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F. Overview of Benefits and Costs

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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 | |
| Costs | | | | | | | | | |
| Low | | \$139 | none | none | none | none | none | ... | \$139 |
| Medium | | \$185 | none | none | none | none | none | ... | \$185 |
| High | | \$275 | none | none | none | none | none | ... | \$275 |
| Benefits | | | | | | | | | |
| 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.

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

of per Barb Sntk 7-8 CL 1

(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 excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat,~~

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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:

§ 101.36 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.

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■ 4. Appendix B to Part 101 is amended by revising the sample label ~~showing~~ ^{to read} graphic enhancements ~~used by FDA~~ as follows:

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

* * * * *
[insert revised label and graphics]

following the list of examples

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