DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date

Docket No. FDA-2011-F-0171

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Final Small Entity Analysis

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Executive Summary

In response to requests we received, the Food and Drug Administration (FDA) is extending the compliance date to July 26, 2018 for certain requirements in the final rule requiring disclosure of calorie declarations for food sold from certain vending machines. The estimated costs to industry do not change; however, because the compliance date is being extended by 20 months, the discounted value of total costs decreases. The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date by 20 months. The principal cost of this final rule will be the reduction in potential benefits associated with extending the compliance date of the vending machine labeling final rule by 20 months. Extending the compliance date for certain requirements of the "Food Labeling: Calorie Labeling of Articles of Food in Vending Machines" final rule by 20 months reduces the annualized costs (discounted at 3 percent) by roughly 3 percent, from $34 million to $33 million.

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I. Introduction and Summary

A. Introduction

FDA has 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 Agencies 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). The Agency believes that this final rule is not a significant regulatory action under 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 only extends the compliance date for certain requirements of the Food Labeling: Calorie Labeling of Articles of Food in Vending Machines final rule (Ref. 1) (vending machine labeling final rule), this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "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. FDA does not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Costs and Benefits

This rule extends the compliance date of certain requirements in the vending machine labeling final rule from December 1, 2016 to July 26, 2018. The estimated costs to industry do not change; however, because the compliance date is being extended by 20 months, the discounted value of total costs decreases, reducing the annualized costs by about 3 percent, from $34 million to $33 million.

The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date of the vending machine labeling final rule to July 26, 2018. Covered vending machine operators[1] will have an additional 20 months to comply with certain requirements in the vending machine labeling final rule. Thus, while all initial costs and recurring costs remain the same as estimated in the final regulatory impact analysis for the vending machine labeling final rule (Ref. 2), the 20-year stream of total costs, discounted at 3 percent, decreases by $1 million.

The principal cost of this final rule will be the reduction in potential benefits associated with extending the compliance date of the vending machine labeling final rule by 20 months. As

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1 The final rule (at 21 CFR 101.8(a)) defines "vending machine operator" as a person or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine, as well as a vending machine operator that is voluntarily registered to be covered under 21 CFR 101.8(d).

in the vending machine final rule, we do not quantify benefits; however we provide a qualitative exposition. We expect there will be little loss in benefits for consumers because this extension applies to a limited number of vended food products.

The total annualized benefit of this final rule, using a 3-percent discount rate over 20 years, would be from $280,000 to $1.3 million; with a 7-percent discount rate, the annualized benefit would be $420,000 to $1.8 million. Estimated benefits are summarized in Table 1.

Table 1: Summary of this final rule's estimated benefits over 20 years, in millions 2015$

		Low	Mean	High
Net Present Value (NPV) over 20 Years	3%	$4.14	$17.18	$19.41
	7%	$4.41	$16.79	$19.36
Annualized over 20 years	***3%***	***$0.28***	***$1.15***	***$1.30***
	7%	***$0.42***	***$1.58***	***$1.83***

II. Final Regulatory Impact Analysis

A. Background and Need for Regulation

In response to requests we received, FDA is extending the compliance date for certain requirements of the vending machine labeling final rule. According to the final rule, visible FOP labeling can be used in place of calorie labeling on vending machines. Since the publication of the final rule, several trade associations indicated that the type size requirement would make the calorie declaration very large on some products and would make label redesign difficult and/or not practical. Thus the compliance date for certain food products sold from a glass-front vending machine that allow prospective purchasers to view packaged foods offered for sale has been extended to July 26, 2018. The Dec. 1, 2016 compliance date still applies in most circumstances. For example, glass-front vending machines still would have to disclose calories by this date but could use existing FOP labeling as long as it is visible to consumers. In addition, the compliance date of Dec. 1, 2016 still applies to vending machines that dispense packaged food without FOP labeling, use electronic displays, or sell unpackaged food (such as fruit).

Additional requests addressed calorie declarations on gums, mints, and roll candy, in particular. The trade associations have asserted that calorie declarations for total calories present in the packaged food are not informative for these products because consumers typically do not consume the entire packaged product at one time. In order to consider this issue further, FDA is extending the compliance date to July 26, 2018 for gums, mints, and roll candy sold from glass-front machines in packages that are too small to bear FOP labeling. In the interim, FDA encourages vending machine operators to provide calorie information for such products through a sign in close proximity to the gums, mints, and roll candy inside the vending machine.

B. Baseline Conditions

The final regulatory impact analysis (FRIA) for the vending machine labeling final rule serves as a baseline for this analysis (Ref. 2). Extending the compliance date for certain requirements changes the timeline of the vending machine labeling final rule, but it does not change the effectiveness of the vending machine 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.

The estimated baseline costs and benefits are summarized in Table 2. These differ slightly from the costs and benefits published in the FRIA for the vending machine labeling final rule because 1) they have been updated from 2012 to 2015 dollars and 2) discounting methods have been altered to provide consistency across possible compliance periods. This small accounting difference can lead to large differences due to the magnitude of the estimates. The analysis has not changed from the FRIA for the vending machine labeling final rule.

Table 2. Summary of vending machine labeling final rule's estimated costs, in millions

		Estimated Costs
Net Present Value over 20 Years	3%	$513
	7%	$377
Annualized over 20 years	***3%***	***$34***
	7%	***$36***

C. Benefits of This Final Rule

The compliance date extension only affects certain food products with FOP labeling sold from glass-front vending machines. We do not have detailed information regarding the number of products with FOP labeling, but an industry census estimates that "multiproduct glass-front venders" represent 26 percent of all machines (Ref. 3). Without more precise information, we therefore estimate that 26 percent of total costs to industry will be delayed by 20 months. It is possible that vending machine operators find managing calorie declarations on a package-by-package basis (i.e. ensuring the calorie label on each individual package will be clear and conspicuous or otherwise unobstructed from view at the point of purchase) may be less cost effective than managing all items together in a single sign. To the extent this is true, this RIA overestimates the proportion of costs delayed.

Extending the compliance date of the vending machine labeling final rule benefits covered vending machine operators because they can delay the cost of complying with the vending machine labeling final rule for an additional 20 months. If the compliance date for the vending machine labeling final rule is December 1, 2016, covered vending machine operators will spend an estimated $66 million in 2016 in order to be in compliance. Total average recurring costs are estimated at $34 million per year. If the compliance date is extended to July 26, 2018, we believe covered vending machine operators will have the same fixed costs, but will delay 26 percent until 2018. Thus, fixed costs in 2016 will be an estimated $49 million ($49 million=0.74 x $66 million). In 2017, covered operators will incur recurring costs of $25 million ($25 million=0.74 x $34 million). In 2018, covered vending machine operators will incur recurring costs of $25 million as well as fixed costs of $17 million ($17 million=0.26 x $66 million), for a total of $42 million. Average recurring costs to industry return to $34 million by 2019. Table 3 summarizes the costs for the vending machine labeling final rule with the published compliance date of December 1, 2016 and with the 20 month extension (to July 26, 2018). The benefits for this final rule are the difference in costs as covered establishments can defer some costs an additional 20 months.

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

	With published compliance date of December 1, 2016	With 20-month extension to July 26, 2018	Difference (i.e. benefits of this rule-making)
2015	$0.00	$0.00	$0.00
2016	$66.13	$48.93	$17.19
2017	$33.58	$24.85	$8.73
2018	$33.58	$42.04	-$8.46
2019	$33.58	$33.58	$0.00
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2034	$33.58	$33.58	$0.00
Total	$670.53	$653.07	$17.46
NPV @3%	*$512.56*	*$495.39*	*$17.18*
NPV @7%	*$377.47*	*$360.68*	*$16.79*
Annualized @3%	***$34.45***	***$33.30***	***$1.15***
Annualized @7%	***$35.63***	***$34.05***	***$1.58***

The benefit of extending the compliance date of the vending machine labeling final rule is the reduction in total cost between the vending machine labeling final rule with the published compliance date (Table 3, column 2) and the vending machine labeling final rule with a partial 20-month extended compliance date (Table 3, column 3), i.e. annualized benefits at 3 percent are an estimated $1.2 million. Table 1 above summarizes low, mean, and high total and annualized benefit estimates. This 90 percent confidence interval is calculated using the low and high estimates from the FRIA of the vending machine labeling final rule (Ref. 2).

D. Costs of This Final Rule

Extending the compliance date of the vending machine labeling final rule creates a cost to consumers because they do not attain the potential benefits of the calorie label for packaged foods in glass-front vending machines. We currently lack the data to accurately quantify the benefits for the extension of the vending machine labeling final rule. Food purchased from vending machines only makes up 0.3 percent of average total calorie intake. Therefore, any benefit accrued to an individual consumer would necessarily be mathematically very small. In addition, because vending machine operators would still have to disclose calories by December 1, 2016, but could use existing front-of-pack labeling as long as it is visible to consumers, it is unclear what the precise loss in potential benefits would be. The costs for this final rule would be the difference in benefits as consumers do not realize benefits for an additional 20 months.

E. Distributional Effects

Extending the compliance date of the vending machine labeling final rule reduces covered vending machine operator's cost burden by an estimated $1 million. If the extension allows packaged food manufacturers time to add FOP labeling to foods in a way that makes calorie information available to consumers in a direct and accessible manner, vending machine operators may not have to declare calorie information for the food. To the extent this occurs, some costs may shift from the vending machine operator to the manufacturer. We have no reason to believe that such a wealth transfer generates any distributional or equity concerns.

F. International Effects

Extending the compliance date should not create any adverse international effects.

G. Uncertainty and Sensitivity Analysis

We present uncertainty analyses within sections C and D describing the benefits and costs of this final rule. We are uncertain how many vended products will be affected by extending the compliance date to July 26, 2018 because we do not know precisely how many vended food products currently have FOP labeling, nor do we know how vending machine operators will elect to provide calorie information to the consumers. The costs to consumers of delaying the compliance date are also uncertain and remain unquantified.

H. Analysis of Regulatory Alternatives to This Final Rule

We present two alternative regulatory options: extending the compliance period one year (from December 1, 2016 to December 1, 2017) and three years (to December 1, 2019). The option to extend the compliance period by one year decreases estimated cost savings by 50 percent. The estimation methods are identical to those described in section C above. This option is summarized in Table 4.

Table 4. Estimated benefits with optional 1-year extension, in millions

		Low	Mean	High
Net Present Value over 20 Years	3%	$4.0	$8.7	$19.1
	7%	$4.0	$8.7	$18.8
Annualized over 20 years	***3%***	***$0.3***	***$0.6***	***$1.3***
	7%	***$0.4***	***$0.8***	***$1.8***

An alternative regulatory option is to extend the compliance period for 3 years (from December 1, 2016 to December 1, 2019) instead of the 20 month extension. This option is summarized in Table 5.

Table 5. Estimated benefits with optional 3-year extension, in millions

		Low	Mean	High
Net Present Value over 20 Years	3%	$4.3	$25.4	$19.7
	7%	$4.8	$24.4	$19.9
Annualized over 20 years	***3%***	***$0.3***	***$1.7***	***$1.3***
	7%	***$0.4***	***$2.3***	***$1.9***

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 97 percent of covered vending machine operators, or 11,000 establishments, are small businesses affected by the requirements of the final rule (Ref. 2). Because almost all affected establishments are part of small businesses, substantial flexibility was built into the vending machine labeling final rule for all establishments rather than adopting special extensions or rules for small entities. In addition to the flexibility provided in the vending machine labeling final rule, delaying the compliance date of the vending machine labeling final rule by 20-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. “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines” (Final Rule). 79 FR 71259, December 1, 2014 Available from: https://federalregister.gov/a/2014-27834

2) FDA. “Final Regulatory Impact Analysis, Food Labeling: Calorie Labeling of Articles of Food in Vending Machines.” November 2014. Available from: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM425973.pdf

3) Vending Times. *2012 Census of the Industry*. Vending Times 2012; 52(12) page 62.