

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))**

**FINAL REGULATORY IMPACT ANALYSIS  
FINAL REGULATORY FLEXIBILITY ANALYSIS**

**April 2018**

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Office of Planning  
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## Executive Summary

The Food and Drug Administration (FDA or we) is extending 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 extending 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 will 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 will be reduced. This final 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 final 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 final 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. Thus, for purposes of this Final Regulatory Impact Analysis, we will 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 final 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 final 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 final 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 final rule, including cost savings to industry and foregone benefits to consumers. We believe that this final rule is a significant regulatory action as defined by Executive Order 12866 and a deregulatory action for purposes of Executive Order 13771. We estimate that this rule generates approximately \$61 million in annualized cost savings, discounted relative to year 2016 and using a 7 percent discount rate, over a perpetual time horizon.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final 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 final 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 final rule will 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 final rule will extend the compliance dates by approximately 1.5 years for provisions in the Nutrition Facts Label and Serving Size Final Rules. FDA is taking 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 final 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 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 final 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 final rule is 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 will reduce the estimated benefits of the Nutrition Facts Label and Serving Size Final Rules because it will delay the realization by consumers of the full annual welfare gains of the Nutrition Facts Label and Serving Size Final Rules. In the Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Final Rules, we acknowledged certain shortcomings related to the estimated benefits of these final rules and sought comment on those issues. We also sought comment on those issues in the proposed rule titled “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; Proposed Extension of Compliance Dates” (the Proposed Compliance Date Extension Rule) that was published on October 2, 2017, in the *Federal Register*. However, the public comments did not provide us with additional information or guidance that allows us to estimate a more reliable and objective measure of benefits. Hence, in the absence of additional data or information, we use the same methodology for calculating costs and benefits here that we used in the Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Final Rules. We estimate that, at the mean, the present value of the foregone benefits to consumers of this final 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 final 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 Final Rule to Extend the Compliance Dates (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Cost Savings</b>	<b>Foregone Benefits</b>	<b>Net Benefits (Cost Savings – Foregone Benefits)</b>
<b>Present Value</b>	3%	\$1.0	\$0.9	\$0.1
	7%	\$1.0	\$0.9	\$0.1
<b>Annualized Amount</b>	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 final rule extends 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).

Table 2 below summarizes the cost savings to industry and foregone benefits to consumers of this final rule to extend the compliance dates using an infinite time horizon instead of a 20-year time horizon.

**Table 2. Summary of the Cost Savings to Industry and Foregone Benefits to Consumers of This Final Rule to Extend the Compliance Dates using an Infinite Time Horizon (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Cost Savings</b>	<b>Foregone Benefits</b>	<b>Net Benefits (Cost Savings – Foregone Benefits)</b>
<b>Present Value</b>	3%	\$1.0	\$0.9	\$0.1
	7%	\$1.0	\$0.9	\$0.1
<b>Annualized Amount</b>	3%	\$0.028	\$0.025	\$0.003
	7%	\$0.061	\$0.055	\$0.006

Notes: Cost savings to industry, foregone benefits to consumers, and net benefits reflect mean estimates. This final rule extends the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. The 20-year time horizon present value amounts in Table 1 and the infinite time horizon present value amounts displayed here are the same because there are no cost savings beyond t = 0 and no foregone benefits beyond t = 4. There are no cost savings beyond t = 0 because one-time costs are incurred up front (in t = 0) and recurring costs do not depend on compliance period and, thus, are the same regardless of compliance period. Benefits were modeled in the Regulatory Impact Analysis of the Nutrition Facts Label and Serving Size Final Rules such that some benefits do accrue prior to the end of the compliance period. However, once the compliance period expires, the full amount of benefits accrues per year and this full amount is the same regardless of compliance period, which is why there are no foregone benefits beyond t = 4. Annualized Amount = Discount Rate \* Present Value Amount and is discounted relative to year 2016.

## **II. Comments on the Preliminary Regulatory Impact Analysis of the Proposed Compliance Date Extension Rule**

FDA’s Proposed Compliance Date Extension Rule was published on October 2, 2017, in the *Federal Register*, and the rule’s comment period ended on November 1, 2017. In this section, we summarize and respond to the comments that we received on the Preliminary Regulatory Impact Analysis of the Proposed Compliance Date Extension Rule.

(Comment) A commenter, citing our acknowledgement of shortcomings related to our estimation of the benefits of the Nutrition Facts Label and Serving Size Final Rules, is concerned that the foregone benefits to consumers might outweigh the cost savings to manufacturers, stating that it is unclear how the Agency can move forward with a cost-benefit analysis that may be incorrect.

(Response) In the Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Final Rules, we acknowledged the shortcomings related to our benefits estimate, in particular of our estimate of  $s_1$ , which reflects the effectiveness of the newly required labels. However, public comments on the Regulatory Impact Analysis for the Nutrition Facts Label and Serving Size Proposed Rules and the Regulatory Impact Analysis for the Supplemental Nutrition Facts Label and Serving Size Proposed Rules did not provide us with information or guidance that would have allowed us to estimate a more reliable and objective  $s_1$ . Hence, in the Preliminary Regulatory Impact Analysis of the Proposed Compliance Date Extension Rule, we again asked for comments on whether additional data or information is available to improve our estimate of  $s_1$  using empirical evidence, but again did not receive any such data or information. Therefore, our estimates of foregone benefits remain unchanged.

Regarding the commenter's concern that our analysis may be incorrect, we note that this is a valid concern for any prospective analysis.

### **III. Final 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 extending 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 extending 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 3 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 3. Summary of the Costs and Benefits of the Nutrition Facts Label and Serving Size Final Rules (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Benefits (Low)</b>	<b>Benefits (Mean)</b>	<b>Benefits (High)</b>	<b>Costs (Low)</b>	<b>Costs (Mean)</b>	<b>Costs (High)</b>
<b>Present Value</b>	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
<b>Annualized Amount</b>	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 Final Rule to Extend the Compliance Dates**

As stated previously, the benefit of this final 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 final 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 4.

**Table 4. 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\$)**

	<b>Discount Rate</b>	<b>Costs (Low)</b>	<b>Costs (Mean)</b>	<b>Costs (High)</b>
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<b>Present Value</b>	3%	\$1.9	\$3.9	\$7.2
	7%	\$1.8	\$3.6	\$6.9
<b>Annualized Amount</b>	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 final rule as the difference between the costs of the Nutrition Facts Label and Serving Size Final Rules presented in Table 3 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 4 above. The cost savings to industry of this final rule are illustrated below in Table 5. We estimate that the present value of the cost savings to industry of this final 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 5. Summary of the Cost Savings to Industry of This Final Rule to Extend the Compliance Dates – 1.5-Year Extension of the Compliance Period (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Cost Savings (Low)</b>	<b>Cost Savings (Mean)</b>	<b>Cost Savings (High)</b>
<b>Present Value</b>	3%	\$0.5	\$1.0	\$1.7
	7%	\$0.5	\$1.0	\$1.6
<b>Annualized Amount</b>	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 Final Rule to Extend the Compliance Dates***

As stated previously, the cost of this final 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 final 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).<sup>1</sup> These benefits are illustrated below in Table 6.

**Table 6. 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\$)**

	<b>Discount Rate</b>	<b>Benefits (Low)</b>	<b>Benefits (Mean)</b>	<b>Benefits (High)</b>
<b>Present Value</b>	3%	\$2.9	\$33.2	\$77.9
	7%	\$2.0	\$22.1	\$52.1
<b>Annualized Amount</b>	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 final rule as the difference between the benefits of the Nutrition Facts Label and Serving Size Final Rules as presented in Table 3 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 6 above. The foregone benefits to consumers of this final rule are illustrated below in Table 7. We estimate that the present value of the foregone benefits to consumers of this final 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\$).

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<sup>1</sup> 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 and a half after the initial regulatory finalization; more specifically, the Labeling Cost Model projects that only approximately 25 percent of UPCs can have coordinated regulatory and non-regulatory label changes within 18 months (and thus most entities would likely not yet be in compliance with the requirements of the 2016 final rule). Additionally, in light of the publication of the Proposed Compliance Date Extension Rule closer to 12 months after publication of the final rules and our assertion at the time that we intended to exercise enforcement discretion with respect to the July 26, 2018, and July 26, 2019, compliance dates pending completion of this rulemaking, it is likely that the number of entities that have come into compliance is even lower than the projections in the Labeling Cost Model at the 18-month mark. We note that the Labeling Cost Model projects that only approximately 8 percent of UPCs can have coordinated regulatory and non-regulatory changes within 12 months.

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

	<b>Discount Rate</b>	<b>Foregone Benefits (Low)</b>	<b>Foregone Benefits (Mean)</b>	<b>Foregone Benefits (High)</b>
<b>Present Value</b>	3%	\$0.0	\$0.9	\$2.1
	7%	\$0.0	\$0.9	\$2.0
<b>Annualized Amount</b>	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 Final Rule to Extend the Compliance Dates***

The present value of the net benefits of this final rule over the next 20 years, which equals the difference between cost savings and foregone benefits and which are illustrated in Table 8 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 8. Summary of the Net Benefits of This Final Rule to Extend the Compliance Dates – 1.5-Year Extension of the Compliance Period (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Net Benefits (Low)</b>	<b>Net Benefits (Mean)</b>	<b>Net Benefits (High)</b>
<b>Present Value</b>	3%	-\$0.4	\$0.1	\$0.5
	7%	-\$0.4	\$0.1	\$0.5
<b>Annualized Amount</b>	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 Final 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 final 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 9.

**Table 9. 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\$)**

	<b>Discount Rate</b>	<b>Costs (Low)</b>	<b>Costs (Mean)</b>	<b>Costs (High)</b>
<b>Present Value</b>	3%	\$2.1	\$4.2	\$7.6
	7%	\$1.9	\$3.9	\$7.3
<b>Annualized Amount</b>	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 final 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 3 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 10 below.

**Table 10. Summary of the Cost Savings to Industry of This Final Rule to Extend the Compliance Dates – 1-Year Extension of the Compliance Dates (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Cost Savings (Low)</b>	<b>Cost Savings (Mean)</b>	<b>Cost Savings (High)</b>
<b>Present Value</b>	3%	\$0.3	\$0.7	\$1.3
	7%	\$0.4	\$0.7	\$1.2
<b>Annualized Amount</b>	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 final 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 11.

**Table 11. 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\$)**

	<b>Discount Rate</b>	<b>Benefits (Low)</b>	<b>Benefits (Mean)</b>	<b>Benefits (High)</b>
<b>Present Value</b>	3%	\$2.9	\$33.4	\$78.4
	7%	\$2.0	\$22.4	\$52.5
<b>Annualized Amount</b>	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 final 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 3 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 12 below.

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

	<b>Discount Rate</b>	<b>Foregone Benefits (Low)</b>	<b>Foregone Benefits (Mean)</b>	<b>Foregone Benefits (High)</b>
<b>Present Value</b>	3%	\$0.0	\$0.7	\$1.6
	7%	\$0.0	\$0.6	\$1.6
<b>Annualized Amount</b>	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 final rule over the next 20 years, which equals the difference between cost savings and foregone benefits, is illustrated in Table 13 below.

**Table 13. Summary of the Net Benefits of This Final Rule to Extend the Compliance Dates– 1-Year Extension of the Compliance Dates (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Net Benefits (Low)</b>	<b>Net Benefits (Mean)</b>	<b>Net Benefits (High)</b>
<b>Present Value</b>	3%	-\$0.3	\$0.0	\$0.3
	7%	-\$0.4	\$0.1	\$0.4
<b>Annualized Amount</b>	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 final 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 14.

**Table 14. 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\$)**

	<b>Discount Rate</b>	<b>Costs (Low)</b>	<b>Costs (Mean)</b>	<b>Costs (High)</b>
<b>Present Value</b>	3%	\$1.6	\$3.6	\$6.7
	7%	\$1.5	\$3.4	\$6.4
<b>Annualized Amount</b>	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 final 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 3 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 15.

**Table 15. Summary of the Cost Savings to Industry of This Final Rule to Extend the Compliance Dates – 2-Year Extension of the Compliance Dates (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Cost Savings (Low)</b>	<b>Cost Savings (Mean)</b>	<b>Cost Savings (High)</b>
<b>Present Value</b>	3%	\$0.8	\$1.3	\$2.2
	7%	\$0.8	\$1.2	\$2.1
<b>Annualized Amount</b>	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 final 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 16.

**Table 16. 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\$)**

	<b>Discount Rate</b>	<b>Benefits (Low)</b>	<b>Benefits (Mean)</b>	<b>Benefits (High)</b>
<b>Present Value</b>	3%	\$2.8	\$33.0	\$77.3
	7%	\$1.9	\$21.9	\$51.6
<b>Annualized Amount</b>	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 final 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 3 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 17 below.

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

	<b>Discount Rate</b>	<b>Foregone Benefits (Low)</b>	<b>Foregone Benefits (Mean)</b>	<b>Foregone Benefits (High)</b>
<b>Present Value</b>	3%	\$0.1	\$1.1	\$2.7
	7%	\$0.1	\$1.1	\$2.5
<b>Annualized Amount</b>	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 final rule over the next 20 years, which equals the difference between cost savings and foregone benefits, is illustrated in Table 18 below.

**Table 18. Summary of the Net Benefits of This Final Rule to Extend the Compliance Dates– 2-Year Extension of the Compliance Dates (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Net Benefits (Low)</b>	<b>Net Benefits (Mean)</b>	<b>Net Benefits (High)</b>
<b>Present Value</b>	3%	-\$0.5	\$0.2	\$0.7
	7%	-\$0.4	\$0.1	\$0.7
<b>Annualized Amount</b>	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 Final Rule to Extend the Compliance Dates by Regulatory Option*

The estimated cost savings to industry, foregone benefits to consumers, and net benefits of this final rule, by regulatory option, are summarized below in Table 19.

**Table 19. Summary of Cost Savings to Industry, Foregone Benefits to Consumers, and Net Benefits of This Final Rule to Extend the Compliance Dates by Regulatory Option (in Billions of 2016\$)**

	<b>Discount Rate</b>	<b>Present Value</b>			<b>Annualized Amount</b>		
		<b>Cost Savings</b>	<b>Foregone Benefits</b>	<b>Net Benefits</b>	<b>Cost Savings</b>	<b>Foregone Benefits</b>	<b>Net Benefits</b>
<b>This Final Rule – No Ext</b>	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
<b>This Final Rule – 1.5Y Ext</b>	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
<b>This Final Rule – 1Y Ext</b>	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
<b>This Final Rule – 2Y Ext</b>	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).

#### **IV. Final 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. For the purposes of the Regulatory Flexibility Act analysis, we use the Small Business Administration’s (SBA’s) definition of a small business as it applies to the relevant economic sectors, in this case, North American Industry Classification System (NAICS) 311, 312, and 325. SBA’s definition of a small food manufacturer for these NAICS codes is based on the number of employees, above which the manufacturer is not defined by the SBA as a small business. This employee threshold varies both within and between these NAICS codes and ranges from 500 to 1,500. Using Dun and Bradstreet data, we estimate that over 99 percent of the over 30,000 affected food manufacturers meet the SBA’s definition of a small food manufacturer. We have analyzed this final rule under the Regulatory Flexibility Act and certify that, because this final 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 final rule would not have a significant economic impact on a substantial number of small entities. More specifically, we estimate that small food manufacturers, defined as those with less than \$10 million in annual food sales<sup>2</sup>, will enjoy a collective cost savings from this final rule of about \$30 million (2016\$).

## V. 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>.

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<sup>2</sup> Using this definition, we estimate using Nielsen data that just 5 percent of sales are earned by small businesses.