

United States for the past few decades. According to the comment, FDA should have projected the future reduction in heart disease that would be expected in the absence of labeling. With such a projection, the baseline for heart disease morbidity and mortality would be progressively lower over time, and the numbers of heart attacks and deaths avoided due to *trans* fat labeling would be commensurately reduced compared with FDA's estimate. One comment stated that an overall decline in CHD from 1970 to 1990 coincided with a decline in intake of fat and saturated fat. The comment stated that margarine intake (per person) was constant during this period. Therefore, the comment concluded that substituting margarine for high saturated fat and cholesterol products had proved beneficial in decreasing CHD.

FDA agrees that the rate of heart disease mortality and morbidity in the United States has been decreasing for several decades (Refs. 132 and 133). For example, the age-adjusted death rate from CHD declined from approximately 290 per 100,000 in 1979 to 190 per 100,000 in 1996 (Ref. 133). However, because the risk of CHD is greater at older ages and the U.S. population is aging, the decline in the overall (crude) CHD death rate in this period was more modest, from approximately 225 per 100,000 to 180 per 100,000. Moreover, because of the increase in the total population, the decline in annual CHD deaths in this period was even more modest, from approximately 550,000 to 500,000, about a 10 percent decrease over 17 years. The number of deaths was fairly level during the period, 1992 through 1996. Thus, the baseline number of CHD deaths, as opposed to age-specific rates, has historically declined at a modest rate, and has been fairly level in recent years. Therefore, FDA did not correct for this in its projection of heart attacks and deaths avoided due to *trans* fat labeling. In response to the comment about correcting

its estimate for overall reductions in heart disease over time, FDA acknowledges that, if the actual number of CHD deaths declines in the future, omitting this correction would result in a modest overestimate of the health benefits of *trans* fat labeling.

Regarding the comment about correlations of changes in dietary intake with declines in CHD from 1970 to 1992, information on *trans* fat intake is limited, as noted in section IV of this document. Therefore, although margarine intake was approximately constant, it is not known whether overall *trans* fat intake increased, decreased or remained the same during this period.

Furthermore, the causes of the decrease in CHD over this time period have not been identified. Decreases in CHD risk factors, such as serum lipids, and decreases in saturated fat intake probably played a role, but the relative contributions of decreases in various risk factors and changes in medical care for heart attack patients are not adequately explained (Ref. 132). Therefore, FDA disagrees with the comment's conclusion that time trends in CHD incidence demonstrate a beneficial effect of margarine intake on incidence of CHD.

Based on the comments received and its own re-evaluation, FDA is not making any changes in the sample calculations for changes in CHD risk (table 8) or in the factors for changes in serum lipids and the examples of changes in CHD risk and the factors for changes in serum lipids with substitution of different macronutrients (table 9), described earlier in this section. Earlier in this section, FDA has revised its estimate of projected decreases in *trans* fat intake due to labeling (table 2) and discussed the likely substitutions of different types of fat for *trans* fat. Using this information, FDA revised the expected changes in CHD risk due to *trans* fat labeling.

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 3 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, 3 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 percent to 0.061 percent for Method 1 and from 0.090 percent to 0.110 percent 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.—PREDICTED CHANGES IN CHD RISK DUE TO *Trans* FAT LABELING ACCORDING TO MACRONUTRIENT SUBSTITUTION FOR *Trans* FAT

Time after Effective Date for Final Rule <sup>1</sup>	Decrease in <i>Trans</i> Fat Intake (% of Energy)	Source of Decrease	Substitution for <i>Trans</i> Fat	Percent Decrease in CHD Risk		
				Method 1, LDL	HDL	Method 2, LDL and HDL
3 years	0.0378	Consumer choice and margarine reformulation	mono	-0.056%	-0.053%	-0.108%
			mono + poly	-0.061%	-0.049%	-0.110%
			mono + sat	-0.027%	-0.062%	-0.090%
			Substitution from probabilistic model.	-0.052%	-0.054%	-0.106%

<sup>1</sup> The time after the effective date for the final rule includes 3 years for decreases in *trans* fat intake to result in changes in CHD risk.

Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows that the 0.0378 percent of energy decrease in *trans* fat intake expected to occur by the effective date of the rule will result, 3 years after the effective date, in a 0.052 percent decrease in CHD risk using Method 1 and a 0.106 percent decrease in CHD risk using Method 2. FDA estimated these decreases in risk using a mathematical model that accounted for the three likely substitutions for *trans* fat in reformulation of margarine and direct consumer choice, discussed previously. Table 10 shows the predicted decrease in CHD risk for each of the substitutions separately, and the overall estimate from the mathematical model.

### 3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this final rule and described calculations of the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA used three specific substitutions 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).

FDA estimated the benefits from the final rule for two methods. The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. Method 1 assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about only through the reduction in LDL-C. Method 2 assumes that the reduction in CHD risk comes about through a combination of reducing LDL-C and increasing HDL-C. Method 2 results in higher benefit estimates than Method 1.

The reduction in CHD risk is highly uncertain primarily because of the difficulties in estimating the amount of reformulation, consumer response, and the reduction in CHD risk due to a decrease in *trans* intake. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD

risk associated with the final rule. The low and high estimated benefits can be interpreted as a range of potential effects. When we lacked direct evidence on uncertain values, we dealt with the uncertainty by choosing values that generated lower-bound estimates of benefits. This practice and the evidence in the previous section both imply that the actual realized benefits may exceed the range given by the two methods.

a. *CHD morbidity and mortality prevented.* FDA calculated the benefits from the final rule as the reduction (from the baseline) in CHD multiplied by the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exist in the population. The AHA estimates that 1.1 million heart attack cases of CHD occur annually, with 40 percent of them fatal (Ref. 134). The average years of life lost per fatal case is 13, or 8 years discounted to the present at 7 percent or 11 years discounted to the present at 3 percent. FDA used these estimates as the baseline for the estimated benefits. The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the final rule. FDA used these estimates in the analysis for the proposed rule, and comments on this are discussed in the previous section on changes in health states. FDA estimated the effects using Method 1, which considers changes only in LDL-C, and using Method 2, which considers changes in both LDL-C and HDL-C.

The benefits are expected to begin 3 years after the effective date. The 3-year lag occurs because a dietary change takes several years to begin to affect

the CHD risk (Ref. 137). With Method 1, FDA estimated that 3 years after the effective date, the final rule would annually prevent 600 cases of CHD and 240 deaths. Preventing 240 deaths would annually save about 1,920 discounted life years (240 deaths x 8 years) using a 7 percent discount rate, or 2,640 discounted life years (240 deaths x 11 years) using a 3 percent discount rate. With Method 2, FDA estimated that 3 years after the effective date, the final rule would annually prevent 1,200 cases of CHD and 480 deaths, saving about 3,840 discounted life years (480 deaths x 8 years) using a 7 percent discount rate, or 5,280 discounted life years (480 deaths x 11 years) using a 3 percent discount rate. Because the association between *trans* fat consumption and CHD through changes in LDL-C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

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 ( $(\$51.1 \text{ billion} - \$25 \text{ billion}) / 13.9 \text{ million}$ ). 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 ( $(0.29 \times \$100,000 \times 8.4) + (\$1,900 \times 8.4) + \$22,700$ ).

b. *Value of CHD morbidity and mortality prevented.* In a May 30, 2003 Memorandum to the President's Management Council, OIRA Administrator John D. Graham recommended that agencies, when performing benefit cost-analysis, present results using both VSL and VSLY methods. Below we present estimates using both methods. The Memorandum also recommends that agencies present analyses with larger VSLY estimates for senior citizens. Since many of the beneficiaries of this final rule are senior citizens, larger VSLY values than the ones we have used will increase benefits further.

FDA therefore estimates the benefits of this rule using two approaches that reflect different methods used in the economics literature. First, it calculates benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the number of nonfatal cases prevented multiplied by the costs of nonfatal cases, plus the savings in medical costs associated with reductions in nonfatal CHD. Its second calculation is like the

first, except that it values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death (rather than the extensions to longevity multiplied by the value of increases in life-years gained), and calculates the value of reducing the number of nonfatal cases as simply the savings in medical costs. This section presents these two approaches in turn, beginning with benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the prevented costs of nonfatal cases and medical costs.

Under the first approach, FDA estimated the costs of nonfatal cases 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 (discounted at 7 percent) and 10.6 discounted years (discounted at 3 percent). 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.

There are also medical costs for nonfatal cases of CHD. The American Heart Association estimates that the cost of a new CHD case 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.

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

In the first approach, FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses \$100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 77) use a similar estimate, and Garber and Phelps (Ref. 157) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that \$100,000 per life year is a reasonable estimate, given that median family income in 2002 was about \$51,000 (Ref. 158). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations implementing the 1990 amendments. FDA received no public comments on that estimate. To reflect other underlying literature, and following suggestions from other Federal agencies, we begin with an estimate of the value of a statistical life (VSL) of \$6.5 million. This estimate is consistent with the survey by Viscusi and Aldy (Ref. 159) on the premium for risk observed in labor markets. Annuitizing this value over 35 years at 3 percent and at 7 percent discount rates, as is consistent with OMB guidance, implies estimates of a

value of an additional year of life of about \$300,000 and \$500,000. Therefore, table 11a shows estimated benefits for three estimates of VSLYs: \$100,000, \$300,000 and \$500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs.

TABLE 11A.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	Discount Rate	Number of Discounted Life Years Gained		Mortality Related Benefits Estimated In Year 3 After the Effective Date and Annually Thereafter (in millions)		Total Benefits (in millions)	
		Method 1	Method 2	Method 1	Method 2	Method 1	Method 2
\$100,000	7 percent	1,920	3,840	\$192	\$384	\$234	\$477
\$300,000	3 percent	2,640	5,280	\$792	\$1,584	\$968	\$1,973
\$500,000	7 percent	1,920	3,840	\$960	\$1,920	\$1,127	\$2,295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of \$5 million and \$6.5 million. These values represent reasonable central tendencies for a larger range of VSL estimates reported in the literature: \$1 million to \$10 million (Ref. 159). The two values FDA uses here are also consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks (Refs. 159 and 160). FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Viscusi and Aldy are relatively low. Table 11B shows the annual benefits estimated in this way for the two different VSLs using both a 3 and 7 percent discount rate. The totals in the final 2 columns of the table are discounted, so direct multiplication of the previous columns does not give the totals in the final columns.

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

VSL and Discount Rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Expected Nonfatal Cases Averted		Total Benefits Estimated in Year 3 After the Effective Date and Annually Thereafter (in millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
\$5,000,000 (3%)	240	480	\$43,000	360	720	\$1,112	\$2,225
\$6,500,000 (3%)			\$43,000			\$1,442	\$2,884
\$5,000,000 (7%)			\$39,000			\$991	\$1,982
\$6,500,000 (7%)			\$39,000			\$1,285	\$2,570

## F. Overview of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated total benefits and costs and summarize the sources of information used in making these estimates.

### 1. 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 percent. 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 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 \$4,500 (\$12 million/2,600 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

	Years After Publication	Effective Date						Cumulative Total as of Year 20	
		2	3	4	5	6	7		
<b>Costs</b>									
Low		\$139	none	none	none	none	none	...	\$139
Medium		\$185	none	none	none	none	none	...	\$185
High		\$275	none	none	none	none	none	...	\$275
<b>Benefits</b>									
Method 1	Annual	none	none	none	\$968	\$940	\$913	...	
	Cumulative				\$968	\$1,908	\$2,821	...	\$13,130
Method 2	Annual	none	none	none	\$1,973	\$1,916	\$1,860	...	
	Cumulative				\$1,973	\$3,889	\$5,784	...	\$26,757

### 2. Summary of Information Sources

Table 12A summarizes the inputs, data sources, and assumptions used in the Final Regulatory Impact Analysis for this final rule.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Current trans fat intake.	Total intake, 2.55% of energy; intake from hydrogenated fat, 2.03% of energy (table 1 of this document).	FDA's best estimate from available data	USDA trans fat food composition database, (Ref. 40); USDA food group data from CSFII, 1994-96, (Ref. 115).
Adjustment of trans fat intake for current level of margarine reformulation.	0.063% of energy, decrease in current amount of trans fat intake from margarine (table 2 of this document).	FDA's best estimate from available data.	15% decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation.	0.0359% of energy decrease (table 2 of this document).	Low assumption based on uncertainty.	Assume 10% decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice.	0.0019% of energy decrease (table 2 of this document).	Low assumption based on uncertainty.	Assume 0.1% decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.
Overall change in trans fat intake due to labeling.	0.0378% of energy decrease (tables 2 and 10 of this document).	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine.	Sum of two previous values.
Number of products to be tested.	154,000 (table 3 of this document).	High estimate based on uncertainty. Includes many products that have already been tested.	Main data sources: RTI labeling cost model (Ref. 129) for number of products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing.	\$261 to \$371 (table 4 of this document).	Data.	RTI labeling cost model, Ref. 129.
Percent of SKU label changes that can be coordinated with scheduled labeling changes.	84% of branded SKUs, 50% of private label SKUs.	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of re-labeling.	Varies (table 5 of this document).	Data.	RTI labeling cost model, Ref. 129.
Number of margarines reformulated.	30 (table 6 of this document).	Low assumption based on uncertainty.	Assume 10% of margarine products reformulate.
Per product cost of reformulation.	\$440,000 (table 6 of this document).	Data.	Industry supplied information (64 FR 62745 at 62782, November 17, 1999).
Overall change in CHD risk per change in trans fat intake.	0.147% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 1 (table 8 of this document).	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: $-0.1\% \times 1.5 \times 0.7 \times 1.4 = -0.147\%$ , decrease in CHD risk.
Overall change in CHD risk per change in trans fat intake.	0.287% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 2 (table 8 of this document).	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: $-0.1\% \times -0.4 \times -2.5 \times 1.4 = -0.140\%$ , decrease in CHD risk due to change in HDL-C. Add to result from Method 1: $-0.147\% + (-0.140\%) = -0.287\%$ , decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake.	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake.	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat.	Various coefficients shown in table 9 of this document.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C.	0.7% increase per 1 mg/dL increase in LDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Changes in CHD risk with changes in HDL-C.	2.5% increase per 1 mg/dL decrease in HDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Adjustment for regression dilution.	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (table 8 of this document).	Data.	Published data, Ref. 64.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Overall change in CHD risk due to labeling	-0.052%, Method 1;-0.106%, Method 2 (table 10 of this document).	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50% cis-monounsaturated and 50% saturated fat as the minimum, the change with 100% cis-monounsaturated fat as intermediate, and the change for a mixture of 50% cis-monounsaturated and 50% cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.
Time lag between effective date of labeling and first health benefits.	3 years (table 10 of this document).	Data.	3 years for serum lipid changes from dietary change. Ref. 137.
Heart attacks per year.	Mean 1.1 million cases, std. dev. 110,000 cases.	Data for mean. Assumption for std. dev.	Published data, Ref. 134.
Percent of heart attacks per year that are fatal.	40%.	Data.	Published data, Ref. 134.
Life-years saved.	13, or 8.4 years discounted to the present at 7% (table 10 of this document).	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.
Life-years saved.	13, or 10.6 years discounted to the present at 3% (table 10 of this document).	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.
Medical Costs saved per non-fatal case.	\$39,000 at 7% discount rate; \$43,000 at 3% discount rate (table 11 of this document).	FDA's best estimate from data and life expectancy calculations.	Published data, Ref. 134
Value of Statistical Life Year (VSLY).	\$100,000; \$300,000; \$500,000 (table 11 of this document).	Data and FDA's best estimate from available data.	\$100,000 from Refs. 77 and 68; \$300,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 3%; \$500,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 7% (Ref. 159).
Value of Statistical Life (VSL).	\$5 million; \$6.5 million (table 11 of this document).	Data.	General VSL literature (Ref. 159).

### G. Peer Review

FDA submitted this economic analysis to the Interagency Economic Peer Review (IEPR) for peer review. The IEPR is a voluntary review process composed of, but not limited to, Federal economists and analysts who review Regulatory Impact Analyses and Regulatory Flexibility Analyses prior to OMB clearance to improve the quality of economic analysis.

Two Federal economists reviewed this analysis. Their specific comments and FDA's responses are detailed in Ref. 155. FDA made the following changes to the analysis in response to the comments of the reviewers:

- Added several sections to repeat information contained in the analysis that accompanied the proposal to provide more background and context for the reader,

- Made some style changes for clarity,
- Added explanations for how some numbers were calculated,
- Added references for the European market experience with margarine reformulation,
- Addressed the comments on costs more explicitly,
- Explained why the costs of reformulation are included in the analysis,
- Added an introduction describing the plan of the benefits model and the linkages between the various parts of the model,
- Corrected our description of study subjects in the 1994–1996 Diet and Health Knowledge Survey (DHKS) in discussing Ref. 119.

## **X. Final Regulatory Flexibility Analysis**

### *A. Introduction*

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this final rule would have a significant economic impact on a substantial number of small entities.

### *B. Economic Effects on Small Entities*

#### 1. Number and Type of Small Entities Affected

FDA used data from the 1999 County Business Patterns (Ref. 136) to estimate the number of small businesses affected by this rule. Table 13 shows the number of small businesses affected by the North American Industry Classification System (NAICS). The final rule will affect almost all

manufacturers of packaged, labeled food sold in the United States, with the exception of exempt manufacturers. The criteria for exemption are: (1) Annual sales of fewer than 100,000 units; (2) no claims or other nutrition information on product labels, labeling, or advertising; (3) fewer than 100 full-time employees; and (4) filing of a notice with the Office of Food Labeling (§ 101.9(j)(18) 2002). FDA has previously estimated that the exemption for all foods would affect about 1.8 percent of FDA regulated foods by volume (see 58 FR 2927 at 2928, January 6, 1993). FDA estimated the effects of exemptions only for the total costs to small businesses.

TABLE 13.—NUMBER OF SMALL ESTABLISHMENTS BY NAICS CODE

Category Description	NAICS Code	No. of Establishments
Rice	311212	60
Refined or Blended Fats and Oils	311225	140
Breakfast Cereals and Related Products	311230	60
Chocolate and Confectionery Products Made from Cacao Beans	311320	150
Nonchocolate Confectionery Products	311340	590
Frozen Fruits and Vegetables	311411	230
Frozen Specialties, NEC	311412	380
Specialty Canned Food	311422	140
Dried and Dehydrated Foods	311423	180
Fluid Milk	311511	570
Creamery Butter	311512	30
Cheese	311513	520
Dry, Condensed and Evaporated Milk	311514	210
Ice Cream and Frozen Desserts	311520	420
Fresh and Frozen Seafood	311712	660
Commercial Bakery Products	311812	2760
Frozen Bakery Products	311813	230
Cookies and Crackers	311821	390
Flour Mixes and Dough Made from Purchased Powder	311822	230
Other Snack Foods	311919	400
Mayonnaise, Dressings and Other Prepared Sauces	311941	340
Spices and Extracts	311942	280
Perishable Prepared Food	311991	480
All Other Miscellaneous Food Preparations	311999	850
Pharmaceutical Preparations (NAICS classification for dietary supplements)	325412	880
Total		11,180

## 2. Costs to Small Entities

FDA calculated the costs to small businesses with the same basic model that we used in section IX.D of this document to estimate the total costs. Although the basic model is the same for large and small firms, the individual components of costs differ for large and small firms. On average, small firms produce fewer products, and market fewer labels. FDA assumes that the estimated margarine reformulation will be done by large producers.

FDA estimated the total costs of the final rule to small business by estimating the individual categories of costs and summing them. The first category is testing costs. Small businesses would need to test their products to determine the amounts of *trans* fats. FDA did not have direct estimates of the number of products produced by the small businesses affected by the final rule. FDA estimated the number of products produced by small businesses by using a sample from the Enhanced Establishment Database (EED) and assuming that the proportion of all products produced by small businesses was the same as the sample proportion (85 percent). FDA then multiplied the 60,000 products estimated to be tested (table 3 of this document) by the proportion of products produced by small businesses (85 percent) to estimate that 51,000 products will be tested by small businesses. Table 14 shows the range of testing costs for all small businesses.

TABLE 14.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS FOR SMALL BUSINESSES

	Low	Medium	High
Cost per Product	\$261	\$291	\$371
Total Testing Cost	\$13,311,000	\$14,841,000	\$18,921,000

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 re-estimate the relabeling costs of this final rule. FDA estimated reprinting costs for information panels on a per label (SKU) basis. FDA assumed that the

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	\$11,870,000	\$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	\$7,819,000
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 neither 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 BUSINESS

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)

place no claims or other nutrition information on product labels, labeling, or advertising would already be exempt from this final rule.

## 2. Longer Compliance Period for Small Businesses

Longer compliance periods provide regulatory relief for small businesses. Some comments requested that the compliance period be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Some small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs, including, loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow them to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. This should be long enough for most small businesses to coordinate the label change for this rule with other label changes and reprinting. However, in this final rule, FDA has decided not to extend the compliance period for small businesses beyond what is given for all businesses. Because this final

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) of the act 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 percent 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 percent. Using Method 2 for calculating benefits, small businesses would only need to account for production of at least 11 percent 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 percent 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.

## **XI. Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than \$100 million in 1 single year. The final rule qualifies as a significant rule under the statute. FDA has carried out the cost- benefit analysis in sections IX.C and IX.D of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule’s effects on the following:

1. Future costs;
2. Particular regions, communities, or industrial sectors;
3. National productivity and economic growth;
4. Full employment and job creation; and,
5. Exports.

### *A. Future Costs*

Most of the costs of this rule will be incurred during the compliance period. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

### *B. Particular Regions, Communities, or Industrial Sectors*

The final rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long run increase in the costs of food production would largely be passed on to the entire population of consumers.

### *C. National Productivity and Economic Growth*

The final rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The

diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be significant, both productivity and economic growth would be higher than in the absence of the rule. In section IX.C.3 of this document, FDA estimated benefits from the reduction in functional disability associated with a reduction in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

#### *D. Full Employment and Job Creation*

The human resources devoted to producing certain foods would be redirected by the final rule. The final rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

#### *E. Exports*

Because the final rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the final rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain lower amounts of partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Products in Germany and certain other European countries, for example, currently use partially hydrogenated oils to a lesser degree than in the United States, so the final rule could make U.S. exports

of margarine more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unreformulated products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

## **XII. Environmental Impact**

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 62746, November 17, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

## **XIII. Paperwork Reduction Act**

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Food Labeling; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims.

*Description:* Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the Nutrition Facts panel disclose information on the amounts of fat and certain fatty acids in the food product. This final rule establishes

§ 101.9(c)(2)(ii) to require that the Nutrition Facts panel disclose information on the amount of *trans* fat in the food product. Similarly, under the provisions of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b)(2) that specify the nutrition information that must be on the label or labeling of dietary supplements. This final rule establishes § 101.36(b)(2) (21 CFR 101.36(b)(2)) to specify that when nutrition information is declared on the label and in labeling, it must include the amount of *trans* fat.

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<sup>1</sup>

21 CFR Section	No. of Respondents	Responses per Respondent	Total No. 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

<sup>1</sup> There 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.

Multiplying the total number of responses by the hours per response gives the total hours. FDA has estimated operating costs by combining the medium testing and relabeling costs from table 7 of this document (\$44.9 million + \$126.8 million for relabeling) to get the total operating cost. This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expects that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by this final rule with other planned labeling changes for their products.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### **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 section 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) of the act. 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) of the act (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.

## **XV. References**

The following references have been placed in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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16. Aro, A., A. F. M. Kardinaal, I. Salminen, et al., "Adipose Tissue Isomeric *Trans* Fatty Acids and Risk of Myocardial Infarction in Nine Countries: The EURAMIC Study," *Lancet*, 345:273–278, 1995.
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158. U.S. Census Bureau, Statistical Abstract of the United States, pp. 413–416 and 436, 2002.

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160. Alberini, A., M. Cropper, A. Krupnik, et al., “Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada,” *Resources for the Future*, pp. 1–34, April 2002.

### **List of Subjects in 21 CFR 101**

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

### **PART 101—FOOD LABELING**

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

■ 2. Section 101.9 is amended by:

- a. Redesignating paragraphs (c)(2)(ii) and (c)(2)(iii) as (c)(2)(iii) and (c)(2)(iv),
- b. Adding new paragraph (c)(2)(ii), and
- c. Revising paragraphs (c)(2)(i), (d)(1)(ii)(A), the first sentence of paragraph (f), the first sentence of paragraph (g)(5), the second sentence of paragraph (g)(6), and the sample labels in paragraphs (d)(11)(iii), (d)(12), (d)(13)(ii), (e)(5), (j)(13)(ii)(A)(1), and (j)(13)(ii)(A)(2).

■ The revisions and additions are to read as follows:

**§ 101.9 Nutrition labeling of food.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) “Saturated fat,” or “Saturated”: A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if “calories from saturated fat” is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement “Not a significant source of saturated fat” shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (1/2) gram increment below 5 grams and to

the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) “*Trans fat*” or “*Trans*”: A statement of the number of grams of *trans fat* in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration, except that label declaration of *trans fat* content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content. The word “*trans*” may be italicized to indicate its Latin origin. *Trans fat* content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the *trans fat* content is not required and, as a result, not declared, the statement “Not a significant source of *trans fat*” shall be placed at the bottom of the table of nutrient values.

\* \* \* \* \*

(d)(1) \* \* \*

(ii) \* \* \*

(A) Except as provided for in paragraph (c)(2)(ii) of this section, a single easy-to-read type style,

\* \* \* \* \*

(11) \* \* \*

(iii) \* \* \* [insert revised label]

(12) \* \* \* [insert revised label]

(13) \* \* \*

(ii) \* \* \* [insert revised label]

\* \* \* \* \*

(e) \* \* \*

(5) \* \* \* [insert revised label]

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; \* \* \*

\* \* \* \* \*

(g) \* \* \*

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. \* \* \*

(6) \* \* \* Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

\* \* \* \* \*

(j) \* \* \*

(13) \* \* \*

(ii) \* \* \*

(A) \* \* \*

(1) \* \* \* [insert revised label]

(2) \* \* \* [insert revised label]

\* \* \* \* \*

■ 3. Section 101.36 is amended by revising paragraph (b)(2)(i) to read as follows:

101.9(d)(11)(iii)

# Nutrition Facts

Serving Size 2 slices (56g)  
 Servings Per Container 10

**Calories 140**  
 Calories from Fat 15

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
<b>Total Fat</b> 1.5g	<b>2%</b>	<b>Total Carbohydrate</b> 26g	<b>9%</b>
Saturated Fat 0.5g	3%	Dietary Fiber 2g	8%
Trans Fat 0.5g		Sugars 1g	
<b>Cholesterol</b> 0mg	<b>0%</b>	<b>Protein</b> 4g	
<b>Sodium</b> 280mg	<b>12%</b>		
Vitamin A 0%	• Vitamin C 0%	• Calcium 6%	• Iron 6%
Thiamin 15%	• Riboflavin 8%	• Niacin 10%	

\* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

101.9(d)(12)

<b>Nutrition Facts</b>	
Serving Size 1 cup (228g)	
Servings Per Container 2	
<b>Amount Per Serving</b>	
<b>Calories</b> 260	Calories from Fat 120
<b>% Daily Value*</b>	
<b>Total Fat</b> 13g	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<i>Trans</i> Fat 2g	
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 660mg	<b>28%</b>
<b>Total Carbohydrate</b> 31g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein</b> 5g	
Vitamin A 4%	• Vitamin C 2%
Calcium 15%	• Iron 4%
*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:	
	Calories: 2,000    2,500
Total Fat	Less than 65g    80g
Sat Fat	Less than 20g    25g
Cholesterol	Less than 300mg    300mg
Sodium	Less than 2,400mg    2,400mg
Total Carbohydrate	300g    375g
Dietary Fiber	25g    30g
Calories per gram:	
Fat 9	• Carbohydrate 4 • Protein 4

101.9(d)(13)(ii)

<b>Nutrition Facts</b>	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
	(35g)	1	(19g)	1	(27g)	1
<b>Amount Per Serving</b>						
<b>Calories</b>	130		70		100	
Calories from Fat	0		0		0	
	<b>% Daily Value*</b>		<b>% Daily Value*</b>		<b>% Daily Value*</b>	
<b>Total Fat</b>	0g	<b>0%</b>	0g	<b>0%</b>	0g	<b>0%</b>
Saturated Fat	0g	<b>0%</b>	0g	<b>0%</b>	0g	<b>0%</b>
Trans Fat	0g		0g		0g	
<b>Cholesterol</b>	0mg	<b>0%</b>	0mg	<b>0%</b>	0mg	<b>0%</b>
<b>Sodium</b>	0mg	<b>0%</b>	200mg	<b>8%</b>	120mg	<b>5%</b>
<b>Potassium</b>	125mg	<b>4%</b>	25mg	<b>1%</b>	30mg	<b>1%</b>
<b>Total Carbohydrate</b>	29g	<b>10%</b>	17g	<b>6%</b>	24g	<b>8%</b>
Dietary Fiber	3g	<b>12%</b>	1g	<b>4%</b>	1g	<b>4%</b>
Sugars	8g		6g		13g	
<b>Protein</b>	4g		1g		1g	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:						
Calories 2,000 2,500						
Total Fat	Less than 65g	80g				
Sat Fat	Less than 20g	25g				
Cholesterol	Less than 300mg	300mg				
Sodium	Less than 2,400mg	2,400mg				
Potassium	3,500mg	3,500mg				
Total Carbohydrate	300g	375g				
Dietary Fiber	25g	30g				
Vitamin A	0%		10%		10%	
Vitamin C	0%		15%		90%	
Calcium	0%		0%		0%	
Iron	10%		6%		20%	
Thiamin	30%		15%		20%	
Riboflavin	30%		15%		20%	
Niacin	30%		15%		20%	
Vitamin B <sub>6</sub>	30%		15%		20%	

101.9(e)(5)

<b>Nutrition Facts</b>			
Serving Size 1/12 package (44g, about 1/4 cup dry mix)			
Servings Per Container 12			
Amount Per Serving	Mix	Baked	
<b>Calories</b>	190	280	
Calories from Fat	45	140	
<b>% Daily Value**</b>			
<b>Total Fat 5g*</b>	<b>8%</b>	<b>24%</b>	
Saturated Fat 2g	10%	13%	
Trans Fat 1g			
<b>Cholesterol 0mg</b>	<b>0%</b>	<b>23%</b>	
<b>Sodium 300mg</b>	<b>13%</b>	<b>13%</b>	
<b>Total Carbohydrate 34g</b>	<b>11%</b>	<b>11%</b>	
Dietary Fiber 0g	0%	0%	
Sugars 18g			
<b>Protein 2g</b>			
Vitamin A	0%	0%	
Vitamin C	0%	0%	
Calcium	6%	8%	
Iron	2%	4%	
* Amount in Mix			
** Percent Daily Values are based on a 2,000 calorie diet Your Daily Values may be higher or lower depending on your calorie needs:			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

**§ 101.36 Nutrition labeling of dietary supplements.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) The (b)(2)-dietary ingredients to be declared, that is total calories, calories from fat, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c) of this part.

\* \* \*

\* \* \* \* \*

■ 4. Appendix B to Part 101 is amended by revising the sample label following the list of examples to read as follows:

**Appendix B to Part 101—Graphic Enhancements Used by the FDA**

\* \* \* \* \*

[insert revised label and graphics]

101.9(j)(13)(ii)(A)(1)

<b>Nutrition Facts</b>		<b>Amount/serving</b>	<b>%DV*</b>	<b>Amount/serving</b>	<b>%DV*</b>
Serving Size 1/3 cup (56g)		<b>Total Fat</b> 2g	<b>3%</b>	<b>Total Carb.</b> 0g	<b>0%</b>
Servings about 3		Sat. Fat 1g	<b>5%</b>	Fiber 0g	<b>0%</b>
<b>Calories</b> 90		<i>Trans</i> Fat 0.5g		Sugars 0g	
Fat Cal. 20		<b>Cholest.</b> 10mg	<b>3%</b>	<b>Protein</b> 17g	
		<b>Sodium</b> 200mg	<b>8%</b>		
*Percent Daily Values (DV) are based on a 2,000 calorie diet.		Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%			

101.9(j)(13)(ii)(A)(2)

**Nutrition Facts** Serv. Size: 1 package, Amount Per Serving:  
**Calories** 45, Fat Cal. 10, **Total Fat** 1g (2% DV), Sat. Fat 0.5g (3% DV), *Trans* Fat 0.5g,  
**Cholest.** 0mg (0% DV), **Sodium** 50mg (2% DV), **Total Carb.** 8g (3% DV), Fiber 1g  
(4% DV), Sugars 4g, **Protein** 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium  
(0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.

Part 101, App. B

Examples of Graphic Enhancements used by the FDA

Annotations on the left side of the label:

- Helvetica Regular 8 point with 1 point of leading
- 3 point rule
- 8 point Helvetica Black with 4 points of leading
- 1/4 point rule centered between nutrients (2 points leading above and 2 points below)
- 8 point Helvetica Regular with 4 points of leading
- 8 point Helvetica Regular, 4 points of leading with 10 point bullets.

Annotations on the right side of the label:

- Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point
- 7 point rule
- 6 point Helvetica Black
- All labels enclosed by 1/2 point box rule within 3 points of text measure
- 1/4 point rule
- Type below vitamins and minerals (footnotes) is 6 point with 1 point of leading

Amount Per Serving	
<b>Calories</b> 260	Calories from Fat 120
% Daily Value*	
<b>Total Fat</b> 13g	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
Trans Fat 2g	
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 660mg	<b>28%</b>
<b>Total Carbohydrate</b> 31g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein</b> 5g	
Vitamin A 4%	Vitamin C 2%
Calcium 15%	Iron 4%
*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g

Dated: May 7, 2003  
May 7, 2003.



Mark B. McClellan,  
Commissioner of Food and Drugs.

Dated: JUL 2 2003  
July 2, 2003.



Tommy G. Thompson,  
Secretary of Health and Human Services.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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