

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
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.