

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