

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Food Labeling; Nutrition Labeling of Standard Menu  
Items in Restaurants and Similar Retail Food  
Establishments; Extension of Compliance Date

Docket No. FDA-2011-F-0172

Final Regulatory Impact Analysis  
Final Regulatory Flexibility Analysis  
Final Small Entity Analysis  
Unfunded Mandates Reform Act Analysis

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## **Executive Summary**

The Food and Drug Administration (FDA) is extending the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and similar retail food establishments. The final rule appeared in the *Federal Register* of December 1, 2014; the compliance date was later extended from December 1, 2015 to December 1, 2016. A guidance document published in the May 5, 2016 *Federal Register* stated the enforcement of the final rule would begin on May 5, 2017. The purpose of this rule is to clarify and confirm that the compliance date for the final rule is May 5, 2017. The estimated costs and benefits accrued in any given year that the menu labeling rule is in effect, relative to the first year of compliance, does not change, however, because the compliance date is being extended by five months, the discounted value of both total costs and total benefits decreases. The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date by five months. The principal cost of this final rule will be the reduction in benefits associated with extending the compliance date by five months. Extending the compliance date of the “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” final rule by five months reduces the annualized net benefits (discounted at 3 percent) approximately 3 percent, from \$457 million to \$442 million. While average annualized net benefits decrease by \$15 million, they are still positive.

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## **I. Introduction and Summary**

### ***A. Introduction***

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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 a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule provides more flexibility by further extending the compliance date for the Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments final rule (FR 80 39675) (menu labeling final rule), we certify the final rule will 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 current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

### ***B. Summary of Costs and Benefits***

This rule extends the compliance date of the menu labeling final rule by approximately five months: from December 1, 2016 to May 5, 2017. The estimated costs and benefits accrued in any given year that the menu labeling final rule is in effect, relative to the first year of compliance, does not change. However, because the compliance date is being extended by five months, the discounted value of both total costs and total benefits decreases, reducing the total net benefits of the menu labeling final rule by 3 percent. We note that this extension of the compliance date will not have an actual effect on the cost or benefits of the menu labeling rule, because, pursuant to section 747 of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), FDA was not authorized to spend funds to "implement, administer, or enforce" the rule until May 5, 2017, a year after the date on which published a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments.

We are presenting the benefits and costs of the menu labeling final rule, which takes effect according to the dates in this rule.

The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date of the menu labeling final rule to May 2017. Covered establishments<sup>1</sup> will have an additional five months to comply with the menu labeling final rule. Thus, while all initial start-up costs and recurring costs remain the same as estimated in the final regulatory impact analysis for the menu labeling final rule (Ref. 1), the 20-year stream of total costs, discounted at 3 percent, decreases by 3 percent from \$1.12 billion to \$1.09 billion.

The principal cost of this final rule will be the reduction in benefits associated with extending the compliance date of the menu labeling final rule by five months. Consumers purchasing standard menu items at covered establishments will not incur potential health benefits attributed to menu labeling for an additional five months. Thus, the 20-year stream of total benefits to consumers, discounted at 2.5 percent, decreases by 3 percent from \$8.1 billion to \$7.9 billion.

The total annualized benefit of this final rule, using a 3-percent discount rate over 20 years, would be from \$1 to \$3 million; with a 7-percent discount rate, the annualized benefit would be \$2 to \$4 million. The total annualized cost of this final rule, using a 3-percent discount rate over 20 years, would be from \$8 to \$29 million; with a 7-percent discount rate, the annualized cost would be \$10 to \$35 million. Average annualized net benefits of this final rule are estimated to be negative \$15 million discounted at 3 percent and negative \$18 million discounted 7 percent. Estimated benefits and costs are summarized in Table 1.

**Table 1: Summary of this final rule’s estimated benefits and costs annualized over 20 years, in millions 2015\$**

		<i>Low</i>	<i>Mean</i>	<i>High</i>
Benefits	3%	\$1	\$2	\$3
	7%	\$2	\$3	\$4
Costs	3%	\$8	\$18	\$29
	7%	\$10	\$21	\$35

## II. Final Regulatory Impact Analysis

### A. Background and Need for Regulation

In the *Federal Register* of July 10, 2015 (80 FR 39675), in response to requests from affected entities, FDA extended the compliance date for the menu labeling final rule one year to December 1, 2016. On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 747 of the Consolidated Appropriations

<sup>1</sup> The final rule (at 21 CFR 101.11(a)) defines “covered establishment” as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is voluntarily registered to be covered under 21 CFR 101.11(d).

Act states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the menu labeling final rule until one year after the date the Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments is published.

The FDA subsequently published the Level 1 guidance in the *Federal Register* of May 5, 2016 (81 FR 27067) and stated that enforcement of the final rule published December 1, 2014 would commence on May 5, 2017. This final rule confirms, through rulemaking, that the compliance date for the menu labeling final rule is May 5, 2017.

**B. Baseline Conditions**

The final regulatory impact analysis (FRIA) for “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date”, published July 2015 serves as a baseline for this analysis (Ref. 2). Extending the compliance date an additional five months changes the timeline of the menu labeling final rule, but it does not change the effectiveness of the menu labeling final rule. The analysis herein estimates how extending the compliance period changes the total cost to covered establishments and the total benefits to consumers. While extending the compliance date decreases net benefits, they are still positive. The estimated baseline costs and benefits are summarized in Table 2.

**Table 2. Summary of menu labeling final rule’s estimated benefits and costs with December 1, 2016 compliance date, in millions**

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$8,124	\$1,122	\$7,003
	7%	\$5,461	\$856	\$4,605
<i>Annualized over 20 years</i>	3%	\$530	\$73	\$457
	7%	\$482	\$75	\$406

**C. Benefits of This Final Rule**

Extending the compliance date of the menu labeling final rule benefits covered establishments because they can delay the cost of complying with the menu labeling final rule for an additional five months. If the compliance date for the menu labeling final rule is December 1, 2016, covered establishments will spend an average estimated \$409 million in 2016 in order to be in compliance. Total average recurring costs are estimated at \$57 million per year. If the compliance date is extended to May 5, 2017, we assume covered establishments will delay initial and fixed costs by five months. To the extent that covered establishments have already incurred start-up costs, these benefits are overestimated because firms have not delayed costs. Table 3 summarizes the costs for the menu labeling final rule with the published compliance date of December 1, 2016 and with the five month extension. The benefits for this final rule are the difference in costs as covered establishments can defer costs.

**Table 3. Average 20-year stream of costs, in millions**

	With published compliance date of December 1, 2016	With 5-month extension to May 5, 2017
2016	\$408.94	\$204.47
2017	\$56.78	\$232.86
2018	\$56.78	\$56.78
.	.	.
.	.	.
.	.	.
2034	\$56.78	\$56.78
<b>Total</b>	<b>\$1,431</b>	<b>\$1,403</b>
<i>NPV @3%</i>	<i>\$1,122</i>	<i>\$1,090</i>
<i>NPV @7%</i>	<i>\$856</i>	<i>\$821</i>
<b><i>Annualized @3%</i></b>	<b><i>\$73</i></b>	<b><i>\$71</i></b>
<b><i>Annualized @7%</i></b>	<b><i>\$75</i></b>	<b><i>\$72</i></b>

The benefit of extending the compliance date of the menu labeling final rule is the reduction in total cost between the menu labeling final rule with the published compliance date (Table 3, column 2) and the menu labeling final rule with a May 5, 2017 compliance date (Table 3, column 3), i.e. annualized benefits at 3 percent are an estimated \$2 million (\$2=\$73-\$71). Table 4 summarizes low, mean, and high annualized benefit estimates. This 90 percent confidence interval is calculated using the low and high estimates from the FRIA of the menu labeling final rule (Ref. 1).

**Table 4. Estimated benefits of this final rule, in millions**

		Low	Mean	High
Total over 20 Years	3%	\$18	\$32	\$45
	7%	\$21	\$35	\$48
<i>Annualized over 20 years</i>	3%	<b><i>\$1</i></b>	<b><i>\$2</i></b>	<b><i>\$3</i></b>
	7%	<b><i>\$2</i></b>	<b><i>\$3</i></b>	<b><i>\$4</i></b>

The total annualized benefit of this final rule, using a 3-percent discount rate over 20 years, would be from \$1 to \$3 million; with a 7-percent discount rate, the annualized benefit would be \$2 to \$4 million.

#### ***D. Costs of This Final Rule***

Extending the compliance date of the menu labeling final rule creates a cost to consumers because they do not incur the potential benefits of the calorie and other nutrition information for standard menu items provided by the menu labeling final rule for an additional five months. If the compliance date for the menu labeling final rule is December 1, 2016, on average, consumers will gain \$582 million in total benefits in the first year. Annual benefits increase each year as the total population increases. If the compliance date is extended to May 5, 2017, we assume

consumers will forego five months of total benefits. It is possible that some covered establishments may provide calorie labeling prior to the required compliance date. To the extent that this occurs, these costs are overestimated as consumers would have positive benefits in the first two years. Table 5 summarizes the benefits for the menu labeling final rule with the published compliance date of December 1, 2016 and with the five month extension. The costs for this final rule are the difference in benefits as consumers forego benefits an additional five months.

**Table 5. Average 20-year stream of benefits, in millions**

	With published compliance date of December 1, 2016	With 5-month extension to May 5, 2017
2016	\$ -	\$ -
2017	\$ 586.74	\$ 293.37
2018	\$ 591.92	\$ 591.92
2019	\$ 597.12	\$ 597.12
2020	\$ 602.33	\$ 602.33
2021	\$ 607.54	\$ 607.54
2022	\$ 612.75	\$ 612.75
2023	\$ 617.95	\$ 617.95
2024	\$ 623.15	\$ 623.15
2025	\$ 628.34	\$ 628.34
2026	\$ 633.51	\$ 633.51
2027	\$ 638.67	\$ 638.67
2028	\$ 643.81	\$ 643.81
2029	\$ 648.93	\$ 648.93
2030	\$ 654.03	\$ 654.03
2031	\$ 659.12	\$ 659.12
2032	\$ 664.20	\$ 664.20
2033	\$ 669.34	\$ 669.34
2034	\$ 674.52	\$ 674.52
<b>Total</b>	<b>\$11,354</b>	<b>\$11,061</b>
<i>NPV @3%</i>	<i>\$8,124</i>	<i>\$7,856</i>
<i>NPV @7%</i>	<i>\$5,461</i>	<i>\$5,222</i>
<b><i>Annualized @3%</i></b>	<b><i>\$530</i></b>	<b><i>\$513</i></b>
<b><i>Annualized @7%</i></b>	<b><i>\$482</i></b>	<b><i>\$460</i></b>

The cost of extending the compliance date of the menu labeling final rule is the reduction in total benefit between the menu labeling final rule with the published compliance date (Table 5, column 2) and the menu labeling final rule with an extended compliance date (Table 5, column 3). Table 6 summarizes low, mean, and high annualized benefit estimates. This 90 percent



confidence interval is determined using the low and high estimates from the FRIA for the menu labeling final rule.

**Table 6. Estimated cost of this final rule, in millions**

		<i>Low</i>	<i>Mean</i>	<i>High</i>
Total over 20 Years	3%	\$128	\$268	\$441
	7%	\$114	\$239	\$394
<i>Annualized over 20 years</i>	3%	\$8	\$18	\$29
	7%	\$10	\$21	\$35

The total annualized cost of this final rule, using a 3-percent discount rate over 20 years, would be from \$8 to \$29 million; with a 7-percent discount rate, the annualized cost would be \$10 to \$35 million.

***E. Analysis of Regulatory Alternatives to This Final Rule***

We present an alternative regulatory option of extending the compliance period one year from December 1, 2016 to December 1, 2017. The estimation methods are identical to those described in sections C and D above. Extending the compliance period one year decreases estimated net benefits by 7 percent. This option is summarized in Table 7.

**Table 7. Estimated benefits and costs with optional 1-year extension, in millions**

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$63	\$537	-\$474
	7%	\$70	\$479	-\$409
<i>Annualized over 20 years</i>	3%	\$4	\$35	-\$31
	7%	\$6	\$42	-\$36

**III. Final Small Entity Analysis**

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that will lessen the economic effect of the rule on small entities. In this final rule, the cost burden lies solely on the consumers in the way of lost benefits. This final rule will not have a significant economic impact on a substantial number of small entities.

We estimate that at least two thirds of the establishments affected by the requirements of the final rule, or approximately 199,000 establishments, will be part of small businesses (Ref. 1). Because of the complicated market structure in the food industry, and because a majority of affected establishments are part of small businesses, substantial flexibility was built into the menu labeling final rule for all establishments rather than adopting special extensions or rules for

small entities. In addition to the flexibility provided in the menu labeling final rule, delaying the compliance date of the menu labeling final rule by an additional five months allows greater flexibility in cost-effective compliance. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

#### **IV. References**

- 1) FDA. “Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.” November 2014. Available from:  
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM426165.pdf>
  
- 2) FDA. “Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Extension of Compliance Date.” July 2015. Available from:  
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm456515.htm>