

studies, that the CHD risk associated with *trans* fat in the prospective studies is much greater than the CHD risk expected due to either Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C). In the 14-year followup of the Nurses Health Study (Ref. 38), the increased risk of CHD associated with *trans* fat intake compared with carbohydrate intake was more than ten times the increased risk for the same amount of saturated fat compared with carbohydrate. This comparison between *trans* fat and saturated fat was in contrast to the prediction based on Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C). In Method 1, *trans* fat would be predicted to be associated with about the same increased risk as saturated fat, and in Method 2, *trans* fat would be predicted to be associated with about twice as much increased risk as saturated fat, comparing both with carbohydrate. This comparison was within a single study, so the difference between the results of this study and what would have been expected due to Method 1 or 2 cannot be attributed to any differences in baseline risk between studies. Moreover, although participants in large prospective studies have different baseline risks of CHD, the increased risk associated with known risk factors is often reasonably consistent across many of the studies. For example, the increased CHD risk associated with saturated fat for female nurses from 1980 to 1994 (Ref. 38) was quite similar to that for male employees of Western Electric Co. from 1958 to 1976 (Ref. 67) (64 FR 62746 at 62771). The changes in CHD risk associated with total cholesterol and HDL-C for male physicians from 1982 to 1987 was comparable to that for men and women from Framingham, MA in the 1970s (Ref. 131).

(P) 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

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*trans* fat contributes to CHD risk. However, as discussed previously in this section, and in the November 1999 proposal (64 FR 62746 at 62771), FDA did not use the results of the prospective studies in its quantitative estimate of the health benefits of *trans* fat labeling. The sole use of the prospective studies was to suggest that there may be additional mechanisms by which *trans* fat contributes to CHD. The prospective studies thus indicate the direction of the uncertainty in the benefits estimate: That the actual benefits may be higher than the benefits estimated using Methods 1 and 2.

In response to the comments about the Ascherio et al. regression equation as discussed in the IOM/NAS report (Ref. 140), FDA notes that according to the NEJM, all submissions to the journal are peer-reviewed before publication. The comments did not cite any published articles questioning the 1999

Ascherio et al. paper (Ref. 83), and did not submit data from the unpublished work that the comments asserted could provide an alternate explanation for the Ascherio et al. results. As noted in section IV of this document, the paper by Ascherio et al. is not the only information that the IOM/NAS used in concluding that *trans* fatty acid consumption should be as low as possible ~~in~~ while consuming a nutritionally adequate diet

~~in order to decrease CHD risk~~ (see comment 3). Additionally, the Ascherio paper is not the only information in the IOM/NAS report that supports a positive linear trend for *trans* fat intake and LDL-C and risk of CHD. For example, as mentioned previously in this section (see comment 39), the study of Lichtenstein et al. (Ref. 82), using six test diets at different levels of *trans* fat intake, found a positive linear trend for *trans* fat intake and LDL-C level. In discussing *trans* fat intake and HDL-C, the IOM/NAS report references work by Zock, Mensink, and Katan (Refs. 69 and 154). These papers pertain not only to HDL-C but also to LDL-C. The work of Zock and colleagues (Refs. 62, 69,

consistent with the conclusions of the IOM/NAS (Ref. 140). As discussed in the IOM/NAS report, the existence of a linear trend of saturated fat and LDL-C is very well-established, as shown by three sets of regression equations described in the IOM/NAS report (Ref. 140, Figure 8-3, pp. 8-47 to 8-48). Thus, the existence of a positive linear trend for *trans* fat intake and LDL-C, as shown by a body of research (Refs. 62, 69, 82, 83, 130, and 154) and recognized by the IOM/NAS (Ref. 140) is not unusual, considering that there is also a positive linear trend between saturated fat intake and LDL-C. Therefore, FDA is not convinced by the comments questioning the existence of linear trends between *trans* fat and lipid levels. FDA finds that, for the purposes of economic analysis, it is appropriate to quantify<sup>fy</sup> the health benefits of *trans* fat labeling using regression equations (Refs. 62 and 69) describing a positive linear trend between *trans* fat intake and LDL-C and a negative linear trend between *trans* fat intake and HDL-C.

(Comment 42) One comment stated that FDA's estimate of benefits of the November 1999 proposal neglected to account for the overall reductions of mortality and morbidity from heart disease that have been occurring in the 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

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) 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 shown in table 10. *Insert 91-1 New FD* *changes in CHD risk*

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%
			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.

*Substitution from probabilistic model*

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

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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 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 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.~~

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.

~~<sup>3</sup>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.~~

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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. 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. <sup>(240 deaths x 8 years)</sup> 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. <sup>(480 deaths x 8 years)</sup> Because the association between *trans*

<sup>deaths</sup>  
(480 ~~years~~ x 8 years)

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.

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b. *Value of CHD morbidity and mortality prevented.* In the proposed analysis, the per case valuations of morbidity and mortality prevented were estimated. There was no controversy over these estimates. The average cost per fatal case of CHD is about \$836,000. The average cost per nonfatal case is about \$281,000.

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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. Because these benefits occur at different times and recur annually, they must be discounted to the time of publication of this final rule. Table 11 shows the timing of the undiscounted expenditures and the present value (discounted at 7 percent) of the costs at the time of publication of the final rule. Because benefits continue in perpetuity, the present value calculation has been made of an infinite stream of benefits discounted at 7 percent.

TABLE 11.—TIMING OF UNDISCOUNTED BENEFITS AND PRESENT VALUE OF BENEFITS (DISCOUNTED AT 7 PERCENT)

	Year 3 and Annually After the Effective Date	Present Value as of the Effective Date
Method 1	\$234 million	\$4.1 billion
Method 2	\$476 million	\$8.3 billion

*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. Although the rule will generate high setup costs, the later benefits should dwarf those costs. 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

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 at <sup>3</sup>7 percent), the medium cost estimate in table 12 comes to about \$<sup>12</sup>16 million per year. With Method 1, the cost per life year saved would be \$<sup>6</sup>10,000 (<sup>12</sup>\$16 million/<sup>2</sup>1,600 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						Infinite Stream	
		2	3	4	5	6	7		
<b>Costs</b>									
Low		\$105	none	none	none	none	none	...	\$100
Medium		\$165	none	none	none	none	none	...	\$150
High		\$255	none	none	none	none	none	...	\$255
<b>Benefits</b>									
Method 1	Annual	none	none	none	\$234	\$240	\$205	...	\$603
	Cumulative				\$234	\$474	\$679	...	\$4,400
Method 2	Annual	none	none	none	\$470	\$410	\$410	...	\$1,230
	Cumulative				\$470	\$922	\$1,332	...	\$8,345

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 - Above table 1: 139, 185, 275  
 - Above table 2: 968, 940, 913, 13, 130  
 - Above table 3: 1973, 1910, 3889, 1860, 5748  
 - Above table 4: 275

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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,

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b. *Value of CHD morbidity and mortality prevented.* **FDA 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 the 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. 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 ( $(\$51.1 \text{ billion} - \$25 \text{ billion}) / 13.9 \text{ million}$ ). FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

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 this case the average cost per nonfatal case was estimated at about \$281,000.

In the first approach FDA uses a range to estimates of 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 Aldy and Viscusi (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.— ANNUAL BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	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	1,920	3,840	\$192	\$384	234	477
\$300,000 (VSL=\$6.5 million, discount rate=3%)			\$576	\$1,152	968	1973
\$500,000 (VSL=\$6.5 million, discount rate=7%)			\$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. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks. (Ref. 159 and Ref. 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 Aldy and Viscusi 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.— ANNUAL 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

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*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

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 <sup>1,100</sup>~~\$250~~ and the average high relabeling cost per SKU is <sup>2,600</sup>~~\$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 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	Low	Medium	High
Baked Goods	\$5,760,000	\$6,968,000	\$15,822,000
Baking Ingredients	\$807,000	\$1,274,000	\$2,167,000
Baby Foods	\$51,000	\$78,000	\$128,000
Selected Beverages	\$15,828,000	\$20,459,000	\$27,941,000
Breakfast Foods	\$422,000	\$696,000	\$1,194,000
Selected Candy	\$1,215,000	\$1,915,000	\$3,161,000
Selected Condiments, Dips and Spreads	\$3,438,000	\$4,898,000	\$7,180,000
Dairy Foods	\$6,102,000	\$9,456,000	\$15,041,000
Desserts	\$1,604,000	\$2,597,000	\$4,409,000
Dietary Supplements	\$9,303,000	\$13,882,000	\$23,150,000
Selected Dressings and Sauces	\$1,848,000	\$2,800,000	\$4,238,000
Eggs	\$1,286,000	\$1,923,000	\$3,447,000
Entrees	\$1,205,000	\$1,892,000	\$3,065,000
Fats and Oils	\$647,000	\$1,020,000	\$1,561,000
Fruits and Vegetables	\$7,839,000	\$11,062,000	\$16,797,000
Seafood	\$1,167,000	\$1,682,000	\$2,446,000
Side Dishes and Starches	\$1,796,000	\$2,897,000	\$4,904,000
Snack Foods	\$1,967,000	\$2,987,000	\$4,821,000
Soups	\$783,000	\$1,105,000	\$1,621,000
Weight Control Foods	\$109,000	\$164,000	\$279,000
Total	\$63,177,000	\$91,775,000	\$143,372,000

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 ~~\$10,000~~.

12,000

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TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	\$13,311,000	\$14,841,000	\$18,921,000
Relabeling	\$65,177,000	\$91,775,000	\$143,372,000
Total	\$76,488,000	\$106,616,000	\$162,293,000
Adjustment for Exemption	-\$2,120,000	-\$ 3,260,000	-\$5,100,000
Adjusted Total	\$74,000,000	\$103,000,000	\$157,000,000

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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 \$<sup>130</sup>~~103~~ million as a result of the final rule, an average of \$<sup>12,000</sup>~~10,000~~ per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of \$<sup>12,000</sup>~~10,000~~ 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)

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 Particular Products Produced by Small Entities

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In the category of breakfast foods, the average intake of *trans* fat for both men and women is less than one-tenth of a gram per day. Because the entire category contributes so little to the overall dietary intake of *trans* fats, exempting small businesses in this category from the rule would have small effects on health. The exemption, however, would provide regulatory relief for approximately 60 small businesses (including cereal and frozen breakfast foods). The total burden on small businesses would fall by \$871,000 (the sum of \$696,000 relabeling costs and \$175,000 testing costs for 600 products). The relief offered by this option, then, would be small.

An objection to this option for regulatory relief is that by exempting an entire class of products, FDA could create incentives for small firms to create products in that category. These new products would have no effective limits

on *trans* fat. The exemption would therefore allow small firms to develop products with high *trans* fat content but no indication of that content on the label. The contribution of breakfast cereals to total dietary intake of *trans* fats could increase because of the exemption. The most telling objection to this option is that exempting some products from the final labeling rule would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would contradict the intent of the 1990 amendments. It would undermine the policy goal of providing consistent nutrition information to consumers.

#### *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 \$<sup>96</sup>~~74~~ and \$<sup>184</sup>~~157~~ million, or about \$<sup>9,300</sup>~~7,200~~ to \$<sup>17,900</sup>~~15,200~~ 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

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	26	270,200	2	540,400	\$130,300
101.36(b)(2)	910	32	29,500	2	59,000	\$12,900
Totals					599,400	\$143,200

<sup>1</sup> There are no capital costs and or maintenance costs associated with this collection of information

See Insert p. 208

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.

(INSERT p. 208)

17 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 (\$17.5 million +

44.9

\$17.5 million +

126.8

for relabeling

\$125.7 million) 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. FDA expects that, with a compliance period of over 2 years, firms will

coordinate labeling revisions required by this final rule with other planned

labeling for its 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 notice 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

New Federalism section Insert 209-210

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 403(A) of the act (21 U.S.C. 343-1) is an express preemption provision. That section prohibits a "State or political subdivision of a State to 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). One such prohibition, that is relevant to this final rule,

same

is any requirement for nutrition labeling of food that is "not identical to the requirement of section 403(q) \* \* \*". Although this rule has preemptive effect in that it would preclude States from issuing regulations that are not identical to the *trans* fat labeling required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403(A) of the act.

Insert 210-1

\* \* \*

^ A

(or adopting or enforcing any requirements)

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's regulatory objective. Further, section 4(e) provides that "when an agency proposed 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**. There were eight comments from State and local governmental entities received and 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 option.

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

150. Pepsico Inc., Press Release, "Frito-Lay Eliminates *Trans* Fats From America's Favorite Salty Snacks: Doritos, Tostitos and Cheetos, 2002.

151. Fischer, K., "Sorting Fat From Fiction," *Prepared Foods*, October, 2002, pp. 39-44.

152. Schakel, S. F., L. Harnack, C. Wold, et al., "Incorporation of *trans*-Fatty Acids into a Comprehensive Nutrient Database," *Journal of Food Composition and Analysis*, 12:323-331, 1999.

153. Bialostosky, K., J. D. Wright, J. Kennedy-Stephenson, et al., "Dietary Intake of Macronutrients, Micronutrients, and Other Dietary Constituents: United States, 1988-94," National Center for Health Statistics: Vital and Health Statistics, series 11, no. 245, 2002, pp. 1-9, 84-85, and 150-158.

154. Zock, P. L. and R. P. Mensink, "Dietary *trans*-Fatty Acids and Serum Lipoproteins in Humans," *Current Opinions in Lipidology*, 7:34-37, 1996.

155. Memo to file from D. Zorn, Comments and responses to comments from Interagency Economic Peer Review, 2002.

➤ 156. Letter to file from J. D. Graham to T. G. Thompson,  
List of Subjects in 21 CFR 101 Sept 18, 2001

RES:  
SECY  
THOMPSON

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