

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates (Docket No. FDA-2012-N-1210 and FDA-2004-N-0258 (Formerly Docket No. 2004N-0456))

**PRELIMINARY REGULATORY IMPACT ANALYSIS
PRELIMINARY REGULATORY FLEXIBILITY ANALYSIS**

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Executive Summary

The Food and Drug Administration (FDA or we) is proposing to extend the compliance dates by approximately 1.5 years for provisions in the Nutrition Facts Label Final Rule (81 FR 33742) and the Serving Size Final Rule (81 FR 34000). FDA is proposing to extend the compliance dates in response to the receipt of information demonstrating that extending the compliance dates would help provide for adequate time to fully implement the provisions of the Nutrition Facts Label and Serving Size Final Rules. Because the compliance dates would be extended by approximately 1.5 years, the discounted value of the estimated costs and benefits of the Nutrition Facts Label and Serving Size Final Rules would be reduced. This proposed rule to extend the compliance dates would *reduce the costs to food manufacturers*. We estimate that, at the mean, the present value of the cost savings (i.e., benefits) to industry of this proposed rule over the next 20 years is \$1.0 billion using a 3 percent discount rate and \$1.0 billion using a 7 percent discount rate (2016\$). The *foregone benefits to consumers* is the principal “cost” of this proposed rule. We acknowledged in the Regulatory Impact Analysis for the Final Rules that there were potential shortcomings related to our estimates of the Rules’ benefits, but public comments have not offered any additional data or information to improve the estimation of benefits. For purposes of this Preliminary Regulatory Impact Analysis, we will thus continue to use the benefit estimates from the Final Rules. We estimate that, at the mean, the present value of the foregone benefits to consumers of this proposed rule over the next 20 years is \$0.9 billion using a 3 percent discount rate and \$0.9 billion using a 7 percent discount rate (2016\$). We estimate that, at the mean, the present value of the net benefits (cost savings minus foregone benefits) of this proposed rule over the next 20 years is \$0.1 billion using a 3 percent discount rate and \$0.1 billion using a 7 percent discount rate (2016\$).

I. Introduction and Summary of Foregone Benefits to Consumers and Cost Savings to Industry

A. Introduction

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed an Economic Analysis of Impacts that assesses the impacts of this proposed rule, including cost savings to industry and foregone benefits to consumers. We believe that this proposed rule would be a significant regulatory action as defined by Executive Order 12866 and a deregulatory action for purposes of Executive Order 13771.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule reduces the burden on food manufacturers by extending the compliance dates for the final rules titled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (the Nutrition Facts Label Final Rule) and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (the Serving Size Final Rule), we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The threshold after adjustment for inflation is \$148 million, using the 2016 Implicit Price Deflator for the Gross Domestic Product. We have determined that this proposed rule would not result in any one-year expenditure that will meet or exceed this amount.

B. Summary of Foregone Benefits to Consumers and Cost Savings to Industry

This proposed rule would extend the compliance dates by approximately 1.5 years for provisions in the Nutrition Facts Label and Serving Size Final Rules. FDA is proposing to take this action in response to requests for an extension and to provide for adequate time to fully implement the provisions of the Nutrition Facts Label and Serving Size Final Rules.

The principal benefit of this proposed rule would be *the reduction in the costs to food manufacturers* related to extending the compliance dates by approximately 1.5 years of the Nutrition Facts Label and Serving Size Final Rules. This reduction in costs can be attributed to a reduction in relabeling and reformulation costs. We estimate that, at the mean, the present value of the cost savings to industry of this proposed rule over the next 20 years would be \$1.0 billion using a 3 percent discount rate and \$1.0 billion using a 7 percent discount rate (2016\$). This is illustrated in Table 1.

The principal cost of this proposed rule would be the *reduction in benefits to consumers* associated with extending the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. Extending the compliance dates by approximately 1.5 years would reduce the estimated benefits of the Nutrition Facts Label and Serving Size Final Rules because it would delay the realization by consumers of the full annual welfare gains of the Nutrition Facts Label and Serving Size Final Rules. In the Original RIA, we acknowledged certain shortcomings related to the estimated benefits of the Final Rules and sought comment on those issues. *See* 2016 Regulatory Impact Analysis at 79 n.34. The public comments did not provide us with additional information or guidance that would have allowed us to estimate a more reliable and objective measure of benefits. In the absence of additional data or information, we use the same methodology for calculating costs and benefits here that we used in the Original RIA. However, we renew our request for comments about whether additional data or information is available to improve our estimates of benefits. We estimate that, at the mean, the present value of the foregone benefits to consumers of this rule over the next 20 years would be \$0.9 billion using a 3 percent discount rate and \$0.9 billion using a 7 percent discount rate (2016\$). This is presented in Table 1.

We estimate that, at the mean, the present value of the net benefits of this proposed rule over the next 20 years would be \$0.1 billion using a 3 percent discount rate and \$0.1 billion using a 7 percent discount rate (2016\$). This is shown in Table 1.

Table 1. Summary of the Cost Savings to Industry and Foregone Benefits to Consumers of This Proposed Rule to Extend the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Cost Savings	Foregone Benefits	Net Benefits (Cost Savings – Foregone Benefits)
Present Value	3%	\$1.0	\$0.9	\$0.1
	7%	\$1.0	\$0.9	\$0.1
Annualized Amount	3%	\$0.07	\$0.06	\$0.01
	7%	\$0.09	\$0.08	\$0.01

Notes: Cost savings to industry, foregone benefits to consumers, and net benefits reflect mean estimates. This proposed rule would extend the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

II. Preliminary Regulatory Impact Analysis

A. Background and Need for Regulation

In response to the receipt of information suggesting a need to provide for adequate time to fully implement the provisions of the Nutrition Facts Label and Serving Size Final Rules, FDA is proposing to extend the compliance dates for the Nutrition Facts Label and Serving Size Final Rules. The Nutrition Facts Label and Serving Size Final Rules were published in the *Federal Register* on May 27, 2016, and provided large businesses (businesses with \$10 million or more in annual food sales) with two years from the effective date of July 26, 2016, to comply with the rules, and small businesses (businesses with less than \$10 million in annual food sales) with three years from the effective date to comply with the rules. FDA is proposing to extend the compliance dates for the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years, to January 1, 2020, for large businesses, and to January 1, 2021, for small businesses. Extending the compliance dates by approximately 1.5 years for both categories of manufacturers is guided by the desire to give industry more time and decrease costs, balanced against the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

B. Baseline Conditions

The Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules serves as the baseline for this analysis (Ref. 1). Table 2 below summarizes the costs and benefits of the Nutrition Facts Label and Serving Size Final Rules. The estimated present value of benefits over the next 20 years ranges from \$2.9 billion to \$80.0 billion, with an estimated mean benefit of \$34.1 billion, using a 3 percent discount rate, and ranges from \$2.0 billion to \$54.1 billion, with an estimated mean benefit of \$23.0 billion, using a 7 percent discount rate (2016\$). The estimated present value of costs over the next 20 years ranges from \$2.4 billion to \$8.9 billion, with an estimated mean cost of \$4.9 billion, using a 3 percent discount rate, and ranges from \$2.3 billion to \$8.5 billion, with an estimated mean cost of \$4.6 billion, using a 7 percent discount rate (2016\$).

Table 2. Summary of the Costs and Benefits of the Nutrition Facts Label and Serving Size Final Rules (in Billions of 2016\$)

	Discount Rate	Benefits (Low)	Benefits (Mean)	Benefits (High)	Costs (Low)	Costs (Mean)	Costs (High)
Present Value	3%	\$2.9	\$34.1	\$80.0	\$2.4	\$4.9	\$8.9
	7%	\$2.0	\$23.0	\$54.1	\$2.3	\$4.6	\$8.5
Annualized Amount	3%	\$0.19	\$2.29	\$5.38	\$0.16	\$0.33	\$0.60
	7%	\$0.19	\$2.17	\$5.11	\$0.22	\$0.43	\$0.80

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

C. Cost Savings to Industry of This Proposed Rule to Extend the Compliance Dates

As stated previously, the benefit of this proposed rule is *the reduction in the costs to food manufacturers* related to extending the compliance dates by approximately 1.5 years of the Nutrition Facts Label and Serving Size Final Rules. This reduction in costs, again, can be attributed to a reduction in relabeling and reformulation costs. Hence, to estimate the cost savings to industry of this proposed rule, we first estimate the costs of the Nutrition Facts Label and Serving Size Final Rules using a 54-month compliance period for small businesses and a 42-month compliance period for large businesses, using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1). These costs are illustrated below in Table 3.

Table 3. Summary of the Costs of the Nutrition Facts Label and Serving Size Final Rules – 54-Month Compliance Period for Small Businesses / 42-Month Compliance Period for Large Businesses (in Billions of 2016\$)

	Discount Rate	Costs (Low)	Costs (Mean)	Costs (High)
Present Value	3%	\$1.9	\$3.9	\$7.2
	7%	\$1.8	\$3.6	\$6.9
Annualized Amount	3%	\$0.13	\$0.26	\$0.48
	7%	\$0.17	\$0.34	\$0.65

Notes: Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the cost savings to industry of this proposed rule as the difference between the costs of the Nutrition Facts Label and Serving Size Final Rules presented in Table 2 above and the costs of the Nutrition Facts Label and Serving Size Final Rules using a 54-month compliance period for small businesses and a 42-month compliance period for large businesses as presented in Table 3 above. The cost savings to industry of this proposed rule are illustrated below in Table 4. We estimate that the present value of the cost savings to industry of this proposed rule over the next 20 years ranges from \$0.5 billion to \$1.7 billion, with an estimated mean cost saving of \$1.0 billion, using a 3 percent discount rate, and from \$0.5 billion to \$1.6 billion, with an estimated mean cost saving of \$1.0 billion, using a 7 percent discount rate (2016\$).

Table 4. Summary of the Cost Savings to Industry of This Proposed Rule to Extend the Compliance Dates – 1.5-Year Extension of the Compliance Period (in Billions of 2016\$)

	Discount Rate	Cost Savings (Low)	Cost Savings (Mean)	Cost Savings (High)
Present Value	3%	\$0.5	\$1.0	\$1.7
	7%	\$0.5	\$1.0	\$1.6
Annualized Amount	3%	\$0.03	\$0.07	\$0.11
	7%	\$0.05	\$0.09	\$0.15

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent

annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

D. Foregone Benefits to Consumers of This Proposed Rule to Extend the Compliance Dates

As stated previously, the cost of this proposed rule would be the *reduction in benefits to consumers* associated with extending the compliance dates by approximately 1.5 years for the Nutrition Facts Label and Serving Size Final Rules. Again, extending the compliance dates by approximately 1.5 years would reduce the estimated benefits of the Nutrition Facts Label and Serving Size Final Rules because it would delay the realization by consumers of the full annual welfare gains of the Nutrition Facts Label and Serving Size Final Rules. Hence, to estimate the foregone benefits to consumers of this proposed rule, we first estimate the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 54-month compliance period for small businesses and a 42-month compliance period for large businesses, using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1).¹ These benefits are illustrated below in Table 5. We renew our request for comments about whether additional data or information is available to improve our estimates of benefits.

Table 5. Summary of the Benefits of the Nutrition Facts Label and Serving Size Final Rules – 54-Month Compliance Period for Small Businesses / 42-Month Compliance Period for Large Businesses (in billions of 2016\$)

	Discount Rate	Benefits (Low)	Benefits (Mean)	Benefits (High)
Present Value	3%	\$2.9	\$33.2	\$77.9
	7%	\$2.0	\$22.1	\$52.1
Annualized Amount	3%	\$0.19	\$2.23	\$5.24
	7%	\$0.19	\$2.09	\$4.92

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the foregone benefits to consumers of this proposed rule as the difference between the benefits of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 2 above and the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 54-month compliance period for small businesses and a 42-month compliance period for large businesses as presented in Table 5 above. The foregone benefits to consumers of this proposed

¹ Having a 42- to 54-month compliance period from the outset is not, from a practical perspective, strictly the same as first having a two- to three-year compliance period and then being granted an extension. However, assuming that these situations' impacts are approximately equal is reasonable in this case because so few entities come into compliance in the first year after the initial regulatory finalization; more specifically, the Labeling Cost Model projects that only approximately 8 percent of UPCs can have coordinated regulatory and non-regulatory label changes within 12 months (and thus most entities would likely not yet be in compliance with the requirements of the 2016 final rule).

rule are illustrated below in Table 6. We estimate that the present value of the foregone benefits to consumers of this proposed rule over the next 20 years ranges from \$0.0 billion to \$2.1 billion, with an estimated mean foregone benefit of \$0.9 billion, using a 3 percent discount rate, and from \$0.0 billion to \$2.0 billion, with an estimated mean foregone benefit of \$0.9 billion, using a 7 percent discount rate (2016\$).

In the RIA of the final rule, we acknowledged the shortcomings related to the estimate of s_1 , which reflected the effectiveness of the newly required labels. However, public comment on the PRIA or the supplementary PRIA did not provide us with information or guidance that would have allowed us to estimate a more reliable and objective s_1 . In the absence of additional data or information, our estimates of foregone benefits remain unchanged. However, we ask for comments on whether additional data or information is available to improve our estimates using empirical evidence.

Table 6. Summary of the Foregone Benefits to Consumers of This Proposed Rule to Extend the Compliance Dates – 1.5-Year Extension of the Compliance Period (in Billions of 2016\$)

	Discount Rate	Foregone Benefits (Low)	Foregone Benefits (Mean)	Foregone Benefits (High)
Present Value	3%	\$0.0	\$0.9	\$2.1
	7%	\$0.0	\$0.9	\$2.0
Annualized Amount	3%	\$0.00	\$0.06	\$0.14
	7%	\$0.00	\$0.08	\$0.19

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

E. Net Benefits of This Proposed Rule to Extend the Compliance Dates

The present value of the net benefits of this proposed rule over the next 20 years, which equals the difference between cost savings and foregone benefits and which are illustrated in Table 7 below, ranges from -\$0.4 billion to \$0.5 billion, with an estimated mean net benefits of \$0.1 billion, using a 3 percent discount rate, and from -\$0.4 billion to \$0.5 billion, with an estimated mean net benefits of \$0.1 billion, using a 7 percent discount rate (2016\$).

Table 7. Summary of the Net Benefits of This Proposed Rule to Extend the Compliance Dates – 1.5-Year Extension of the Compliance Period (in Billions of 2016\$)

	Discount Rate	Net Benefits (Low)	Net Benefits (Mean)	Net Benefits (High)
Present Value	3%	-\$0.4	\$0.1	\$0.5
	7%	-\$0.4	\$0.1	\$0.5
Annualized Amount	3%	-\$0.03	\$0.01	\$0.03
	7%	-\$0.04	\$0.01	\$0.05

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

F. Analysis of Regulatory Alternatives to This Proposed Rule to Extend the Compliance Dates

We present two regulatory options: (i) extending the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by one year and (ii) extending the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by two years.

i. Extension of the Compliance Dates of the Nutrition Facts Label and Serving Size Final Rules by One Year

One regulatory option is to extend the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by one year, to July 26, 2019, for large businesses and to July 26, 2020, for small businesses.

To estimate the cost savings to industry of this proposed rule under this regulatory option, we first estimate the costs of the Nutrition Facts Label and Serving Size Final Rules using a 48-month compliance date for small businesses and a 36-month compliance date for large businesses, using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1). These costs are illustrated below in Table 8.

Table 8. Summary of the Costs of the Nutrition Facts Label and Serving Size Final Rules – 48-Month Compliance Date for Small Businesses / 36-Month Compliance Date for Large Businesses (in Billions of 2016\$)

	Discount Rate	Costs (Low)	Costs (Mean)	Costs (High)
Present Value	3%	\$2.1	\$4.2	\$7.6
	7%	\$1.9	\$3.9	\$7.3
Annualized Amount	3%	\$0.14	\$0.28	\$0.51
	7%	\$0.18	\$0.37	\$0.69

Notes: Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the cost savings to industry of this proposed rule under this regulatory option as the difference between the cost of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 2 above and the cost of the Nutrition Facts Label and Serving Size Final Rules using a 48-month compliance date for small businesses and a 36-month compliance date for large businesses. This is illustrated in Table 9 below.

Table 9. Summary of the Cost Savings to Industry of This Proposed Rule to Extend the Compliance Dates – 1-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Cost Savings (Low)	Cost Savings (Mean)	Cost Savings (High)
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Present Value	3%	\$0.3	\$0.7	\$1.3
	7%	\$0.4	\$0.7	\$1.2
Annualized Amount	3%	\$0.02	\$0.05	\$0.09
	7%	\$0.04	\$0.07	\$0.11

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

To estimate the foregone benefits to consumers of this proposed rule under this regulatory option, we first estimate the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 48-month compliance date for small businesses and a 36-month compliance date for large businesses, using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1). These benefits are illustrated below in Table 10.

Table 10. Summary of the Benefits of the Nutrition Facts Label and Serving Size Final Rules – 48-Month Compliance Date for Small Businesses / 36-Month Compliance Date for Large Businesses (in Billions of 2016\$)

	Discount Rate	Benefits (Low)	Benefits (Mean)	Benefits (High)
Present Value	3%	\$2.9	\$33.4	\$78.4
	7%	\$2.0	\$22.4	\$52.5
Annualized Amount	3%	\$0.19	\$2.24	\$5.27
	7%	\$0.19	\$2.12	\$4.96

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the foregone benefits to consumers of this proposed rule under this regulatory option as the difference between the benefits of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 2 above and the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 48-month compliance date for small businesses and a 36-month compliance date for large businesses. This is illustrated in Table 11 below.

Table 11. Summary of the Foregone Benefits to Consumers of This Proposed Rule to Extend the Compliance Dates – 1-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Foregone Benefits (Low)	Foregone Benefits (Mean)	Foregone Benefits (High)
Present Value	3%	\$0.0	\$0.7	\$1.6
	7%	\$0.0	\$0.6	\$1.6
Annualized Amount	3%	\$0.00	\$0.05	\$0.11
	7%	\$0.00	\$0.06	\$0.15

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

The present value of the net benefits of this proposed rule over the next 20 years, which equals the difference between cost savings and foregone benefits, is illustrated in Table 12 below.

Table 12. Summary of the Net Benefits of This Proposed Rule to Extend the Compliance Dates– 1-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Net Benefits (Low)	Net Benefits (Mean)	Net Benefits (High)
Present Value	3%	-\$0.3	\$0.0	\$0.3
	7%	-\$0.4	\$0.1	\$0.4
Annualized Amount	3%	-\$0.02	\$0.00	\$0.02
	7%	-\$0.04	\$0.01	\$0.04

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

ii. Extension of the Compliance Dates of the Nutrition Facts Label and Serving Size Final Rules by Two Years

An alternative regulatory option is to extend the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by two years, to July 26, 2020, for large businesses and to July 26, 2021, for small businesses.

To estimate the cost savings to industry of this proposed rule under this regulatory option, we first estimate the cost of the Nutrition Facts Label and Serving Size Final Rules using a 60-month compliance date for small businesses and a 48-month compliance date for large businesses, and using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1). These costs are illustrated below in Table 13.

Table 13. Summary of the Costs of the Nutrition Facts Label and Serving Size Final Rules – 60-Month Compliance Date for Small Businesses / 48-Month Compliance Date for Large Businesses (in Billions of 2016\$)

	Discount Rate	Costs (Low)	Costs (Mean)	Costs (High)
Present Value	3%	\$1.6	\$3.6	\$6.7
	7%	\$1.5	\$3.4	\$6.4
Annualized Amount	3%	\$0.11	\$0.24	\$0.45
	7%	\$0.14	\$0.32	\$0.60

Notes: Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the cost savings to industry of this proposed rule under this regulatory option as the difference between the cost of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 2 above and the cost of the Nutrition Facts Label and Serving Size

Final Rules using a 60-month compliance date for small businesses and a 48-month compliance date for large businesses. This is illustrated below in Table 14.

Table 14. Summary of the Cost Savings to Industry of This Proposed Rule to Extend the Compliance Dates – 2-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Cost Savings (Low)	Cost Savings (Mean)	Cost Savings (High)
Present Value	3%	\$0.8	\$1.3	\$2.2
	7%	\$0.8	\$1.2	\$2.1
Annualized Amount	3%	\$0.05	\$0.09	\$0.15
	7%	\$0.08	\$0.11	\$0.20

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

To estimate the foregone benefits to consumers of this proposed rule under this regulatory option, we first estimate the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 60-month compliance date for small businesses and a 48-month compliance date for large businesses, and using the same approach and methods used in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules (Ref. 1). These benefits are illustrated below in Table 15.

Table 15. Summary of the Benefits of the Nutrition Facts Label and Serving Size Final Rules – 60-Month Compliance Date for Small Businesses / 48-Month Compliance Date for Large Businesses (in Billions of 2016\$)

	Discount Rate	Benefits (Low)	Benefits (Mean)	Benefits (High)
Present Value	3%	\$2.8	\$33.0	\$77.3
	7%	\$1.9	\$21.9	\$51.6
Annualized Amount	3%	\$0.19	\$2.22	\$5.19
	7%	\$0.18	\$2.07	\$4.87

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

We then estimate the foregone benefits to consumers of this proposed rule under this regulatory option as the difference between the benefits of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 2 above and the benefits of the Nutrition Facts Label and Serving Size Final Rules using a 60-month compliance date for small businesses and a 48-month compliance date for large businesses. This is illustrated in Table 16 below.

Table 16. Summary of the Foregone Benefits to Consumers of This Proposed Rule to Extend the Compliance Dates– 2-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Foregone Benefits (Low)	Foregone Benefits (Mean)	Foregone Benefits (High)
Present Value	3%	\$0.1	\$1.1	\$2.7

	7%	\$0.1	\$1.1	\$2.5
Annualized Amount	3%	\$0.01	\$0.07	\$0.18
	7%	\$0.01	\$0.10	\$0.24

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

The present value of the net benefits of this proposed rule over the next 20 years, which equals the difference between cost savings and foregone benefits, is illustrated in Table 17 below.

Table 17. Summary of the Net Benefits of This Proposed Rule to Extend the Compliance Dates– 2-Year Extension of the Compliance Dates (in Billions of 2016\$)

	Discount Rate	Net Benefits (Low)	Net Benefits (Mean)	Net Benefits (High)
Present Value	3%	-\$0.5	\$0.2	\$0.7
	7%	-\$0.4	\$0.1	\$0.7
Annualized Amount	3%	-\$0.03	\$0.01	\$0.05
	7%	-\$0.04	\$0.01	\$0.07

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

iii. Summary of Cost Savings to Industry, Foregone Benefits to Consumers, and Net Benefits of This Proposed Rule to Extend the Compliance Dates by Regulatory Option

The estimated cost savings to industry, foregone benefits to consumers, and net benefits of this proposed rule, by regulatory option, are summarized below in Table 18.

Table 18. Summary of Cost Savings to Industry, Foregone Benefits to Consumers, and Net Benefits of This Proposed Rule to Extend the Compliance Dates by Regulatory Option (in Billions of 2016\$)

	Discount Rate	Present Value				Annualized Amount		
		Cost Savings	Foregone Benefits	Net Benefits		Cost Savings	Foregone Benefits	Net Benefits
This Proposed Rule – No Ext	3%	\$0.0	\$0.0	\$0.0		\$0.00	\$0.00	\$0.00
	7%	\$0.0	\$0.0	\$0.0		\$0.00	\$0.00	\$0.00
This Proposed Rule – 1.5Y Ext	3%	\$1.0	\$0.9	\$0.1		\$0.07	\$0.06	\$0.01
	7%	\$1.0	\$0.9	\$0.1		\$0.09	\$0.08	\$0.01
This Proposed Rule – 1Y Ext	3%	\$0.7	\$0.7	\$0.0		\$0.05	\$0.05	\$0.00
	7%	\$0.7	\$0.6	\$0.1		\$0.07	\$0.06	\$0.01
This Proposed Rule – 2Y Ext	3%	\$1.3	\$1.1	\$0.2		\$0.09	\$0.07	\$0.01
	7%	\$1.2	\$1.1	\$0.1		\$0.11	\$0.10	\$0.01

Notes: Cost savings, foregone benefits, and net benefits reflect mean estimates. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

III. Preliminary Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities when “the agency publishes a general notice of proposed rulemaking” (5 U.S.C. § 601(2)). We have analyzed this proposed rule under the Regulatory Flexibility Act and certify that, because this proposed rule would reduce the burden on food manufacturers by extending the compliance dates for the Nutrition Facts Label Final Rule and the Serving Size Final Rule, this proposed rule would not have a significant economic impact on a substantial number of small entities.

IV. References

1. United States Food and Drug Administration. Regulatory Impact Analysis for Final Rules on “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” and “Food Labeling: Serving Sizes of Foods that can Reasonably be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments.” May 27, 2016. Available from <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm506796.htm>.