has determined, based on this scientific evidence, that consumers need this information to maintain healthy dietary practices. Thus, the agency is not precluded under the APA, as the comment suggests, from issuing this final rule. In addition, the agency has discussed why it believes that this final rule

comports with the first amendment, and thus, disagrees with the comment that suggests that because it did not meet its burdens under the first amendment, it did not satisfy the APA requirements.

IV. Review of the Science

A. Reviews by the Federal Government and the Institute of Medicine (IOM)/ National Academy of Sciences (NAS)

In the November 1999 proposal, FDA reviewed reports published by the U.S. Federal government and the IOM/NAS. These reports, which were published between 1988 and 1995, showed that conclusions about the role of *trans* fat in raising LDL-C, the primary risk factor for CHD, and dietary recommendations were evolving as results from new studies became available (64 FR 62746 at 62749). For example, the 1988 Surgeon General's Report (Ref. 2) and the 1989 IOM/NAS Report (Ref. 4) found no adverse effects of *trans* fat. Later, the 1993 publication from the NCEP stated that "*trans* fatty acids raise LDL-C levels nearly as much as do cholesterol-raising saturated fatty acids" (Ref. 5). The fourth edition of Dietary Guidelines for Americans, a joint 1995 publication from the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA) stated that, "Partially hydrogenated vegetable oils, such as those used in many margarines and shortenings, contain a particular form of unsaturated fat known as *trans*-fatty acids that may raise blood cholesterol levels, although not as much as saturated fat" (Ref. 6).

Subsequent to the November 1999 proposal, new expert panels have been convened to update, in light of new scientific evidence, the conclusions and recommendations in the reports discussed previously. FDA has reviewed these new reports to evaluate whether their updated conclusions reversed or significantly altered ^{its} ~~their~~ earlier conclusions.

NCEP report is an evidence-based report that extensively references the scientific literature. The expert panel concluded that:

Trans fatty acids raise serum LDL-cholesterol levels. Through this mechanism, higher intakes of *trans* fatty acids thus should increase risk for CHD. Prospective studies support an association between higher intakes of *trans* fatty acids and CHD incidence. (Ref. 89, p. V-15).

Based on these conclusions, the Expert Panel recommended that:

Intakes of *trans* fatty acids should be kept low. The use of liquid vegetable oil, soft margarine, and *trans* fatty acid-free margarine are encouraged instead of butter, stick margarine, and shortening. (Ref. 89, p. V-15).

Lastly, a recent report of the IOM/NAS found “a positive linear trend between *trans* fatty acid intake and LDL cholesterol concentration, and therefore increased risk of CHD” (Ref. 140). The report summarized that this would suggest a Tolerable Upper Intake Level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended “that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.”

In summary, the recently updated Dietary Guidelines (Ref. 87), NCEP (Ref. 89), and IOM/NAS (Ref. 140) reports, based on current scientific evidence, consistently find that *trans* fatty acids are associated with increased LDL-C levels and, therefore, that lower intakes of both *trans* and saturated fatty acids are important dietary factors in reducing the risk of CHD. In addition, these new reports (Refs. 87, 89, and 140) either reversed previous scientific conclusions of no deleterious effects of *trans* fatty acids (Refs. 2 and 4), or

in the general population and for those at increased risk for CHD.

(Reverse order sat and trans)

strengthened previous scientific conclusions of an adverse effect of *trans* fat intakes on CHD risk (Refs. 5 and 6). Thus, based on the current body of scientific evidence, there is strong agreement among the expert panels that the available evidence is sufficiently compelling to conclude that *trans* fat intakes increase CHD risk. Accordingly, these expert panels recommended, in addition to their longstanding recommendations that Americans consume diets limited in saturated fat, that consumers also select food products that are low in *trans* fat. Although the expert panels' primary emphases remain on limiting intakes of saturated fat (which contributes on average about ¹¹⁻¹²~~13~~ percent of calories in U.S. diets), they also have recommended limiting intakes of *trans* fats (which contribute, on average, about 3 percent of calories in U.S. diets). These recommendations are made for the general population (Refs. 87 and 140) and persons at ^{increased for} high risk of CHD ^{whose LDL-C is above goal levels,} (Ref. 89).

(Comment 1) Several comments on the November 1999 proposal questioned whether the conclusions regarding *trans* fat would be supported by pending scientific reviews. Some of these comments recommended that FDA not issue a final rule until after publication of Dietary Guidelines 2000. Other comments recommended waiting until the IOM/NAS completes work on a review of dietary reference values for macronutrients.

The Dietary Guidelines 2000 have been published (Refs. 87 and 88). While they do not mention *trans* fat in its broad guideline, "Choose a diet that is low in saturated fat and cholesterol and moderate in total fat," the recommendations from the Dietary Guidelines 2000 and the accompanying advisory committee review clearly state that foods high in *trans* fatty acids tend to raise blood LDL-C which increases the risk of CHD. Reductions in intakes of both ^(reverse order) *trans* and saturated fats are suggested for maintaining total fat

measures are recognized as valid predictors of increased risk for CHD (Ref. 5). FDA concluded that controlled intervention studies, in different population groups in the United States and other countries, consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL-C (^{as} the major dietary risk factor for CHD) compared with consumption of diets containing *cis*-monounsaturated or *cis*-polyunsaturated fat sources (64 FR 62746 at 62753). The agency also compiled reports of changes in serum total and high density lipoprotein cholesterol (HDL-C) and serum lipoproteins to present a more complete picture of serum lipid changes (64 FR 62746 at 62799-62821).

In the November 1999 proposal, FDA also reviewed nine publications that examined associations between *trans* fatty acids, serum lipids and CHD endpoints: Four publications describing three prospective cohort studies (Refs. 19 through 21 and 38), one publication describing an inter-cohort study (Ref. 22), three publications describing case control studies (Refs. 16 through 18), and one publication describing a cross-sectional study (Ref. 23). FDA stated that these epidemiological investigations of associations between dietary *trans* fatty acids and risk of CHD must be interpreted cautiously because of the imprecision associated with the dietary collection methodologies used, the difficulty of eliminating confounding factors, and because no dose-response relationship has been demonstrated in the studies (64 FR 62746 at 62752). FDA also stated that despite these generally recognized deficiencies in the observational studies, the repeated and consistent findings from these studies show that consumption of *trans* fatty acids is associated with adverse effects on CHD risk in humans, which supports the findings from intervention studies (64 FR 62746 at 62752).

reviewing the same scientific evidence as FDA described in the proposed rule, and given their knowledge of U.S. dietary patterns, consistently concluded that *trans* fat intakes are associated with increased CHD risk and recommended that U.S. consumers and those who need to lower their LDL-C level minimize their intakes of *trans* fat to reduce their risk of CHD.

For example, the IOM/NAS noted “a positive linear trend between *trans* fatty acid intake and total and LDL-C concentrations, and therefore, increased risk of CHD, thus suggesting an upper limit of zero” (Ref. 90). However, they further stated that, because *trans* fatty acids are unavoidable in ordinary diets, a complete avoidance of these fats is not possible without extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods such as dairy products and meats that contain *trans* fatty acids may result in inadequate intakes of protein and certain micronutrients). For these reasons, the IOM/NAS recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet. In response to the comments about the scientific validity of an article used in the IOM/NAS report, FDA notes that the paper by Ascherio and coworkers (Ref. 83) is not the only information that the IOM/NAS relied on to conclude that *trans* fatty acid consumption should be as low as possible relative to CHD risk. Moreover, FDA did not find the LDL/HDL cholesterol ratio used in the Ascherio et al. analysis to be a useful endpoint for purposes of the *trans* fatty acid rule-making (see Comment 10).

Additionally, FDA’s independent evaluation of the scientific evidence concluded that there is consistency in finding adverse effects of *trans* fat on risk of CHD. Therefore, even though the independent reviews of FDA and the other expert panels differed to some degree in how they used the available scientific evidence, the resultant consistency of the conclusions across these

reviews provides strong credence to the finding that *trans* fatty acid consumption increases CHD risk via increases in LDL-C.

In summary, based on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trials and prospective cohort studies) that were conducted using a range of test conditions and across different geographical regions and populations, the agency ^{now} agrees with the comments that stated that the available evidence for an adverse relationship between *trans* fat intakes and CHD risk is strong. FDA also finds the results from the large prospective cohort studies among free-living U.S. population groups to be persuasive evidence that the *trans* fat intakes associated with U.S. dietary patterns can have a significant adverse effect on CHD risk for U.S. consumers. The scientific agreement for this relationship among the various expert groups and consensus among these expert groups in recommending that U.S. consumers limit their intakes of saturated and *trans* fats ^{now} provide further evidence of the strength of the science and the public health importance of lowering *trans* fat intakes for U.S. consumers. Therefore, the comments do not persuade FDA to change its position in the proposed rule that labeling of *trans* fatty acids is warranted based on: (1) The scientific evidence; and (2) the public health importance of the guidelines recommending that consumers limit their intakes of both of the LDL-C-raising fats: *trans* and saturated fats. Thus, FDA concludes that its tentative conclusion in the proposed rule that "under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL-C levels, which increases the risk of CHD" (64 FR 62746 at 62754) is no longer tentative. FDA continues to find the overall weight of scientific evidence in support of this conclusion to be sufficiently compelling to ^{now} warrant *trans* fatty acid labeling.

have demonstrated consistently that consumption of *trans* fat increases LDL-C, ^{a major} ~~the primary~~ risk factor for CHD.

New studies and recent expert reports (Refs. 87, 90, 95, and 140) have been published and confirm the relationship between *trans* fat intake and risk of CHD. These studies' reports corroborate the agency's earlier finding in the proposed rule that information on *trans* fat on the nutrition label will assist consumers to maintain healthy dietary practices. Dietary Guidelines 2000 cautions consumers that foods high in *trans* fatty acids tend to raise blood cholesterol and gives examples of food sources of *trans* fat (Ref. 87). The Guidelines advise Americans who need to reduce fat intake to "do so primarily by cutting back on saturated and *trans* fats" (Ref. 87). Likewise, the Executive Summary of the NCEP 2001 report urges primary prevention of CHD in the United States through lifestyle changes (Ref. 95). The NCEP's Therapeutic Lifestyle Changes Diet recommends that those who wish to ^{lower their} ~~maintain an~~ optimal LDL-C level reduce their intake of saturated fat and keep consumption of *trans* fat low (Ref. 89). Similarly, the IOM/NAS report recommends "that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet" (Ref. 90). It is clear that persons interested in following these recommendations and maintaining optimal LDL-C levels must be able to determine levels of both saturated and *trans* fats in individual food products. This information provides consumers with the ability to maintain healthy dietary practices. Information on saturated fat content is already available in Nutrition Facts panels on food labels. The practical way to inform consumers of the level of *trans* fat in individual food products is for the information also to be included in the Nutrition Facts panel.

recommended intake level for total fat in a manner that is consistent with the most recent dietary guidance.

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, ~~would be~~ ^{is} ~~inconsistent~~ ^{consistent} with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are

of nutrition labeling information was voluntary except in certain circumstances. At the time when nutrition labeling was voluntary, many foods did not provide nutrition labeling, demonstrating that the disclosure suggested by the "unfolding principle" was incomplete. To remedy this situation, Congress enacted the 1990 amendments, mandating that nutrients of public health significance be declared on food labels under section 403(q) of the act.

As mentioned earlier, section 403(q)(2)(A) of the act provides for the inclusion of an additional nutrient(s) if the Secretary (as delegated to FDA in ~~21 CFR~~ § 5.10) determines that it should be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. FDA is not asserting, as its basis for mandatory *trans* fat nutrition labeling, a rationale that is different from that which Congress declared by statute for such mandatory labeling.

Lacking any congressional direction to do otherwise, the agency considers it implicit that any such added nutrients would be listed in a similar manner

to those specified in section 403(q)(1) of the act. Accordingly, the agency is amending § 101.9 *Nutrition Labeling of Food*, to add *trans* fat as a mandatory component of nutrition labeling on all foods in accordance with section 403(q)(2)(A) of the act.

B. Format, Including Percent of Daily Value (% DV), for Nutrition Labeling of Trans Fat

FDA received many comments regarding the proposed option for nutrition labeling of *trans* fatty acids and other options discussed in the preamble. In addition, comments were received suggesting that *trans* fat be listed in conjunction with the listing of total fat.

The agency did not receive comments supporting either of the two options that would declare only the combined amount of saturated fat and *trans* fat

stat already def. ok

stat previously def.

Other comments stated that, because of the magnitude of CHD risk in the prospective studies, *trans* fat should be labeled more prominently than proposed in the November 1999 proposal. These comments argued that listing the amount of *trans* fat in a footnote is more confusing and implies that it is unimportant. In addition, comments stated that footnotes, which can use smaller type size, are more difficult to read. One comment stated that it was not surprising that consumers were unfamiliar with the term since it was not allowed to appear on Nutrition Facts labels. This comment suggested that consumer knowledge about *trans* fat would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in food labeling.

Other comments objected to including *trans* fats when calculating the % DV for saturated fat stating that the effects of *trans* fat on LDL-C have not been proven to equal the effects of saturated fat on LDL-C, so they should not be held to the same standard. These comments argued that including *trans* fat in the calculation of % DV assumes that *trans* fat is equivalent to saturated fat on a gram-for-gram basis, whereas the agency admitted in the proposal that available studies do not allow for such a conclusion. The comments stated that no authoritative bodies have recommended that *trans* fat be considered as a part of the dietary recommendation for saturated fat. Also, they stated that including *trans* fat, in effect, lowers the DRV for saturated fat and there is no new data on saturated fat that supports this action, i.e., that there is no basis for concluding that saturated fats are now sufficiently worse than previously believed to justify an apparent reduction in recommended intakes. One comment also argued that if the declaration of % DV changed on a product as a result of including *trans* fat with saturated fat, consumers may incorrectly

Consequently, consumers may overlook quantitative information on *trans* fat content placed there.

In the November 1999 proposal, FDA expressed concern that consumers may not yet know what *trans* fats are or know about their impact on health (64 FR 62746 at 62755). The agency agrees with the comment that suggested that consumer knowledge would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in nutrition labeling.

In addition, the agency notes that media attention to *trans* fat has been widespread since publication of the November 1999 proposal. For example, public awareness about *trans* fats was increased as reports of the IOM/NAS report on *trans* fatty acids were issued (Ref. 140), as consumer and health groups issue press releases and reports about *trans* fats (Refs. 147 and 148),

as food manufacturers add information about the *trans* fat content of products to labels, and as industry announcements are made about the *trans* fat content of packaged and restaurant foods (Refs. 149 and 150). In addition, the agency is planning a consumer education program discussed later in Comment 28 to further heighten consumers' knowledge of what *trans* fats are and their impact on health. Thus, the agency no longer believes that its prior reasoning, i.e., that *trans* fat would need to be included in the declaration of saturated fats in order for consumers to understand that *trans* fats are heart unhealthy is

necessarily true. Consumers should be more aware of *trans* fat based on the public exposure to information on *trans* fat over the past years, ^{and FDA efforts before the rule becomes effective.}

In the November 1999 proposal, FDA tentatively concluded that, in the absence of dietary recommendations for *trans* fats, it was reasonable to include *trans* fats in the % DV for saturated fat (46 FR 62746 at 62756). Consequently, FDA proposed that the % DV be calculated by combining the amount of

was proposed by Canada in June 2001, for use in mandatory nutrition labeling in that country (Ref. 103).

Other comments did not favor listing saturated and *trans* fats on the same line as "Saturated + *trans* fat" for the same reasons expressed in opposition to the proposed option, namely because *trans* and saturated fats are chemically different, because they have different effects on HDL-C, and because, according to preliminary data, *trans* fat may have effects on non-heart disease risks that saturated fats are not reported to have. In addition to concerns about the chemical and physiological differences between *trans* and saturated fats, some comments expressed opposition to labeling the two on the same line because public health and scientific organizations that are instrumental in establishing daily reference intake values have not yet established a DV for *trans* fat. Many other comments objected to having saturated and *trans* fats on one line, in any manner, if it resulted in *trans* fat being included in the calculation of the % DV for saturated fat. Specific arguments against including *trans* fat when calculating the % DV for saturated fat are discussed in the preceding comment.

The agency is not persuaded by comments supporting this option. While this option does indicate more clearly than the proposed rule that saturated and *trans* fats represent two different categories of fat, it would still necessitate a displacement of the % DV for saturated fat by *trans* fat and ^{would} not disassociate the two fats in terms of potential physiologic effects. Based on the reasons set forth in response to Comment 13, we believe that it would be scientifically more accurate to not displace the % DV for saturated fat with *trans* fat. In addition, this option would not be consistent with our rationale, as explained in the response to Comment 13, for why a chemical definition approach to labeling is preferred. Such an approach avoids the uncertainty about

physiological effects now or in the future. While the two fatty acids do both lead to increased LDL-C, advisory groups (as noted in comment 10 of this document) have stated that substitution of *trans* fat for saturated fat lowers HDL-C, ~~which~~ ^{Low levels of HDL-C} can be a predictor of CHD. While evidence concerning the differing effects of saturated fat and *trans* fat on other disease risk factors is preliminary, FDA is convinced by comments that it is preferable to disassociate the two fatty acids and maintain a chemical definition approach to labeling. Accordingly, the agency finds this option unacceptable.

Those comments stating that saturated and *trans* fat are substituted for each other recognized that the two types of fats have some functional similarities. However, comments were not unanimous in stating that the combined total amount of saturated and *trans* fats would stay constant when one of the two fatty acids was raised or lowered. Some comments indicated that *trans* fats could be reduced significantly with a smaller concomitant increase in saturated fat. In addition, FDA points out that the intent of this rulemaking is not to make such substitutions easier from a labeling perspective but to encourage the reduction of both types of fats to assist consumers in maintaining healthy dietary practices.

FDA recognizes that Canada has issued final rules on nutrition labeling that declare saturated fat and *trans* fat on one line. However, FDA has determined, based on comments to this final rule, that such declaration would not be an appropriate approach for the agency at this time. Such an option would not account for the chemical and physiological differences between saturated and *trans* fat, and thus, would be inconsistent with the agency's past approach to labeling that is based on chemical differences. Further, there are additional differences between Canada's new nutrition labeling rule and

existing U.S. regulations, under § 101.9, that will need to be reviewed by both countries. After further review and discussion, the United States and Canada can consider the possibility ^{of} ~~for~~ mutual recognition of nutrition labels.

3. Option to Include *Trans* Fat as a Part of Total Fat

(Comment 15) Several comments recommended a new option that would place an asterisk (or other symbol) after the declaration of total fat (i.e., “Total Fat*”) that references a footnote stating the number of grams of *trans* fat included in the total fat declaration (e.g., “*Includes__g *trans* fat”). A few comments proposed an alternative to this option that would declare *trans* fat in a parenthetical statement on the same line with “total fat” (i.e., “Total Fat __ g (includes__ g *trans* fat)”).

Some of these comments suggested that declaring *trans* fat as a part of total fat alleviates many of the concerns voiced about the proposed option. The comments stated that this option discloses the amount of *trans* fat in scientifically accurate terms and is consistent with current regulations that include the quantity of *trans* fat within the amount declared for total fat. A comment said that this option should be used until a DRV is established for *trans* fat. Another comment suggested that the DRV for total fat should be increased to accommodate *trans* fat. Other comments stated that current dietary guidelines recommend monitoring both total fat and saturated fat intake, especially for consumers concerned about their heart health, and that the AHA recommends focusing on the total amount of fat consumed to address concerns about *trans* fat consumption.

The comments stated that placing the asterisk beside “total fat” has advantages for consumers. At least one comment stated that this type of listing may be more readily seen by consumers since it gives greater prominence to

the *trans* fat information. Other comments stated that including *trans* fat as a part of total fat avoids the confusion that consumers would experience with FDA's proposed option when amounts declared for saturated fat would appear to have increased.

The agency disagrees with those comments suggesting that concerns about *trans* fat consumption can be addressed by focusing on the total amount of fat consumed. FDA agrees that *trans* fats are chemically a component of total fat; however, that is also true for saturated, polyunsaturated, and monounsaturated fatty acids that are listed as subcomponents of total fat in many food labels. Therefore, the agency does not agree that *trans* fatty acids should be listed only as a part of total fat until there is an established DRV for *trans* fatty acids, particularly since DRVs also have not been established for poly- or monounsaturated fatty acids. The agency also points out that the current DRV for total fat includes all fatty acids, so does not need to be increased to accommodate *trans* fatty acids.

Further, placing an asterisk after "Total Fat" on the label with a footnote stating the grams of *trans* fat, or a statement of the grams of *trans* fat beside the total fat on the label likely would lead to the same types of objections that were raised when that approach was considered for saturated fat. ^{moreover,} Previous comments in comment 13 raised concerns about consumers overlooking quantitative information in a footnote. Further, comments raised concern about not maintaining the chemical distinction for individual fatty acids, as has been the past agency practice. Placing *trans* fat on the same line of total fat may raise questions about how *trans* fat is to fit within the % DV for total fat. The agency is not persuaded by any the comments that the problems with this option would be any different than those with the option to label *trans* fat

on the same line as saturated fat. Thus, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

Moreover, while total fat in the diet is important, the composition of that total fat intake is at least equally, if not more, important. Recent recommendations from the Dietary Guidelines 2000 (Ref. 87) ^{and} the Dietary Guidelines Advisory Committee (Ref. 88) ~~and NCEP 2001 report (Ref. 89)~~ have emphasized reducing intake of both saturated and *trans* fats while placing less emphasis on reducing total fat intake. For example, while the 1995 edition of the Dietary Guidelines recommended that Americans choose a diet "low" in fat and saturated fat (Ref. 6), the 2000 edition now recommends "moderate" total fat (Ref. 87) with guidance that consumers needing to reduce their total fat intake do so by cutting back on saturated and *trans* fats, ^{and} the 2001 NCEP report increased the recommendation for total fat intake from 30 to 35 percent for individuals with elevated LDL-C of calories provided that saturated and *trans* fats be kept low (Ref. 89).

Similarly, the 2000 AHA Guidelines specifically recommend limiting "intake of foods with high content of cholesterol-raising fatty acids" (i.e., saturated and *trans* fatty acids) rather than total fat (Ref. 91).

The comments suggesting that *trans* fat information would have greater prominence and be more readily seen when related to total fat rather than saturated fat did not provide any data to support this position. While doing so would move *trans* fat up one line in the Nutrition Facts label, FDA has no basis to conclude that this would make it more prominent to consumers.

The agency acknowledges that the options of using an asterisk next to total fat with a footnote listing *trans* fat or listing *trans* fat parenthetically next to total fat would avoid any possible confusion experienced by consumers as a

As pointed out by comments, doing so has the advantage of being consistent with: (1) The format used to list the other subcomponents of total fat, namely saturated, polyunsaturated and monounsaturated fats; (2) the declaration of quantitative amounts contiguous to the listing of the nutrient rather than in a footnote; and (3) the agency's regulatory precedent of classifying nutrients based on their chemical definition or structure. Consistency with the existing format can be expected to assist consumers in recognizing *trans* fat as a subcomponent of total fat. It will also be responsive to consumer interest in knowing the full breakout of fatty acids since, when poly- and monounsaturated fats are declared, the amounts for saturated, *trans*, polyunsaturated, and monounsaturated fats will add up to the amount of total fat except for minor deviations that may result from application of rounding rules in § 101.9(c)(2).

The agency agrees with the majority of the comments that the scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat at this time. The comments that attempted to suggest a basis for doing so did not suggest particular values or submit scientific evidence to justify the establishment of such values. FDA emphasizes that existing DRVs are based on quantitative dietary intake recommendations developed from extensive scientific evidence that establishes values that will promote public health (58 FR 2206 at 2217). DRVs have not been based on international recommendations, which may not be germane in the United States, or on average dietary intake levels, which may not represent healthy dietary consumption patterns. The FDA is not aware of any international recommendations that it could rely on nor did the comment provide any such specific recommendations. The agency has relied extensively on reports from

the IOM/NAS in developing the current Reference Dietary Intake (RDIs) and DRVs. However, the recent IOM/NAS report on DRIs for macronutrients (Ref. 140) did not make quantitative recommendations for *trans* fat for establishing a DRV. Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information ^{that the agency can use to establish} an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence of a % DV for *trans* fat on food labels, nutrition educators will need to direct efforts at educating consumers further about the effects of *trans* fat on LDL-C levels and CHD risk. However, because of the public health impact of CHD in the United States, the agency believes it is necessary to proceed at this time with this final rule to list *trans* fat in nutrition labeling so that consumers will have quantitative information to use in implementing dietary guidelines to cut back on *trans* fat. By adding quantitative information on *trans* fat content, consumers will have information to use in comparing products and making diet selections that will reduce their intake of *trans* fat in the context of their daily diet by substituting lower *trans* fat products for those previously consumed that were higher in *trans* fat.

The agency does not believe it would be any more difficult for consumers to look at a separate line for information on *trans* fats than it has been for any other separate fat listing. Listing them separately will allow consumers to readily see levels of each in food products and make decisions accordingly. In addition, the agency stated earlier that it believes public awareness about *trans* fat has increased since publication of the November 1999 proposal as a result of media attention, press releases, label statements, and industry

announcements. FDA concludes that this increased awareness, in conjunction with an education program about the change, will allow consumers to use this new information to help maintain healthy dietary practices and will minimize any confusion caused by the change. To maximize the impact of declaring

trans fat in the Nutrition Facts panel, a coordinated educational effort among

(focusing on all three cholesterol-raising dietary components, i.e., saturated fat, trans fat, and cholesterol,

public health professionals and organizations will be required. Such a program is discussed in Comment 28 below.

The comment that was concerned that use of a separate line for *trans* fat would not encourage industry to reduce “heart-unhealthy” fats did not present any data to show the effectiveness of the various options in achieving this goal. Following implementation of mandatory nutrition labeling rules in 1993, the industry reformulated many foods products to reduce levels of nutrients about which consumers were concerned (Ref. 96). Accordingly, FDA believes that the required addition of information on *trans* fat content to nutrition labels, coupled with a consumer education program on the health effects of dietary *trans* fat, will provide incentive to the food industry to minimize the level of *trans* fat present in individual food products. Some parts of the food industry have responded to consumer concerns, e.g., levels of *trans* fat in margarine products have been lowered (Ref. 104), and companies have announced plans to use reformulated fats that are lower in *trans* fat (Refs. 149 and 150). The agency believes that requiring *trans* fat labeling will prompt others in the food industry to reformulate some of their products to offer lower *trans* fat alternatives.

Accordingly, FDA is revising § 101.9(c) by adding paragraph

§ 101.9(c)(2)(ii) to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. This new paragraph requires the listing of *trans* fat on

undue emphasis to *trans* fat and will cause some consumers to evaluate products based on the content of *trans* fat instead of on the content of both *trans* and saturated fats, as is recommended in dietary guidance. One of the comments included the results of a national online survey that tested the communication effectiveness of the proposed footnote relative to no footnote and to the alternative footnote "Combined total intake of saturated and *trans* fats should be as low as possible." Respondents were faced with a food comparison that required them to take both saturated fat and *trans* fat into account to correctly identify the "more healthful" of two food products, described by the comment as the product with the lowest total amount of saturated and *trans* fats combined. The two foods being compared were both high in saturated fat (70% DV (14 g) and 35% DV (7 g) saturated fat) but the food highest in saturated fat (14 g) had no *trans* fat (food 1) while the one with half as much saturated fat (7 g) had 2g of *trans* fat (food 2). With no footnote, over half of the respondents who identified a product as more healthful (57 percent) correctly identified the more healthful food (food 2) and 12 percent chose food 1. In the presence of the FDA proposed footnote, 39 percent of the respondents who identified a product as more healthful chose food 1 as more healthful, presumably focusing on the zero *trans* fat content in the higher fat food, with only 45 percent choosing the food with the lowest total amount of saturated and *trans* fats combined. ^{in incorrectly} The alternative footnote, which mentioned the need to keep the intake of both saturated and *trans* fats low, ~~reversed the effect of the proposed footnote,~~ ^{in the presence of the} a majority again chose food 2 (69 percent) as more healthful, with 17 percent choosing food 1. ^{of respondents correctly}

The majority of the comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the

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} ~~foot~~ 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, that while the footnote would provide guidance on dietary recommendations therefore, that based on arguments presented in the comments, 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.

for trans fat

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 ~~advance notice of proposed rulemaking (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. ~~In light of the need for consumer research on possible footnote statements~~ 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.

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).

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. 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

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or other labeling required

footnote 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 2002 notice (67 FR 69171) to reopen the comment period, about the shortness of the comment period and requests to extend the comment period. However due to the high level of interest in the public health and economic aspects of this rule, the agency did not believe it was in the public interest to provide for additional time for comment. A longer comment period, however, will be provided for the ANPRM being published elsewhere in this issue of the **Federal Register**.

(Comment 18) A few comments requested that the term "*trans* fatty acids" not be used interchangeably with "*trans* fat" as proposed in § 101.9(c)(2)(i)(B) in the November 1999 proposal. These comments stated that the term "fatty acid" would be confusing to consumers and is inconsistent with the terminology used in nutrition labeling and claims for other fatty acids, i.e., "saturated fat," "polyunsaturated fat," and "monounsaturated fat." The comments stated that while "fatty acid" is technically correct, labels should use the easier term to understand, i.e., "*trans* fat."

FDA disagrees with these recommendations. FDA notes that while these recommended levels might be quantifiable by laboratories using GC methodology such as that described in AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105), they will pose a problem for laboratories that are set up to ~~quantitate~~ ^{quantify} *trans* fatty acids by infrared spectroscopy (IR) methodology because the detection limits of the currently available IR methods are higher than those of the GC methods. More importantly, however, there are no unambiguous methods for confirming the very low levels suggested by the comment.

Moreover, FDA notes that the increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat. Therefore, the agency is finalizing § 101.9(c)(2)(ii) to state that *trans* fat shall be expressed, as proposed, to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g.

(Comment 24) One comment noted that the IR method of choice in the November 1999 proposal, AOCS Recommended Practice Cd 14d-96 (Ref. 45), generally overestimates *trans* fat at low levels because of interferences and issues with both accuracy and detection limits. The comment noted further that the AOCS GC method Ce 1f-96 (Ref. 46) has better sensitivity, but has not been validated for many types of food products and that significant work is needed to validate this method for other food matrices.

FDA agrees that the detection limits of the AOCS GC method (Ce 1f-96) (Revised 2002, Ref. 146) are lower than those of the AOCS IR recommended practice (Cd 14d-96) (Revised 1999, Ref. 145). FDA notes that AOCS Recommended Practice Cd-14d-96 is applicable to the determination of isolated *trans* double bonds in natural or processed oils and fats with *trans*

justification, while others stated that the agency should have acted sooner.

There was disagreement as to whether the adverse effects of *trans* fat are comparable to that of saturated fat. Some of the comments stated that the proposed definitions assume that *trans* fat and saturated fat are “bioequivalent.” These comments particularly objected to changing the disclosure and disqualifying level of 4 g of saturated fat to 4 g of saturated and *trans* fat combined (i.e, holding the current level constant and including *trans* fat). These comments argued that the effects of saturated fat and *trans* fat have not been proven to be the same on a gram-for-gram basis and, therefore, should not be treated interchangeably. Other comments stated that there is no scientific evidence showing any adverse effects on serum cholesterol levels or cardiovascular health from *trans* fat in a mixed diet to support FDA’s proposed definitions for nutrient content claims.

Other comments argued that the proposed claims should be included in the final rule for public health reasons, while others argued that less restrictive claims would benefit the public health to a greater extent because they would encourage more reformulation. Some of these comments pointed out that the “*trans* fat free” claim, in particular, is ~~impractical~~ ^{not meaningful} because very few foods could meet the proposed criteria and therefore would not be used enough to be helpful.

Several comments asserted that FDA did not meet its burden under the first amendment because the threshold levels proposed by FDA for *trans* fat for certain nutrient content and health claims, which, if exceeded, would prohibit the use of the claims on food and have the effect of restricting the use of specific claims that would be truthful and not misleading. The comments reasoned that FDA could only limit claims where the level of *trans*

fat in a food product would make the claim misleading. Further, the comments reasoned that, before FDA could prohibit a claim, FDA would need to establish that the use of a disclaimer on the label or the disclosure of *trans* fat on the label could not prevent the claim from being potentially misleading.

Economic concerns regarding the proposed nutrient content claims are discussed in section IX of this document.

FDA has carefully reviewed the comments and finds that it has insufficient scientific information at this point in time to support a decision on the appropriate definition for the nutrient content claims discussed in the November 1999 proposal and the December 5, 2000, notice to reopen the comment period. The comments that expressed a preference for a specific threshold level of *trans* fat for various claims did not provide a scientific rationale to support the level. In the past, the development of definitions for nutrient content claims and the establishment of disclosure and disqualifying levels generally have been dependent upon scientific agreement of appropriate quantitative reference values for daily consumption of the 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, ^{INSERT} ~~the agency does not believe that the~~ ^{PRZ} 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.

✓ ~~Insert 123-1~~
NEW^A Insert 123-2

Insert 123-1

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/ncep/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.

C. Changes Resulting From This Rule

As stated in the analysis to the proposed rule (64 FR 62746 at 62764), to estimate the impacts of this rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

1. Changes in Existing Labeling Regulations

This final rule ^{requires} ~~authorizes~~ the mandatory declaration in the nutrition label of the amount of *trans* fat present in foods. According to this final rule, the amount of *trans* fat must be on a separate line immediately under the amount of saturated fat, but it will not include a % DV that is required for some of the other mandatory nutrients, such as saturated fat. This change to the existing regulations will increase the information available to consumers that they can use to maintain a healthy diet. It will also change the constraints and incentives faced by producers of food.

The final rule will increase the information provided to consumers on food packages. This change in the nutrition label will reduce the cost to consumers of obtaining information on the *trans* fat content of food. FDA anticipates that, once the rule takes effect, consumers will use information on the Nutrition Facts panel to adjust their purchasing practices among foods, consistent with their consumption preferences.

These changes must be made within a period of 30 months.

also estimated the current *trans* fat intake of the population as a starting point for its scenarios for projected intake changes.

a. *Revised estimate of current trans fat intake.* In section IV of this document, FDA discussed the uncertainties associated with estimates of *trans* fat intake from: (1) National food consumption survey, (2) national disappearance data, and (3) food frequency questionnaires done in observational studies of U.S. population groups. Although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. Estimates of intake based on national disappearance data generally overestimate intake due to losses in processing and use, and food groups derived from disappearance data correspond to commodities rather than to foods as consumed. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on national disappearance data. Estimates of *trans* fat intake based on food frequency questionnaires may have the advantage of having been validated versus biomarkers such as *trans* fat content of adipose tissue. Such estimates are suitable for their intended use in ranking and classifying *trans* fat intake of subjects in observation studies. However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. ~~As described in section IV of this document, available estimates of *trans* fat intake from food frequency questionnaires tend to underestimate *trans* fat intake compared with estimates of *trans* fat intake from a national food consumption survey.~~ Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S.

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population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in section IV, food intake is generally under-reported in consumption surveys. ^(Ref. 26) Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake.

~~However, it is likely to underestimate actual intake of *trans* fat to a lesser extent from National Consumption Survey data than from data based on the intake of *trans* fat from food frequencies done in observation studies.~~

Additionally, intake of *trans* fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

As described in the November 1999 proposal (64 FR 62746 at 62765), information on *trans* fat content of foods is limited, and there have been few estimates of *trans* fat intake based on national dietary surveys using food records or recalls. As described in section IV of this document and in the November 1999 proposal (64 FR 62746 at 62752 and 62765), an available estimate by Allison et al. (Ref. 26), based on CSFII 1989–91, reported mean *trans* fat intake of 5.3 g/day (d) (2.6 percent of energy). However, for the purposes of economic analysis, FDA needed to estimate the mean intake of *trans* fat from specific food groups. Therefore, in the November 1999 proposal, FDA indirectly estimated *trans* fat intake based on a report from the Research Triangle Institute (RTI) (Ref. 73). The RTI report used a special 1995 USDA database of *trans* fat content of foods (Ref. 40), together with the mean intake of food groups from USDA's CSFII 1994–96, and matched the CSFII 1994–96 food groups with Standard Industrial Classification (SIC) Codes for food

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS

	CSFII 94–96 ¹	Men	Women	All	All
Mean daily energy intake, kcal ²		2455	1646	2058	
Mean daily <i>trans</i> fat intake ^{3,4}					
Food group	Grams	Grams	Grams	% of energy	
Hydrogenated products					
Total yeast bread	0.475	0.330	0.404	0.177%	
Cakes, pies, doughnuts, sweet rolls, biscuits, muffins, quick breads, pancakes, waffles, tortillas	1.607	1.163	1.391	0.607%	
Cookies, crackers	0.624	0.515	0.571	0.249%	
Ready to eat breakfast cereal	0.093	0.074	0.084	0.037%	
French-fried, home-fried potatoes	0.635	0.332	0.486	0.213%	
Potato chips, corn chips, popcorn	0.345	0.215	0.281	0.123%	
Pourable and mayo type salad dressing	0.181	0.136	0.159	0.069%	
Total candy containing chocolate	0.048	0.040	0.044	0.019%	
Total margarine	1.072	0.859	0.967	0.423%	
Household shortening	0.277	0.222	0.250	0.109%	
Total hydrogenated products	5.357	3.866	4.637	2.026%	
Animal products					
Total milk, including on cereal	0.125	0.085	0.105	0.046%	
Ice cream and ice milk	0.092	0.057	0.075	0.033%	
Total cheese and cottage cheese	0.227	0.148	0.188	0.083%	
Total beef, ground and not ground	0.569	0.319	0.447	0.195%	
Total frankfurter and lunch meat	0.360	0.188	0.276	0.121%	
Total fluid and sour cream	0.061	0.044	0.052	0.023%	
Total butter	0.071	0.049	0.060	0.026%	
Total animal products	1.505	0.890	1.203	0.527%	
Total all products	6.862	4.776	5.840	2.553%	

¹ Continuing Survey of Food Intakes of Individuals, 1994–1996

² kcal; kilocalories

³ Source of *trans* fat content of foods: Ref. 40.

⁴ Source of food intake data: Smiciklas-Wright H., D.C. Mitchell, S.J. Mickle, A.J. Cook and J.D. Goldman. Foods Commonly Eaten in the United States. Quantities per Eating Occasion and in a Day, 1994–1996. U.S. Department of Agriculture NFS Report No 96–5, pre-publication version, 2002. www.barcc.usda.gov/bhnrc/foodsurvey/Products9496.html.

The revised estimate of *trans* fat intake based on CSFII 1994–96 and shown in table 1 is slightly lower than the estimate in the November 1999 proposal (64 FR 62746 at 62765). Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. Major sources of *trans* fat intake as a percent of energy include margarine, 0.42 percent; cake and related products, 0.61 percent; cookies and crackers, 0.25 percent; fried potatoes, 0.21 percent; chips and snacks, 0.12 percent; and household shortening, 0.11 percent. For comparison, FDA also calculated the *trans* fat intake based on CSFII 1989–91, using the same method as for the estimate based on CSFII 1994–96 (Ref. 116 and 117). The overall total *trans* fat intake from CSFII 1989–91 is 6.47 g/d for men, 4.51 g/d for women and 5.32 g/d for all adults, or

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in *trans* fat intake could be thought of as a 2.2 percent decrease in *trans* fat intake by the 45 percent of consumers shown in previous research to use food labels to make purchase decisions (Refs. 68 and 74) (64 FR 62746 at 62766).

In the process of evaluating these comments about consumer awareness, FDA has identified additional data relevant to these issues. In the 1999 Discovery Health survey, 66 percent of those responding to the survey knew that saturated fat was related to disease and 31 percent knew that partially hydrogenated fat was related to disease (Ref. 118). In the 2001–2002 Consumer Attitudes About Nutrition survey, 83 percent of respondents reported that saturated fat is unhealthy, 46 percent reported that *trans* fat is unhealthy and 44 percent reported that hydrogenated fat is unhealthy (Ref. 135). These results indicate that survey respondents were about half as likely to know that partially hydrogenated fat was “unhealthy” or related to disease as to know that saturated fat was related to disease. If these surveys are representative of the population, this indicates a significant level of awareness of the health effect of partially hydrogenated fat, and its component, *trans* fat, even though consumers have very little easily obtainable information on *trans* fat and even though nutrition education efforts, until very recently, have focused on saturated fat to the exclusion of *trans* fat. Once nutrition education efforts include *trans* fat in their messages and once consumers have information on nutrition labels about *trans* fat content, consumer awareness of the relationship between saturated fat, cholesterol and *trans* fat and heart disease will increase. Another recent study, by Kim et al., estimated that food label use has a large effect on nutrient intake. (Ref. 119) This study reported that 73 percent of individuals surveyed use nutrition labels and look for information on saturated fat.

to demonstrate that even reformulated margarines were not likely to be able to comply with the proposed definitions for nutrient content claims.

FDA accepts the comment about current margarine products. For this analysis, FDA estimates that about 15 percent of margarine has already been reformulated to remove *trans* fat. In response to the comments about projected margarine reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation. In that analysis, FDA did not include higher ingredient costs for margarine reformulation, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, in response to the comments, FDA acknowledges that, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

As noted earlier regarding consumer response to *trans* fat labeling, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature may tend to increase the incentives for manufacturers to reformulate their products to be lower in *trans* fat. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features may tend to decrease the incentives for manufacturers to reformulate their products to be lower in *trans* fat. Therefore, in response to the comments regarding projected margarine reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentive for reformulation.

proposed rule.

(in comparison to the incentives that would have been introduced)

also insert same sentence here

notes that there is interest in development of fats and oils lower in *trans* fat for many product categories (Refs. 120 to 122 and 151). At least one manufacturer has announced the reformulation of its snacks and chips to decrease *trans* fat (Ref. 150). To the extent that these product categories reformulate to decrease *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

FDA acknowledges that a large proportion of the U.S. French fried potato intake is consumed in restaurants. Foods typically consumed in restaurants also include other food sources of *trans* fat. Restaurant food is not subject to mandatory nutrition labeling requirements, unless a nutrition-related claim is made. In its estimate of reformulation, FDA did not project reformulation of French fries or of baked goods. Therefore, FDA's estimate did not assume reformulation of restaurant foods. However, FDA is aware of some interest by restaurants in using ^{the} absence of *trans* fat as a marketing device to gain competitive advantage (Ref. 123). If, as seems possible, frying oils and shortenings are developed for reformulation of packaged foods and become available in the market, they may become competitive choices with traditional fats and oils, even for restaurants that do not wish to use absence of *trans* fat for competitive advantage. To the extent that restaurants adopt reformulated baking and frying oils and purchase other products reformulated to be lower in *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

iii. *Quantitative decrease in intake.* Table 2 of this document summarizes FDA's revised estimate of projected decreases in *trans* fat intake due to labeling. In table 2, current *trans* fat intake from margarine is 0.359 percent of energy, reduced 15 percent from the 0.423 percent of energy intake in table

1 of this document to adjust for the estimated 15 percent of margarine that has already been reformulated to remove *trans* fat. This adjustment reduces the total *trans* fat intake from hydrogenated products to 1.96 percent of energy in table 2, compared with 2.03 percent of energy in table 1. Table 2 shows that, by the effective date of the rule, FDA projects that *trans* fat intake will decrease by 0.0378 percent of energy. This decrease will be composed of 0.0359 percent of energy due to removal of 10 percent of *trans* fat from margarine by reformulation, and an additional 0.0019 percent of energy due to direct consumer choice. ← Insert 15b-1

TABLE 2.—ESTIMATED DECREASES IN *Trans* FAT INTAKE AND CONTRIBUTION FROM FOOD GROUPS DUE TO LABELING, AT EFFECTIVE DATE OF RULE

Food group	Before Effective Date of Rule	Change at Effective Date of Rule	
	Mean daily <i>trans</i> intake ¹	Decrease in <i>trans</i> fat contribution from food group	Decrease in <i>trans</i> fat intake
	Percent of energy from <i>trans</i> fat	Percent decrease in <i>trans</i> fat	Decrease in percent of energy from <i>trans</i> fat
Total Margarine	0.359% ²	10%	0.0359% ³
Other food groups with partially hydrogenated fats and oils	1.605%	none	
Total from hydrogenated products	1.964%		
Total decrease due to reformulation			0.0359%
Additional decrease due to consumer choice			0.0019%
Total decrease			0.0378%

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¹ *Trans* fat intake for men and women age 20 and over from CSFII 1994–96, see table 1 of this document.

² *Trans* fat intake from margarine, 0.359 percent of energy, already decreased by 15 percent from intake in table 1, to account for margarine that has already been reformulated to decrease *trans* fat.

³ Estimated decrease due to consumer choice at effective date is 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation.

iv. *Substitutions for trans fat.* In the November 1999 proposal, FDA assumed that manufacturers would most likely replace *trans* fat in margarine with: (1) *Cis*-monounsaturated fat, (2) 50 percent *cis*-monounsaturated fat and 50 percent *cis*-polyunsaturated fat, or (3) 50 percent *cis*-monounsaturated fat and 50 percent saturated fat, and that they would most likely replace *trans* fat in baked products with 50 percent *cis*-monounsaturated fat and 50 percent saturated fat (64 FR 62746 at 62771). In making these assumptions, FDA relied, in part, on a report from RTI estimating that current food technology would

fat due to direct consumer choice, and therefore assumes (for simplicity) that direct consumer choice will show the same range of substitutions as does margarine reformulation. We will describe the effects of these substitutions for *trans* fat on the health benefits of *trans* fat labeling in section VI.E of this document.

Because of the functional requirements for baked products, FDA continues to believe that the most plausible replacement for *trans* fat in baked products is 50 percent *cis*-monounsaturated fat and 50 percent saturated fat. However, because of the uncertainty in quantitative estimation of baked product reformulation, FDA is not including baked product reformulation in its quantitative estimate of benefits and costs of *trans* fat labeling. As noted earlier, to the extent that baked products are reformulated, this analysis will be an underestimate of the actual benefits of this rule.

D. Costs

The costs of this rule are the activities that change as a result of this rule. The total cost of these regulations is the sum of the total testing costs, total relabeling costs, and total reformulation costs. All labels must be in compliance with this final rule by a single effective date. All costs are estimated at the effective date, ^{taken} presumed to be 30 months from the publication date of this final rule. If the effective date is more than 30 months from the date of publication, then the actual costs of this rule will be lower than estimated here. ~~_____~~

1. Products Affected

This final rule covers all food and dietary supplement labeling within FDA's jurisdiction. With a few exceptions, labeling for all FDA regulated foods and dietary supplements will have to be changed by the next uniform effective date following publication of this rule, or about 2 to 3 years after the date

of publication. One exception is for products with less than 0.5 g *trans* fat per serving that also use the "simplified format" for labeling and that do not make nutrition claims or declare vitamins or minerals. The labeling for these products will not have to be changed. FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule. The other exception is for products that sell less than 100,000 units per year in the United States, that are made by firms that have fewer than 100 employees, that do not make nutrition or health claims, and that have filed a notification with FDA in accordance with § 101.9(j)(18). These products are not required to display the Nutrition Facts panel that is being amended by this rule. Again, FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule.

To estimate the costs of this rule, FDA has used the FDA Labeling Cost Model developed for FDA under contract by RTI International in April 2002 (Ref. 129). This labeling model has more current data than the previous labeling cost model developed for the implementing rules of the 1990 amendments (Ref. 74). The model indicates that there are approximately ~~300,000~~^{308,000} food and dietary supplement stock keeping units (SKUs) sold in the United States in categories for which some products will need to be relabeled. A SKU is a specific product sold in a specific size. For example, there is one SKU for 16 ounce (oz) containers of Brand X Diet Peach Tea. The same brand and flavor of tea (a product) in a 12 oz container would be another SKU, and a 12 oz container of the same brand but different flavor of tea would be still another SKU. ~~Based on information from the food industry, the model assumes~~

The model also indicates that there are about 154,000

that, on average, there are 5 SKUs per product, yielding a total of about 60,000 products potentially affected by this rule. Table 3 of this document shows the data on the number of SKUs and products affected. From the categories listed in table 3 as "Selected ^{Baking Ingredients} Beverages," "Selected Candy," "Selected Condiments, Dips and Spreads," and "Selected Dressings and Sauces," FDA excluded products, such as ^{baking powder} bottled water, gum, jam, and vinegar, that qualify for the "simplified" format and are certain not to be affected by this rule. Even with these products removed, this estimate is still certain to be an overestimate of the actual SKUs and products affected by this rule because FDA has imputed costs to all products and SKUs within these broad product categories. Labels on many products categories such as "Selected Beverages" and "Dietary Supplements" are not likely to need to be changed. However, FDA has no basis to make better estimates of the actual number of products and SKUs affected by this rule.

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY

Product Categories	Number of SKUs	Number of Products
Baked Goods	47,200	29,600 9,400
<i>Selected</i> Baking Ingredients	7,700 2,900	3,300 1,600
Baby Foods	1,100 200	800 100
Selected Beverages	32,100 31,600	8,400 6,300
Breakfast Foods	3,600	2,400 700
Selected Candy	20,600 13,800	12,200 2,700
Selected Condiments, Dips and Spreads	15,200	2,300 3,000
Dairy Foods	33,800	22,100 6,800
Desserts	10,700	7,200 2,100
Dietary Supplements	29,500	9,800 5,900
Selected Dressings and Sauces	14,200	11,300 2,800
Eggs	5,800	1,800 1,200
Entrees	10,300	7,900 2,100
Fats and Oils	3,100	1,900 600
Fruits and Vegetables	25,100	2,500 5,000
Seafood	6,800	4,200 1,400
Side Dishes and Starches	18,000	13,200 3,600
Snack Foods	17,800	10,000 3,600

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY—Continued

Product Categories	Number of SKUs	Number of Products
Soups	3,700	700 2,800
Weight Control Foods	1,300	300 700
Total	299,700 307,600	59,900 154,400

2. Testing Costs

In the proposed analysis, FDA assumed that all product formulations that include partially hydrogenated oil as an ingredient would be tested to determine the quantity of *trans* fat (except for margarine products, which were all expected to reformulate). Some comments stated that FDA's estimate of the number of products that would need to be tested was too low because products in other categories than those acknowledged by FDA could potentially contain a reportable amount of *trans* fat. Indeed, other comments stated that all products would have to be tested for *trans* content. FDA disagrees with the comment that all products need to be tested because manufacturers will know that some products do not contain *trans* fat, but does agree that more products need to be tested than previously estimated. In the proposed analysis, FDA estimated costs for testing only for the estimated portion of products containing partially hydrogenated oil in several categories of foods anticipated to be most affected by the rule (an estimated 42,000 products). In this final analysis based on information in the FDA Labeling Cost Model (Ref. 129), FDA estimates that 60,000 food products in categories that could possibly include *trans* fat will be tested for *trans* fat content as a result of this rulemaking.

In the proposed rule, FDA used a per product cost of testing for *trans* fat of \$200. Some comments stated that this estimate is too low. They stated that tests had to be calibrated for each type of food to demonstrate accuracy of the test in the food matrix. FDA notes that manufacturers of many different types

of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at \$14.73 per hour) and delivery charges for one two-pound package delivered overnight (at \$26.30). The model reports a range of testing costs for *trans* fat given in table 4. *insert 163-1*

TABLE 4. RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	\$261	\$291	\$371
Total Testing Cost	\$15,660,000	\$17,460,000	\$22,260,000

One comment suggested that butter and other products with high butter fat contents, such as some ice cream, would contain a reportable amount of naturally occurring *trans* fat, and that therefore, FDA had underestimated the costs of testing these products. In this final analysis, FDA has included testing and relabeling costs for all dairy products including butter and other products that are high in butter fat.

3. Relabeling Costs

In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of \$30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. ~~Based on the new model~~ FDA estimates that almost 300,000 SKUs will be changed. Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing

Insert 163-2

and engraving, and the lost value of discarded labels. Across product categories, the average low relabeling cost per SKU is about ^{1,100}\$250 and the average high relabeling cost per SKU is ^{2,600}\$585. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows the total ^{SKUs changed earlier than planned and the total} estimated costs of relabeling per product category and for the entire industry.

TABLE 5. RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

see Insert 164-1

Product Categories	Low	Medium	High
Baked Goods	\$7,890,000	\$12,313,000	\$21,674,000
Baking Ingredients	\$1,105,000	\$1,745,000	\$2,968,000
Baby Foods	\$70,000	\$107,000	\$175,000
Selected Beverages	\$21,682,000	\$28,026,000	\$38,276,000
Breakfast Foods	\$578,000	\$954,000	\$1,636,000
Selected Candy	\$1,664,000	\$2,623,000	\$4,330,000
Selected Condiments, Dips and Spreads	\$4,710,000	\$6,709,000	\$9,836,000
Dairy Foods	\$8,359,000	\$12,953,000	\$20,604,000
Desserts	\$2,197,000	\$3,558,000	\$6,040,000
Dietary Supplements	\$12,744,000	\$19,017,000	\$31,712,000
Selected Dressings and Sauces	\$2,532,000	\$3,835,000	\$5,805,000
Eggs	\$1,762,000	\$2,634,000	\$4,722,000
Entrees	\$1,651,000	\$2,592,000	\$4,198,000
Fats and Oils	\$886,000	\$1,397,000	\$2,138,000
Fruits and Vegetables	\$10,738,000	\$15,154,000	\$23,010,000
Seafood	\$1,598,000	\$2,304,000	\$3,351,000
Side Dishes and Starches	\$2,460,000	\$3,969,000	\$6,718,000
Snack Foods	\$2,684,000	\$4,092,000	\$6,604,000
Soups	\$1,073,000	\$1,514,000	\$2,221,000
Weight Control Foods	\$149,000	\$224,000	\$382,000
Total	\$86,542,000	\$125,720,000	\$196,400,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are attributable to this rule, the costs of reformulation are counted here. The benefits to consumers of being able to choose reformulated foods containing

less *trans* fat will be counted in section VI.E of this document. In the analysis of the proposed rule, FDA estimated the average reformulation would cost \$440,000 per product and would take a full year. Some comments stated that reformulation was very expensive, required a long time to accomplish and would, under certain circumstances, require the use of more expensive inputs. No comments contradicted FDA's estimate of the per product cost of reformulation or provided information to change that estimate, so FDA will continue to use a per product reformulation cost of \$440,000. In the proposed analysis FDA assumed that only large firms would reformulate. There was no controversy over this assumption.

As mentioned previously, based on comments, FDA estimates that 15 percent of margarine products have already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. ✓ Insert 165-1

Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that ~~the products that will be reformulated contain average amounts of *trans* fat, so the fraction of margarine products reformulated will equal the fraction of *trans* fat removed from margarine.~~ The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule,

FDA
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reformulating 10 percent
of margarine products
will result in a 10
percent reduction in the
average *trans* fat
content of margarine
as a product category

FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only ³⁰⁰84 margarine products. ^{the new data}Both estimates will be used to ^{estimate that 30}derive a range for the number of margarine products that will reformulate as the result of this rule from 8 (10 percent of 84) to 82 (10 percent of 820), if 10 percent of the total number of margarine products are reformulated. Table 6 shows the cost of margarine reformulation.

TABLE 6.—^{COST}RANGE OF MARGARINE REFORMULATION AND TOTAL COST

	Low	Medium	High
Products Reformulating	8	45	82
Total Cost	\$3,520,000	\$19,800,000	\$36,080,000

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new page
insert*

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) can increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, there is good reason to believe that [↑]in the long run [↑]ingredient costs may not increase. To the extent that producers rely on newly formulated ingredients made with new technologies, the price of these ingredients largely depends on the industrial capacity to produce them. As the demand for such ingredients increases, producers will have more incentive to increase capacity and the prices of these ingredients will fall. In the case where producers make use of different mixes of oils, agricultural inputs are well known for being able to be supplied in greater and greater quantities without an increase in price. FDA does not have sufficient information on the types of substitutes that will be used, on the

volume of substitutes that will be needed, or on the future price of the substitutes at the time that reformulation is completed.

5. Cost Summary

Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

See Insert 1671

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	\$15,660,000	\$17,460,000	\$22,280,000
Relabeling	\$86,542,000	\$125,720,000	\$196,400,000
Reformulation	\$3,520,000	\$19,800,000	\$36,080,000
Total	\$106,000,000	\$163,000,000	\$255,000,000

ALL NUMBERS REVISED

FDA acknowledges that there is a significant degree of uncertainty in the cost estimates provided here. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant area of uncertainty. The unknowns include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products of the same or different type. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation.

A third major area of uncertainty includes the number of labels that will be changed. Actual costs are likely to be lower than those estimated here

because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits. [INSERT p 168]

1. Changes in *Trans* Fat Intake

FDA has estimated the current *trans* fat intake of the population and the estimated changes in *trans* fat intake. Based on comments received and on its own reevaluation, FDA revised its estimate of current *trans* fat intake, shown in table 1 (section IX.C) and its projected estimate for changes in *trans* fat intake due to labeling (table 2, section IX.C). The estimate projects quantitative decreases in *trans* fat intake with implementation of the final rule, and discusses the qualitative replacement of *trans* fat by other types of fat.

2. Changes in Health States

In the November 1999 proposal, FDA used two methods to estimate the potential decrease in CHD likely to result from decreased intake of *trans* fat in response to the labeling change.

a. *Method 1.* Decrease in CHD risk due to decreased serum concentrations of LDL-C.

accounted for by either Method 1 (changes in LDL-C) or by Method 2 (changes in both LDL-C and HDL-C) (64 FR 62746 at 62770 to 62771). The estimates in Method 1 and Method 2 are calculated using factors from regression equations summarizing the results of short-term feeding trials (intervention studies). In the intervention studies, *trans* fat is fed to people for a few weeks, changes in serum lipids are measured, and it is assumed that the CHD risk associated with *trans* fat intake occurs through the mechanism of changes in LDL-C and possibly HDL-C. In contrast, the prospective studies measure actual CHD occurrence in a large group of people over a period of years, and describe all CHD risk associated with *trans* fat intake, regardless of the mechanism of action by which *trans* fat intake may be associated with CHD. Thus, the results of the prospective studies suggest that there may be additional mechanisms by which *trans* fat contributes to CHD risk. Because prospective studies do not show direct cause and effect, and because the relative risks determined in observational studies are imprecise, FDA did not use the results of the prospective studies in quantitative estimates of changes in *trans* fat intake and CHD risk. However, FDA noted that, if there are additional mechanisms by which *trans* fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be greater than estimated using either Method 1 (changes in LDL-C) or Method 2 (changes in LDL-C and HDL-C) (64 FR 62746 at 62771).

Sample calculations using Method 1 and Method 2 are summarized in Table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk.

~~The estimate shows that replacement of 0.1 percent of energy from *trans* fat~~

← See insert 170-1

See insert
170-2

~~with the same percent of energy from cis-monounsaturated fat would decrease~~
~~CHD risk by 0.147 percent based on changes in LDL-C (-0.1 x 1.5 x 0.7 x 1.4~~
~~= -0.147), and 0.287 percent based on changes in both LDL-C and HDL-C~~
~~(-0.1 x -0.4 x -2.5 x 1.4 = -0.140 and -0.147 plus -0.140 = -0.287).~~ FDA used
 these estimation methods to project the decrease in CHD risk in the November
 1999 proposal (64 FR 62746 at 62767).

TABLE 8.—SAMPLE CALCULATION FOR CHANGE IN CHD RISK WITH SUBSTITUTION OF *Cis*-MONOUNSATURATED FAT FOR *Trans* FAT

Estimation Method	Change in <i>Trans</i> Intake (% of Energy)	Type of Serum Lipid	Factor for Change in Serum Lipids (mg/dL per 1% of Energy)	Factor for Change in CHD Risk (% per mg/dL)	Factor for Adjustment of Regression Dilution	Change in CHD Risk (%)
Method 1 LDL	-0.1	LDL	1.5	0.7	1.4	-0.147
Method 2 LDL + HDL	-0.1	LDL	1.5	0.7	1.4	-0.147
		HDL	-0.4	-2.5	1.4	-0.14
		LDL+HDL				-0.287

In the scientific literature, *cis*-monounsaturated fat is commonly used as a reference point in describing effects of *trans* fat intake. Therefore, FDA first estimated the effect on CHD risk by assuming that a given amount of *trans* fat would be replaced by the same amount of *cis*-monounsaturated fat in the diet (table 8 in this document and 64 FR 62746 at 62767). However, it is likely that *trans* fat in the diet would actually be replaced by a combination of *cis*-monounsaturated fat, *cis*-polyunsaturated fat, and saturated fat. Therefore, FDA also considered the changes in LDL-C and HDL-C associated with replacement of *trans* fat by different types of fatty acids or carbohydrate (64 FR 62746 at 62767 to 62770). Table 9 in this document summarizes the factors for changes in LDL-C and HDL-C with different macronutrients and combinations of macronutrients ~~replacing~~ ^{replaced by} *trans* fat. ^{Insert 171-1} FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771–62773).

TABLE 9. ~~SUMMARY OF FACTORS FOR CHANGE IN SERUM LIPIDS WITH SUBSTITUTION OF *Trans* FATTY ACIDS FOR DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE~~

A. Change in (See INSERT 172-1 "A. Change in...")

TYPE OF FATTY ACID REPLACED BY 1 PERCENT OF ENERGY FROM *Trans* FAT

Type of serum lipid	Cis-monounsaturated	Cis-polyunsaturated	Saturated	Carbohydrate	Half cis-monounsaturated and half cis-polyunsaturated	Half cis-monounsaturated and half saturated	Half cis-monounsaturated and half carbohydrate
	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy				
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. ← insert 172-1

(Comment 39) As described previously in this document, FDA received numerous comments in support of the November 1999 proposal. Several of these comments noted specifically that labeling of *trans* fat has the potential for substantial public health benefits. A number of comments noted that consumption of *trans* fat increases the risk of CHD by increasing total blood cholesterol and LDL-C, and that *trans* fat labeling would enable consumers to decrease their *trans* fat intake and therefore decrease their risk of CHD. Some comments added that, because *trans* fat also increases the risk of CHD by decreasing HDL-C, therefore the health benefits of *trans* fat labeling would be greater than the benefits associated with the effect of *trans* fat on LDL-C alone. A few comments specifically stated that the prospective studies suggest that there may be other biological mechanisms by which *trans* fat contributes to CHD, in addition to the effects of *trans* fat on LDL-C and HDL-C. These comments therefore supported the possibility that the actual benefits of *trans* fat labeling may be greater than FDA's estimate using either Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C).

Other comments, which were opposed to the November 1999 proposal or some of its provisions, questioned FDA's conclusions regarding the net health benefits of *trans* fat labeling. Some comments stated that the potential harm to the public remedied by *trans* fat labeling was not sufficient to outweigh the cost burden to specific industries. These comments suggested that,

although *trans* fat was shown to increase LDL-C in some studies, the evidence was inconclusive on how to ~~quantify~~ ^{quantity} the increase in LDL-C and CHD risk due to *trans* fat intake and on whether the increase in LDL-C and CHD risk due to *trans* fat intake were as large as those due to saturated fat. These comments suggested that FDA's estimate of health benefits of *trans* fat labeling was too high. One comment stated that it is premature to conclude that *trans* fat intake lowers HDL-C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL-C. The comment implied that consumption of *trans* fat may not increase CHD risk by decreasing HDL-C. A few comments cited an FDA statement from the November 1999 proposal that no dose-response relationship had been demonstrated between *trans* fat intake and CHD (64 FR 62746 at 62752). The comments argued that, therefore, it is not possible to project quantitative health benefits due to *trans* fat labeling. One comment also stated that the health benefits estimate was inaccurate because it did not account for either other CHD risk factors, such as obesity, or other CHD prevention efforts.

A few comments questioned whether health benefits could result from *trans* fat labeling because the in the intervention studies the intakes of *trans* fat were very high and not representative of U.S. intakes of about 5.3 g/d (3 percent of calories). Some comments stated that, even if *trans* fat has adverse health effects at higher levels of intake, there is no clinical evidence that lower levels of intake, such as 0.5 g *trans* fat in a serving of a food product, has any adverse effect. These comments therefore questioned whether health benefits could result from labeling of *trans* fat present in relatively small amounts in individual foods. Other comments suggested that the emphasis on *trans* fat in the proposed labeling regulations was out of proportion to the

emphasis on saturated fat, because the overall amount of saturated fat in the diet is approximately five times that of *trans* fat. The comments stated that, therefore, decreased *trans* fat intake has much less potential for lowering CHD risk than does decreased saturated fat intake, and this should be considered when estimating the health benefits of *trans* fat labeling.

Regarding the comments that questioned whether the increase in LDL-C and CHD risk due to *trans* fat intake could be ^{quantified} ~~quantitated~~ and whether the increase in LDL-C and CHD risk due to *trans* fat intake were as large as those due to saturated fat, FDA stated in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL-C and CHD risk equivalent to saturated fat on a gram-for-gram basis. FDA noted that interpretation of the intervention studies is complicated because, in the individual studies, *trans* fatty acids replace other dietary fatty acids that also affect serum cholesterol levels (64 FR 62746 at 62751). This evaluation was based on a review and analysis of the individual studies, it was not done for purposes of an economic analysis. To overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). As noted in section IV of this document, and in the November 1999 proposal, the regression equations do predict a very similar increase in LDL-C with each one percent of energy increase in either saturated fat or *trans* fat. Thus, table 9 in this document shows that the change in LDL-C is negligible when one percent of energy from *trans* fat is substituted for

trans fat with *cis*-monounsaturated fat would decrease CHD risk by 0.29 percent based on LDL-C and 0.57 percent based on LDL-C and HDL-C. Because CHD is so common in the U.S. population, a relatively small decrease in risk corresponds to a large number of cases and deaths avoided and large dollar value of such benefits, as shown in the example in section IX.A of this document. Awareness of *trans* fat contributions from food products containing 0.5 g and above will assist individual consumers in maintaining healthy dietary practices, reducing the average 2.6 percent of energy from *trans* fat consumed throughout the day.

FDA agrees with the comments that average saturated fat intake in the United States is about 5 times greater than average *trans* fat intake. FDA stated in the November 1999 proposal that it did not want to distract consumers from years of dietary guidance messages about saturated fat (64 FR 62746 at 62755). But the potential health benefits from decreasing *trans* fat intake compared with decreasing saturated fat intake do not depend solely upon the average total amount of each in the diet. The potential health benefits also depend upon the feasibility of decreasing intake of saturated fat compared with *trans* fat. Average U.S. saturated fat intake in 1980 was about 13 percent of energy and decreased to 11 or 12 percent of energy by the mid-1990s (Ref. 113). Many additional heart attacks and deaths might be prevented if saturated fat intake could be decreased to the recommended ^{less than} 10 percent of energy. The targeted decrease in saturated fat intake of one or two percent of energy can be compared with the average *trans* fat intake of 2 percent of energy from partially hydrogenated fats and oils. Labeling of *trans* fat will create new potential for decreased *trans* fat intake by providing an incentive to food manufacturers to reduce the amount of *trans* fat in their products and by providing consumers