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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, (on) 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.

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"OR"

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.

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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.~~ 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.

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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

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cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at \$14.73 per hour) and delivery charges for one two-pound package delivered overnight (at \$26.30). The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible. The model reports a range of testing costs for *trans* fat given in table

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TABLE 4.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	\$261	\$291	\$371
Total Testing Cost	\$15,000,000	\$17,480,000	\$22,250,000

\$ 44,930,000

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\$ 40,298,000

\$ 57,282,000

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

### 3. Relabeling Costs

In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of \$30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. Based

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on information in the model, three-quarters of the labels normally will be scheduled to be changed during the 30 month compliance period. FDA estimates that about 78,000 (25 percent) of the almost 308,000 SKUs will have to be changed earlier than would have been planned without this rule.

Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing and engraving, and the lost value of discarded labels.

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

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*switch column headings*

TABLE 5.—RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

SKUs Changed	Product Categories	Low	Medium	High
Baked Goods	12,500	\$10,941,000	\$18,137,000	\$27,231,000
Baking Ingredients	1,700	\$1,615,000	\$2,380,000	\$3,899,000
Baby Foods	200	\$184,000	\$249,000	\$404,000
Selected Beverages	9,000	\$11,871,000	\$16,659,000	\$25,437,000
Breakfast Foods	1,000	\$801,000	\$1,237,000	\$2,044,000
Selected Candy	4,100	\$4,801,000	\$6,974,000	\$10,846,000
Selected Condiments, Dips and Spreads	3,700	\$4,026,000	\$5,970,000	\$8,283,000
Dairy Foods	8,700	\$10,744,000	\$18,025,000	\$25,032,000
Desserts	3,500	\$2,762,000	\$4,263,000	\$7,042,000
Dietary Supplements	8,100	\$13,449,000	\$20,110,000	\$34,041,000
Selected Dressings and Sauces	2,800	\$2,908,000	\$4,352,000	\$6,757,000
Eggs	2,400	\$1,983,000	\$2,898,000	\$5,086,000
Entrees	2,400	\$2,012,000	\$3,078,000	\$5,032,000
Fats and Oils	800	\$759,000	\$1,160,000	\$1,848,000
Fruits and Vegetables	7,500	\$7,426,000	\$10,915,000	\$17,882,000
Seafood	1,400	\$1,732,000	\$2,541,000	\$3,786,000
Side Dishes and Starches	4,100	\$3,361,000	\$5,124,000	\$8,494,000
Snack Foods	3,600	\$3,604,000	\$5,288,000	\$8,499,000
Soups	700	\$809,000	\$1,194,000	\$1,854,000
Weight Control Foods	200	\$198,000	\$283,000	\$489,000