

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labeling:  
Calorie Labeling of Articles of Food in Vending  
Machines NPRM

Preliminary Regulatory Impact Analysis  
Docket No. FDA-2011-F 0171

Office of Regulations Policy and Social Sciences  
Center for Food Safety and Applied Nutrition  
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**SUMMARY:** The Food and Drug Administration (FDA) is proposing requirements for providing calorie information for certain articles of food sold from vending machines to implement the vending machine labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). The Affordable Care Act, in part, amended the Federal Food, Drug and Cosmetic Act (FD&C Act) to, among other things, require that for an article of food sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase, and is operated by a person engaged in the business of owning or operating 20 or more vending machines, the vending machine operator must disclose the number of calories for the article of food. Vending machine operators not subject to the requirements of the Affordable Care Act may elect to be subject to the Federal requirements by registering with FDA. Providing calorie disclosures for food sold from vending machines would assist consumers in making healthier dietary choices. The analysis of benefits and costs included in this document is the basis for the summary analysis included in the Proposed Rule: Food Labeling; Calorie Labeling of Articles of Food in Vending Machines [Docket No. FDA-2011-F 0171].



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## I. Introduction

FDA has examined the impacts of the proposed rule under Executive Orders 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated an “economically” significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget (OMB).

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Using the Small Business Administration (SBA) definition of small vending machine operators as classified by the North American Industry Classification System (NAICS 45421), FDA estimates that a significant number of operators impacted by this proposed rule are small businesses. As directed by statute, the requirements of the proposed rule only apply to vending machine operators that own or operate 20 or more vending machines. However, according to data from the Vending Times Census and from the National Automatic Merchandising Association (NAMA), the average annual revenue per machine is less than \$7,000 (Refs. 1 and 2). An operator with only 20 machines may have vending machine revenue of less than \$140,000. In order to exceed the SBA’s definition of a small vending machine operator, a firm would need at least \$10 million in annual revenue (Ref. 3). This suggests that a firm with revenue exclusively from vending

machine sales would need more than 1,400 machines to exceed the definition of small business. Based on the latest available U.S. Economic Census data that breaks down establishments by revenue, we project that 97 percent of firms selling covered vending machine food, as that term is used in this document, that identify primarily as vending machine operators that are engaged in the business of owning or operating 20 or more vending machines would be small businesses as defined by SBA. Therefore, the Agency believes that the proposed rule would have a significant economic impact on a substantial number of small entities. This impact is discussed further in section V of this document.

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 \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

### **A. Need for This Regulation**

This proposed rule is necessary to implement section 4205 of the Affordable Care Act, which principally amends sections 403 and 403A of the FD&C Act, and requires operators of 20 or more vending machines to disclose calorie information for covered vending machine food. The provision of calorie information for covered vending machine food may help consumers make better informed dietary choices.

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. In the case of food sold from a vending machine, the private market is particularly robust and competitive. Thousands of individual firms vie for consumer dollars in millions of vending machines across the United States (Ref. 1). Low entry costs for firms and low switching costs for customers suggest that if a sizable fraction of consumers were willing to pay for--and discriminate based on--the visible calorie information at the point of purchase then the industry would provide it to them. In fact, some vending machine operators are voluntarily providing more healthful choices and additional information on machines (Refs. 2 and 6).

Although many of the usual market failures that justify regulatory action, such as the existence of market power or of ill-defined property rights, do not apply here (Refs. 5 and 6), the primary support for regulatory intervention is that there are systematic biases in how consumers process information and weigh current benefits (from consuming higher calorie foods) against future costs (higher probability of obesity and its comorbidities).

The bias is more directly related to the requirements of this proposed rule: Consumer demand for calorie information does not create incentives for the provision of calorie information at the vending machine. This market failure occurs because at the time of purchase, consumers do not value calorie information as much as they do later, when the effects of excess calorie consumption are evident. Studies have shown that consumers have present-based preferences, meaning that they are continually optimistic about the healthfulness of their future choices (Refs. 7, 8 and 9).

These studies suggest that calorie information often lacks salience, or relevance, for consumers at the time of purchase and consumption, even though they may experience regret

about their decisions at a later date. This tendency may explain why consumers have not generally demanded calorie and other nutrition information for food sold from vending machines before, or at, the point of purchase, even if they may, at a later point in time, value that information. Because of competition for consumer time and attention vending machine operators have limited time and space in which to convey information to consumers. These limits mean that there is a substantial opportunity cost to the operator of providing calorie information. That is, just as an operator may have to decide which possible foods to leave out of a vending machine with limited space (thus giving up the opportunity to sell those items), it must choose which pieces of information about its foods it wants to convey. Adding an additional piece of information means that an operator may need to downplay or remove some other piece of information. This opportunity cost of information holds true whether the calorie information is displayed on the machine or, as with an increasing number of packaged foods, on the principal display panel of the package.

The proposed requirements mitigate the apparent market failure in information provision stemming from present-biased preferences, although not necessarily the tendency of consumers to underutilize that information. Specifically, for a covered vending machine food, this proposed rule requires that the vending machine operator provide a sign in close proximity to the food or the selection button, i.e. in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its name, price, or selection number is visible. This information must be presented in a color that is sufficiently contrasted with the background, must be in close proximity to the vignette or name or in close proximity to the selection button when a name or vignette is displayed, and, for electronic vending machines, the calorie information may be displayed when the selection

numbers are entered but before the selection is confirmed. These requirements are designed so that the calorie information is made available to consumers before they purchase such food. Providing the information will likely increase consumer awareness regarding the calorie content in covered vending machine food and increase the perceived relevance of that information to their decision making. Providing the information may serve to highlight the potential future costs of additional calorie consumption. This increased attention to the caloric content of covered vending machine food may then result in an increased availability of lower calorie options, and an increased demand for these options.

## **B. Summary of Costs and Benefits of the Proposed Requirements and Regulatory Options**

In this section FDA describes the bases of benefits and costs of the proposed requirements and summarizes the results of the detailed Preliminary Regulatory Impact Analysis (PRIA).

**Benefits in response to the proposed requirements.** Obesity is a major public health concern in the United States and one of the top leading health indicators addressed by the United States Healthy People 2020 goals. Nationally representative data indicate an increase in the prevalence of obesity over the past three decades (Ref. 10). The 2007-2008 National Health and Nutrition Examination Survey (NHANES) data showed that 34 percent of the adult U.S. population is obese and 34 percent are overweight (Ref. 11).

Excess body weight has many health (Ref. 12), social (Refs. 13 and 14), psychological (Refs. 15 and 16), and economic consequences (Ref. 17) for the affected individuals. Lower life expectancy, elevated risk of diabetes, hypertension, stroke and other cardiovascular diseases have been documented to rise simultaneously with the increased prevalence of obesity (Ref. 12). The economic impact is especially evident in health-care costs in terms of greater health-care

utilization and higher medical expenditures (Ref. 18). More specifically, medical expenditures attributable to overweight and obesity accounted for more than 9 percent of the total U.S. medical expenditures in 1998, or between \$85.7 billion and \$147 billion (Ref. 18). Researchers have proposed various factors to explain this dramatic rise in obesity including declining food prices and physical requirements of labor (Refs. 19 and 20), declining time costs of food preparation (Ref. 21), fast-food restaurant density (Ref. 22) and social interactions (Refs. 23).

Although the relationship between obesity and poor dietary choices is multi-faceted, there is a general agreement in the literature that reduction in excess calories is helpful in preventing or delaying the onset of excess weight gain (Ref. 24). Vending machines are a likely source of high-calorie snack or discretionary foods, as well as some high-calorie meal items. Industry data indicate that there is approximately one vending machine for every 40 adults in the United States, and that up to 5 percent of the money consumers spend on food away from home is spent on vending machine food (Ref. 25). This suggests that providing calorie information for covered vending machine food to consumers may have a significant effect on calorie intake, the prevalence of obesity, and thus the cost of health care and lost productivity.

To the extent that the proposed requirements mitigate the increase in the prevalence of obesity and the prevalence of these costly co-morbidities such as hypertension and diabetes, society gains the opportunity cost of the averted medical expenditures and an increase in productivity from averted debilitation and death. In addition to educating consumers about calorie content, major predicted elements of the consumer and industry response to this proposed rule are:

1. Increased awareness regarding the caloric content in covered vending machine foods, and the perceived relevance of that information to decision making, which may help reduce the present-bias in preferences, and thus encourage the consumption of lower calorie options.

2. Increased consumer interest in lower calorie options, and greater transparency in the caloric content of foods sold in vending machines, which may give manufacturers an incentive to:

- a. Reduce the calorie content of foods sold in vending machines through reformulation or by decreasing portion size.

- b. Provide additional items with lower calorie formulations.

These changes may reduce consumers' caloric intake from food sold in vending machines. Note that any reduction in calorie intake in these settings may be at least partially offset by increases in calorie intake during other meals or snacks. Because FDA lacks data on how consumers will substitute among caloric sources, the benefit estimations given here may be higher or lower than those that will be realized if the rule is finalized as proposed.

**Coverage of the proposed rule and industry overview.** The proposed rule covers certain vending machine operators that are engaged in the business of owning or operating 20 or more vending machines and those vending machine operators that voluntarily register with FDA to become subject to the Federal requirements. The proposed rule does not cover vending machines without a selection button, including bulk vending machines that dispense gum, candy and nuts. Vending machines are operated both by food service firms and by firms in other businesses that operate machines for the benefit of their customers or employees and do not identify as vending machine operators. Because this latter group cannot be accurately counted, published estimates of the number of vending machine operators will generally undercount the

number of covered operators under the proposed rule. For the purposes of this preliminary regulatory impact analysis, we will use the term “covered operators” or “covered vending machines” to refer to operators or machines that sell covered vending machine foods.

According to the NAMA, there are approximately 13,500 companies that operate vending machines in the United States (Ref. 2). Other estimates put the total closer to 10,000 (Ref. 1).

This total includes 5,000 firms whose primary business identification is as vending machine operators (NAICS 4542), plus a variety of other firms that operate vending machines, but do not primarily identify as such. These other companies include, for example, beverage manufacturers and food service contractors. Because of the difficulty in determining which firms are covered, and because FDA has no data on the potentially significant number of covered vending machine operators that self-identify as businesses outside the food industry, we take NAMA’s higher estimate of 13,500 firms as the number of covered firms.

FDA estimates that 97 percent of firms selling covered vending machine food that identify primarily as vending machine operators that are engaged in the business of owning or operating 20 or more vending machines are small businesses as defined by the SBA. Other estimates indicate that more than 90 percent of the firms covered by the proposed rule are defined as small businesses (Ref. 1). This percentage may be lower for firms that have primary business identification other than as vending machine operators, but the majority of covered businesses will likely still be defined as small businesses. Because very small, informal businesses that are not captured by economic census data might operate 20 or more machines, these figures may underestimate the number of affected small businesses. Conversely, approximately 72 percent of industry revenue--and thus a comparably large fraction of

consumption--comes from firms with more than \$10 million in annual sales, and 85 percent comes from firms with more than \$5 million in revenue (Ref. 1).

Vending machine operators together operate an estimated 5 to 7 million machines (Refs. 1 and 2) in at least 1.5 million locations (Ref. 1). Approximately 70 percent of these machines sell packaged food, including beverages, that are required to bear nutrition labeling under section 403(q)(1) of the FD&C Act and FDA regulations at § 101.9, and thus have Nutrition Facts. This 70 percent is comprised mostly of packaged beverage machines, which account for more than 50 percent of all vending machines, with the remainder--approximately 20 percent of all machines--selling packaged confections or snacks. Ten percent sell a variety of hot and cold cup beverages, frozen or fresh food products and miscellaneous other food products. The final 20 percent of machines are bulk candy, nut or gum machines that are not covered by section 403(q)(5)(H)(viii) and the proposed requirements because they lack selection buttons. While these bulk machines form a large percentage of vending machines, they account for less than 0.5 percent of vending machine sales (Ref. 2).

**Summary of costs and benefits of the proposed rule and regulatory options.** In this section we briefly summarize the costs and benefits of the proposed rule that are analyzed in the detailed PRIA. These estimates are collected in table 1. Costs of complying with the proposed requirements have been estimated for three major areas: Cost of nutrition analysis, cost of new signs or posters, and labor costs. In the case of the proposed rule, FDA estimates that there would be approximately 10,800 operators under the proposed requirements, controlling between 4 million and 5.6 million machines that sell covered vending machine foods. The initial mean estimated cost of complying with the proposed requirements is \$25.8 million, with an estimated mean ongoing cost of \$24.0 million. Mean annualized costs are \$24.5 million at a 7 percent

discount rate, and \$24.2 million at 3 percent discount rate. Per operator costs are estimated to be \$2,400. FDA estimates that average per machine costs are less than \$10 annually.

FDA has not estimated the actual benefits associated with proposed requirements. Food choice and consumption decisions are complex and FDA is unaware of any comprehensive data allowing accurate predictions of the effect of the proposed requirements on consumer choice and vended foods. Therefore, FDA has constructed a plausible individual effect of the proposed rule, and has conducted a break-even analysis in order to determine the proportion of the U.S. obese adult population that would need to attain this minimal response in order for the proposed requirement to yield a positive net benefit. Using a 100 calorie per week reduction in intake as the benchmark effect, FDA estimates that at least 0.02 percent of the adult obese population would need to reach this benchmark in order for the rule to break even on the initial total cost. On an ongoing basis, again, at least 0.02 percent of the adult obese population would need to reach this benchmark in order for the rule to break even on the recurring annual costs. These effects are summarized in table 1 of this document.

Finally, although registration by firms wishing to register with FDA in order to come under the proposed requirements and the associated preemption from State or local regulations is voluntary, and will only occur to the extent that the costs of registration and compliance with Federal regulation is lower than that of State or local laws, this registration constitutes a collection of information under the Paperwork Reduction Act of 1995.

**Table 1a. Accounting Statement: Annualized Cost and Break-Even Benefit Point for the Proposed Requirements**

	<b>Primary Estimate</b>	<b>Low Estimate</b>	<b>High Estimate</b>	<b>Year Dollar</b>	<b>Discount Rate</b>	<b>Period Covered</b>
<b>Benefits</b>						
Annualized Monetized (\$millions/year)	Not Quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.02 percent of the adult obese population would need to reduce caloric intake by at least 100 calories per week in order for benefits from the proposed requirements to reach a break even point on annualized costs (at either 3% or 7%)						
<b>Costs</b>						
Annualized Monetized (\$millions/year)	\$24.5	\$12.5	\$39.8	2009	7%	10
	\$24.2	\$12.1	\$39.6	2009	3%	10

### C. Regulatory Options

In addition to a baseline, FDA has identified four regulatory options for this proposed rule. The costs and benefits of these options are summarized in table 1b of this document.

(0) Baseline for the purpose of analysis--No new Federal regulatory action.

(1) Option 1, the proposed rule, allowing a sign in close proximity to the article of food or selection button, i.e. in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its name, price, or selection number is visible, and with an effective date of 1 year after publication of the final rule.

(2) Option 2, similar to the proposed rule, but requiring that calorie declarations be immediately adjacent to the article of food or selection button for all calorie disclosures. For this option, FDA estimates the cost of individual signs for each article of food or selection button.

(3) Option 3, Similar to the proposed rule, but with an additional year in compliance period for vendors with less than \$500,000 in annual revenue from vending machines.

(4) Option 4, similar to the proposed rule, but with coverage extended to bulk vending machines without selection buttons.

**Table 1b: Summary of Estimated Annualized Compliance Costs for Each Option**

Summary Of Options	Primary Estimate (in millions)	Low Estimate (in millions)	High Estimate (in millions)	Percent Discount Rate (10 year horizon)	Proportional Cost Relative to Primary Estimate of the Proposed Requirements	Proportional Dollar Sales of Restaurant Food Relative to Primary Estimate of the Proposed Requirements
(Baseline)	N/A	N/A	N/A	N/A	N/A	
Option 1: the Proposed Rule	\$24.2	\$12.1	\$39.6	3%	0.0%	0.0%
	\$24.5	\$12.5	\$39.8	7%		
Option 2: Individual Signs	\$81.8	\$36.1	\$140.4	3%	+229.2%	0.0%
	\$82.5	\$36.6	\$141.1	7%		
Option 3: Longer Compliance Time for Small Businesses	\$24.2	\$12.1	\$39.6	3%	0.0%	0.0%
	\$24.5	\$12.5	\$39.8	7%		
Option 4: Extended Scope to Include Bulk Machines	\$30.2	\$15.1	\$49.4	3%	+25.6%	+0.5%
	\$31.0	\$15.8	\$50.3	7%		

FDA estimates that Option 2, which would require individual signs or labels for each covered vended food, has a ten-year annualized costs of between \$36.1 million per year and \$140.4 million per year at a 3 percent discount rate, with a primary estimate of \$81.8 million. Averaged over primary, low and high estimates, the costs of Option 2 are 229.2 percent higher than those of the proposed requirements. These changes are discussed more fully in the detailed analysis.

Option 3 which considers a longer compliance time for small businesses represents only a delay in the costs. This delay has a small positive impact on the annualized cost, but one that

does not change the (rounded) estimate of costs for Option 3 from the estimate, of costs for Option 1. Option 4, expands the scope of the requirements to include foods in bulk vending machines without selection buttons, has costs that are 25.6 percent higher than the proposed option, and covers an additional 0.5 percent of sales of vended foods.

## **II. Costs and Benefits of Regulatory Options: Detailed Analysis**

This section describes the costs and benefits for the proposed rule and the regulatory options.

### **A. Baseline No New Regulatory Action**

Imposing no new nutrition labeling requirements for covered vending machine food is the baseline for our analysis. Section 4205 of the Affordable Care Act requires that FDA issue regulations to carry out section 403(q)(5)(H) of the FD&C Act, which includes nutrition labeling requirements for covered vending machine food. Therefore, this is not a legally viable option. However, OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of the Executive Order 12866. This option will serve as the baseline against which other options will be measured for assessing costs and benefits.

Section 4205 of the Affordable Care Act established the first Federal nutrition labeling requirements related to vending machines. We are not aware of any State or local nutrition labeling requirements related to vending machines. Because there is increasing attention on and concern for the role that foods from vending machines play in the obesity epidemic, some

vending machine operators have voluntarily provided more healthful options and additional information on the outside of machines (Refs. 2 and 4).

Because efforts to reduce the prevalence of obesity in the United States will likely continue to grow, FDA expects some State and local jurisdictions to begin requiring nutrition information disclosure on vending machines. If this were to occur, in the absence of the enactment of section 4205 of the Affordable Care Act, costs to industry could be several times the cost of this proposed rule, and the benefit to consumers may be lower because of incomplete coverage and fragmented presentation of nutrition information.

### **B. Option 1: Proposed Rule**

Under this option FDA proposes the following requirements for the placement of calorie declarations for covered vending machine food:

(A) This calorie information may be placed (1) On a sign in close proximity to each article of food in the vending machine or the selection button or (2) On a sign, such as a poster in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its description name, price, or selection button number is visible.

(B) This information must be presented in a color that is sufficiently contrasted with the background.

(C) Where the vending machine only displays a vignette or name of the food item, the calorie information must be in close proximity to the vignette or name or in close proximity to the selection button.

(D) For electronic vending machines (e.g., machines with digital or electronic or LCD displays), the calorie information may be displayed when the selection numbers are entered but before the selection is confirmed.

For vending machine operators that are not subject to the requirements of section 403(q)(5)(H) of the FD&C Act, the proposed rule specifies the terms and conditions for how these operators can voluntarily become subject to the proposed requirements by registering with FDA. Because this registration is voluntary, only operators that see a positive net benefit to themselves will choose to register, therefore, FDA estimates that the registration provision by itself will have no net cost.

i. Costs. In order to comply with the proposed rule, each affected operator will need to have or acquire calorie content data for its covered vending machine food. Because almost all vending machines sell food that is manufactured and packaged, calorie analysis and the design and printing of calorie analysis displays will be most efficiently done by manufacturers rather than vending machine operators. Furthermore, most package food sold from vending machines are subject to the nutrition labeling requirements of section 403(q) of the FD&C Act and § 101.9, which means that calorie information is already on the labels of these foods and collected and available for these foods.

Because section 403(q)(5)(H) of the FD&C Act and the proposed rule does not cover vending machines without selection buttons, including certain bulk vending machines or vending machines that are not operated by a person who is engaged in the business of owning or operating 20 or more vending machines, FDA estimates that the approximately 80 percent of all vending machines, or between 4 million and 5.6 million machines will be covered for the purposes of this analysis. Note that some of these vending machines may permit consumers to examine the

Nutrition Facts Panels for the food sold in the machines before purchasing the food or otherwise provide visible nutrition information for the food sold in the machines at the point of purchase, and therefore might not contribute to the costs analyzed for this proposed rule because these are not covered vending machine foods. FDA lacks data that breaks down vending machine firms by the kinds of machines that they operate; therefore, FDA uses the proportion of generally covered machines as the estimate for the proportion of covered firms, yielding approximately 10,800 covered firms. To the extent that vending machines do permit consumers to examine the Nutrition Facts Panels for the food sold in the machines before purchasing the food or otherwise provide visible nutrition information for the food sold in the machines, at the point of purchase, this analysis may overestimate the costs of the proposed rule.

FDA estimates that approximately 10 percent of all vending machines, or between 500,000 and 700,000 machines, sell products that might not already have calorie information on their packages. The manufacturer of these foods (mostly hot and cold cup beverages) would not necessarily have calorie information if the products were not otherwise subject to some nutrition labeling requirements. In addition, there are operators providing fresh or frozen foods for a relatively small number of machines, and these foods may also lack nutrition labeling. FDA tentatively estimates that between 5 and 10 percent of all affected firms, or between 540 and 1,080 firms will need to acquire nutrition information for at least some of their products. FDA tentatively estimates that each vending machine operator within these groups sells approximately 5 to 10 covered vending machine foods that do not have nutrition labeling. Thus the range of possible calorie estimates that would need to be made in order to comply with this proposed rule, if finalized, would be between roughly 2,700 items (5 items/firm x 540 firms) and 10,800 items

(10 items/firm x 1,080 firms), with a mean estimate of 6,800 items. FDA requests comment on these estimates.

Cost estimates for nutrition analyses vary widely: By complexity of the item, sophistication and accuracy of the analysis, detail of the nutrition report, and by whether the analysis is based on existing databases or on item-specific laboratory testing. However, because of the small profit margins in the vending industry (Ref. 1), we expect firms to use cheaper database nutrition analysis. One database nutrition analysis service quotes prices starting at \$25 per item, going up to \$100 per item for more complicated items (Ref. 26). Another service offers flat rates of \$49 for ten items where the purchaser enters the recipe into a calculator (Ref. 27). A senior dietician or nutritionist earns \$35.91 per hour (Ref. 28). Taking into account 50 percent overhead costs, the labor cost to the firm of 1 hour to enter a recipe is approximately \$54. The total cost per item at this Web site would be approximately \$59 per item (and potentially lower with high volume discounts).

Based on data from FDA's Recordkeeping Cost Model (Ref. 29), we estimate approximately 4 hours as the time per analyzed food for creating and administering the record of nutritional information. Although the proposed rule does not mandate recordkeeping, vending machine operators will likely need to be able to ensure that calorie disclosures for covered vending machine foods are accurate and consistent without needing to re-analyze these foods. Again using the hourly wage plus overhead for dietitians and nutritionists of \$54 per hour, we estimate the costs for administering the records of nutritional analysis to be \$216 per item (4 hours/item x \$54/hour). We estimate that the per-item estimated cost of calorie analysis for covered vending machine food will be approximately \$275 per item (\$59 database + \$216 administration). The total estimated cost for calorie analysis for covered vending machine food is

between \$0.7 million (2,700 items x \$275/item) and \$3 million (10,800 items x \$275/item), with a mean estimate of \$1.7 million.

Because the market for unpackaged food sold from vending machines is small and appeared to decline over the period from 2005 to 2008 (Ref. 1), FDA estimates that very few new products will be introduced that will need calorie analysis solely as a result of the proposed requirements, if finalized. In addition, because new vending machine operators likely would use existing suppliers, growth in the vending machine industry likely would not create the need for new calorie analysis.

**Labeling Costs.** The primary cost of the proposed rule will be in affixing and maintaining calorie information for covered vending machine food on, in or adjacent to vending machines. Because there is wide variation in the kinds of vending machines used--in materials, display, and mechanism--there will likely be a variety of methods used for compliance. On the high end, a calorie or nutrition display that is integrated with the graphics on the machine would require a new front display, and thus may cost several hundred dollars, or more. On the low end, a sign, including a poster that could be affixed to the front of the machine could cost significantly less than \$1 per year. Given the low profit margins in the vending machine industry, and given that most of the regulated vending machine operators will be small businesses, FDA anticipates that almost all operators will, at least initially, choose to include calorie information on signs, including posters adjacent to vending machines. In the long run, the manufacturers of vending machines, and the larger vending machine operators, such as the soft drink companies, may use more integrated signs, and thus more expensive, methods as part of regular updates and replacement of machines.

If total calories were included on the label for a food sold from a vending machine and the calorie information met the requirements for visible, , that food would not be subject to the nutrition labeling requirements under section 403(q)(5)(H)(viii)(I) of the FD&C Act. Therefore, vending machine operators that operate glass front machines, or other kinds of vending machines that displays food products with visible nutrition information would not have to provide the calorie information described in section 403(q)(5)(H)(viii)(I) of the FD&C Act and § 101.8(c)(2) of this proposed rule. In other cases, operators may not need to comply with the proposed requirements by placing the products in a way that permits the consumer to examine the Nutrition Facts Panels for the products prior to purchase.

In addition, the increased use of electronic displays on vending machines will reduce the need for physical signs. As a conservative estimate, with between 4 million and 5.6 million machines, FDA estimates that the sign cost will between \$4 million and \$5.6 million annually. However, we expect this amount to fall over time as manufacturers continue to add the required calorie information to of the principal display panel of the package.

Because signs would not always need to be updated every time a machine's product mix changed, FDA estimates an average recurring burden of between 5 and 15 minutes per machine per year to install or refresh the calorie displays. FDA requests comment on this estimate. The U.S. Bureau of Labor Statistics gives the average hourly wage of a nonsupervisory employee of a vending machine operator as \$16 per hour. Including a 50 percent increase for overhead costs, the average hourly cost of an employee in this sector is approximately \$24 per hour.

Using the estimate of between 4 million and 5.6 million machines, and between 0.08 hours (5 minutes/60 minutes/hour) and 0.25 hours (15 minutes/60 minutes/hour) per machine, the annual cost of labeling vending machines is between \$8 million (0.08 hours/machine x

\$24/hour x 4,000,000 machines) and \$33.6 million (0.25 hour/machine x 4/year x \$24/hour x 5,600,000 machines), with a mean estimate of \$19.2 million. As with the cost of signs themselves, we expect this cost to fall over time as more products introduce principal display panels with calorie and other nutrition information and as vending machines integrate signs that are electronic displays. Because estimates of the number of machines have not shown consistent growth in the last few years, FDA takes the number of machines as constant.

The estimated costs of calorie disclosure using this option are given in table 2 of this document. As noted above, initial, non-recurring costs are limited to calorie analysis, given the products covered. All other costs will be ongoing.

**Table 2.--Costs of the Proposed Rule**

Cost	Low Estimate	Mean Estimate	High Estimate
Initial Calorie Analysis	\$0.7 million	\$1.8 million	\$3.0 million
Sign Costs	\$4.0 million	\$4.8 million	\$5.6 million
Sign Labor Costs	\$8.0 million	\$19.2 million	\$33.6 million
Total First Year Costs	\$12.7 million	\$25.8 million	\$42.2 million
Total Recurring Costs	\$12.0 million	\$24.0 million	\$39.2 million
Annualized Costs, 3%	\$12.1 million	\$24.2 million	\$39.6 million
Annualized Costs 7%	\$12.5 million	\$24.5 million	\$39.8 million

ii. Benefits. The potential benefit from the proposed rule stems from the effect that decreasing the consumption of calories from vended food may have on mitigating obesity rates and growth in the U.S. population. The literature on access to vending machines and its relation to body weight to date is very limited and has focused mostly on soft drink consumption, with a particular emphasis on how soda taxes impact the demand for such beverages. However, this literature provides evidence that shows that consumption of sugar-sweetened beverages as well as other common types of vended foods, such as candies, cookies, and chips is associated with higher energy intake, lower nutrient intake, and increased weight gain and risk for obesity among the U.S. population (Refs. 30 through 33).

Kakarala and colleagues (Ref. 34) estimate that the consumption of sugar-sweetened beverages and snack items contributes about an additional 250 calories per day among the overweight and obese population, and Krebs-Smith (Ref. 35) estimates that about 20 percent of that extra calorie intake is attributable to items purchased from vending machines. Twenty percent of 250 calories amounts to 50 calories per day from items purchased from vending machines. However, it is important to note that these studies were not based on a representative sample of the U.S. population and thus might over- or under-estimate the amount of calorie intake from food sold from vending machines. In addition, many potential substitutes to sugar-sweetened beverages and snack items typically have a similar number of calories per serving. For example, 12 ounces (oz) of fruit juice or reduced-fat 2-percent milk contain a similar number of calories as 12 oz of sugar-sweetened beverage (140 calories). In other words, calorie labeling may not necessarily drive substitution toward lower calorie items.

Because FDA does not have comprehensive data on how consumption patterns would change in the long run due to the proposed requirements, and because FDA does not have data on how vending machine operators would respond to the proposed requirements, FDA estimates a benchmark response by the adult obese population that would be needed for the proposed requirements to have a positive net benefit. This benchmark is not an estimate of the real effect of the implementation of the proposed requirements, but an exercise to illustrate the magnitude of the response needed. The benchmark benefits are calculated by summing Quality Adjusted Life Years (QALYs) gained and medical costs averted from the benchmark decline in obesity.

QALYs One approach to estimating health benefits involves the use of QALYs. QALYs can be used to measure the loss of well-being that an individual suffers due to a disease or condition. QALYs do not include the value of health expenditures caused by the condition in

question; we estimate health expenditures separately. QALYs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health for 1 year. A number of methods have been constructed to measure QALYs. In this analysis we rely on estimates of the obesity related QALYs by Jia and Lubetkin that use a statistical method developed by Cutler and Richardson (Refs. 36, 37, 38). In this context, the method uses regression analysis to estimate the effect of particular conditions on overall health status (Ref. 38). The study finds that the QALYs lost by the U.S. adult population due to annual obesity related illness and lost quality adjusted life expectancy based on 2005 through 2008 data are 0.0410 per adult, with approximately 57 percent of this burden coming from disability and activity limitations rather than premature death (Refs. 37 and 38). Based on the U.S. Census Bureau Statistical Abstract of the United States: 2011, the 18 and over population of the United States in 2009 was 232,458,000 (Ref. 39). The total estimate of lost QALYs from obesity for adults in the United States is then 9,530,778 QALYs. FDA notes in section I.A. of this document that 34 percent of the adult population is obese. Therefore, approximately 79,035,720 adults ( $232,458,000 \times 34\%$ ) are obese, and the lost QALY per obese adult is 0.121 QALY.

FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature on valuation. Beginning with an estimate of the value of a statistical life year (VSLY) of \$7.9 million, we annualize this estimate to yield a value of an additional year of life of \$106,000, \$213,000, \$319,000 and \$532,000. Calculations for estimated benefits will reflect these four estimates of the VSLY. Using these values and the estimate of 0.121 QALY per obese adult, the annualized cost per obese adult of lost QALYs, including both disability and premature death due to obesity is estimated as in the range of \$13,000 ( $\$106,000 \times 0.121$ ), \$26,000 ( $\$213,000 \times 0.121$ ), \$38,000 ( $\$319,000 \times 0.121$ ) and \$64,000 ( $\$532,000 \times 0.121$ ). The

corresponding total burdens from lost QALYs associated with obesity in the U.S. adult population are then \$1.028 trillion, \$2.055 trillion, \$3.003 trillion and \$5.058 trillion. Note that these estimates are for the annual lost QALYs of all obese adults and are not estimates of the benefits of the proposed requirements.

**Medical Costs.** The estimated medical expense reduction is calculated using data from the Medical Expenditure Panel Survey (MEPS). MEPS is a nationally representative survey of the civilian non-institutionalized population. MEPS contain detailed information on the respondents' medical expenditures, such as total annual medical expense by type of service and source of payment. In addition, the data also include demographic information (age, race, gender etc.) along with individual's body mass index (BMI) based on self-reported measure of height and weight.

Using 2006 MEPS data, Finkelstein and colleagues found that the annual obesity attributable medical costs for obese adults (BMI greater or equal to 30) relative to normal weight adults (BMI greater than or equal to 18.5 and less than 25) was between \$85,739,000 and \$146,624,000 in 2008 dollars. From Flegal and colleagues, 34 percent of adults were obese in 2006. With an adult population in 2006 of 224,583,000, the number of obese adults in 2006 was approximately 76,358,220 ( $224,583,000 \times 34\%$ ), yielding a per-obese cost of between \$1.14 and \$1.94 per obese adult in 2010 dollars (Ref. 18). Using the previous estimate of 79,035,720 obese adults, this translates into between \$89.9 billion and \$153.7 billion in medical costs associated obesity, and a mean estimate of \$121.8 billion. Note that these estimates are additional medical costs for all obese adults and are not estimates of the benefits of the proposed requirements.

**Calorie reduction.** Based on 2003 through 2004 NHANES data, Mancino and colleagues estimate that consuming a meal not prepared at home added an extra 239 calories to

the diet of obese individuals when compared to consuming a meal prepared at home (Ref. 40). NHANES data shows an estimated four meals eaten away from home per week (Ref. 40). This translates to an average of roughly 140 extra calories per day ( $239 \text{ cal/meal} \times 4 \text{ meals/week} / 7 \text{ days/week}$ ).

Studies of consumer response to vending machine calorie disclosure have been difficult to find. Restaurant menus studies of calorie disclosure have found that responses were often small or insignificant, but varied widely across different subgroups, ranging from increases in calorie intake for some populations to reductions of up to approximately 50 calories per meal for other groups (Refs. 41 through 46). Consumer response to reformulations and menu changes are also likely to be highly diverse. Taking a rough, unweighted average of the range of observed consumer responses for restaurant menus suggests that a 10-percent reduction in the additional calories consumed may be possible. For this proposed rule, we use a 10-percent reduction of the calories from vended food as a benchmark. This reduction may be possible for at least some populations, and may be supported by additional changes to the calorie amounts in the foods offered in vending machines. We therefore base our benchmark on an average decrease in calorie intake of 24 calories per meal ( $240 \text{ calories per meal} \times 10\%$ ), or 14 calories per day ( $140 \text{ calories per day} \times 10\%$ ) or 100 per week ( $14 \text{ calories per day} \times 7 \text{ days/week}$ ) by obese adults. We will further reduce this amount relative to the fraction of calories from vended food versus all restaurant and restaurant-type food.

**Weight and BMI reduction.** In order to convert this benchmark calorie reduction to U.S. population weight and BMI reductions we use a non-linear steady state model developed by Hall and Jordan for the calculation of individual weight loss using daily calorie reduction, height, initial weight, age, gender, fat mass, and physical activity level, (Ref. 47). In order to calculate

weight loss using NHANES U.S. population we implemented this model in symbolic algebra software which can solve nonlinear systems involving large matrices of data.

On the advice of Hall and Jordan, we use 2003 through 2004 NHANES data rather than the most recent (2007 through 2008) NHANES data in order to be able to use the dual energy x-ray absorptiometry data file. This data measures total fat mass for individuals, allowing for a much more accurate calculation of weight reduction than would be possible without this data. We do not use the MEPS data because height and weight are needed for calculating weight loss, and are not given in the public dataset. Furthermore, height and weight are self reported in MEPS, and may therefore be biased.

In addition to the NHANES dual x-ray data file, we use demography, body measurement and physical activity questionnaire data. The physical activity data is converted into physical activity level/metabolic equivalent of task, or PAL/MET scores using the recommended values given in the NHANES documentation. For missing values (approximately 1/3 of the observations), we assume the lowest level of activity (1.4). Given that individuals with lower levels of background activity lose more weight, this assumption means that the calculated weight reductions may be slightly higher than if all scores were known.

Using the weight reduction calculator and NHANES data, we estimate that a 14 calorie per day or 100 calorie per week reduction translates to a mean weight loss of 1.2 kilograms, from a range of 0.5 to 1.8 kilograms for U.S. adults over the age of 18. This decrease in weight translates to a mean decline in BMI of 0.455 BMI per obese adult from a range of 0.14 to 0.73. We contextualize this drop against the decline in BMI needed to bring the average obese adult BMI down to the average non-obese BMI. From NHANES 2003 through 2004 data the mean non-obese BMI is 24.7 and the mean obese BMI is 35.4, for a difference of 10.7 BMI points. We

can then characterize the 0.455 drop in BMI as a 4.3 percent drop in obesity as measured by excess BMI relative to the non-obese. Summing the estimates of QALY gains and medical cost abatement for all obese adults and taking 4.3 percent yields a range of \$91 billion to \$222 billion, with an intermediate estimate of \$133 billion for the total cost of obesity in adults. Note that this is not an estimate of the benefit of the proposed requirements.

**Benchmark fraction of obese adults.** Owing to the complexity of the causes of the obesity problem, and the complexity of the choices involved in choosing food away from home, we do not expect the proposed rule to reduce calories by this amount. However, we illustrate benefits by using a benchmark response that would be needed to create a positive net benefit from the rule. As a benchmark only, and not as an estimate of the actual benefits associated with the proposed rule, we consider the benefit associated with a 4.3 percent reduction in excess BMI. In particular, we calculate the minimum percentage of obese consumers that would need to reduce calorie intake in order for the proposed requirements to have positive net benefits.

Given the estimated mean cost for the proposed requirements of approximately \$25.8 million, and the estimated intermediate benefit of \$133 billion for all obese adults, if at least 0.02 percent ( $\$25.8 \text{ million} / \$133 \text{ billion}$ ) of the adult obese population responded to the calorie disclosure, then the proposed requirements would have a positive net benefit.

It is important to note here that these benchmark figures were drawn from data that was restricted to obese adults only (age greater than 18). As such, the estimated reductions in medical expenses may be conservative estimates (Ref. 48). Conversely, this research suggests that weight-reducing behavior in one person might spread to others as well, and thus policies designed to bring about a reduction in body weight might be more cost effective than estimated.

We did not account for the benefit that might be accrued by children in our analysis. Reduction in childhood obesity has been linked with many dimensions of human capital formation such as better educational and labor market outcomes (Ref. 48). It is reasonable to expect that the reduction in calorie consumption due to nutrition labeling of food sold in vending machines will not be limited to adults, but may also benefit children and adolescents in terms of healthier eating choices. Eighty-seven percent of all junior high and middle schools and 25 percent of all elementary schools have vending machines where children can buy foods, including drinks (Refs. 49).

**C. Option 2: Similar to the Proposed Rule, But Estimating the Cost of Individual Signs for Each Article of Food or Selection Button.**

i. Costs. This option would substantially increase the cost of disclosing calories. Because firms would need to manage signs for each covered vending machine food (or small groups of covered vending machine food) under this option, the displayed calorie information would potentially need to be changed every time a machine was filled. FDA estimates that displays would need to be changed an average of four times per year, under this option. FDA requests comment on this estimate. Workers would have to sort, affix, and change signs as the product mix changed. Therefore, FDA estimates that this approach would increase the labor costs of the proposed option to between \$32 million and \$134.4 million. Total initial costs for this option are between \$36.5 million and \$142.2 million. FDA requests comment on this estimate. The total costs of this option are provided in table 3 of this document.

**Table 3.--Option 2 Costs**

Cost	Low Estimate	Mean Estimate	High Estimate
Initial Calorie Analysis	\$0.7 million	\$1.8 million	\$3.0 million
Sign Costs	\$4.0 million	\$4.8 million	\$5.6 million
Signage Labor Costs	\$32.0 million	\$76.8 million	\$134.4 million
Total First Year Costs	\$36.7 million	\$83.4 million	\$143.0 million
Total Recurring Costs	\$36.0 million	\$81.6 million	\$140.0 million
Annualized Costs, 3%	\$36.1 million	\$81.8 million	\$140.4 million
Annualized Costs 7%	\$36.6 million	\$82.5 million	\$141.1 million

ii. Benefits. Because calorie information would likely be more prominently displayed under this option, consumers are more likely to absorb and respond to the information. Therefore, this option makes a higher response scenario more likely. However, because FDA does not have the data on how consumers' consumption pattern would change due to this proposed option, it is not possible to estimate the probability with which a response might occur. The substantially higher costs for this option would require a greater effect in order to break even. In this case, given the estimated mean cost for the proposed requirements of approximately \$82.9 million, and the estimated intermediate benefit of \$133 billion for all obese adults, if at least 0.06 percent ( $\$82.9 \text{ million} / \$133 \text{ billion}$ ) of the adult obese population responded to the calorie disclosure, then the proposed requirements would have a positive net benefit over the initial costs.

**D. Option 3: Similar to the Proposed Rule, But With an Additional Year of Compliance Time for Firms With Less Than \$500,000 in Annual Revenue.**

i. Costs. This option would give smaller firms more time to comply with the proposed requirements. Given the recurring nature of the costs, giving these firms more time to come into compliance would, in effect, relieve these firms from the costs of compliance for an additional year. From the 2007 Economic Census, more than 50 percent of vending machine operators and

food service contractors had sales less than \$500,000. If this figure holds for all operators of vending machines selling covered vending machine food, then at least 6,750 operators would have extra time to comply. Based on the share of sales, FDA estimates that the vending machine operators with sales below \$500,000 account for approximately 13 percent of vending machines. Taking a 13 percent reduction in the costs of labeling yields a first-year cost of between \$11.7 million and \$38.4 million, with a mean estimate of \$23.5 million. It is important to note, that the lower costs in this option are simply avoided costs for the additional year for small firms rather than a reduction in the initial or ongoing costs of compliance. FDA believes that the compliance time given in the proposed rule is adequate to prevent additional costs of compliance from additional staff, overtime or expedited analysis and printing jobs that would disproportionately affect smaller entities.

ii. Benefits. Under this option, consumers would see calorie declarations for some food sold in vending machines later and in a more piecemeal fashion than under the proposed rule. This delay may lower the initial health impact of the proposed rule, and delay the expected increase in consumer awareness of calorie intake from vending machine food. This may, in turn, lower, or at least delay, the overall benefit of requiring calorie disclosures for covered vending machine food in proportion to the number of machines that would fall into the delayed compliance period. In general, however, the benefits associated with calorie reduction are long term, and therefore relatively unaffected by a 1-year delay in compliance for small businesses. FDA estimates that the benefits associated with Option 3 are not different from the benefits associated with the proposed rule.

**E. Option 4: Similar to the Proposed Rule, But With Coverage Extended to All Bulk Vending Machines.**

Under this option, coverage would extend to bulk vending machines without selection buttons.

i. Costs. Under this option, between 5 million and 7 million machines and approximately 13,500 firms would be covered. This means that all costs would increase by approximately 20 percent over the costs of the proposed rule. Although the average cost per covered bulk machine would be under \$5 ( $(\$31.7 \text{ million} - \$25.3 \text{ million}) / 1.3 \text{ million}$ ), this represents a significantly higher proportion of per machine annual revenue, approximately 3 percent per machine ( $\$5 \text{ average cost} / \$147 \text{ average annual revenue}$ ) (Ref. 2). For machines covered under the proposed rule, this ratio of cost to revenue is less than one-tenth of 1 percent of average annual revenue ( $\$5 \text{ average cost} / \$6,722 \text{ annual revenue}$ ) (Ref. 2). The costs of Option 4 are given in table 4 of this document.

**Table 4.--Total Costs, Option 4**

Cost	Low Estimate	Mean Estimate	High Estimate
Initial calorie analysis	\$0.7 million	\$1.8 million	\$3.0 million
Sign costs	\$5.0 million	\$6.0 million	\$7.0 million
Signage adjustment costs	\$10.0 million	\$24.0 million	\$42.0 million
Total first year costs	\$15.7 million	\$31.8 million	\$52.0 million
Total recurring costs	\$15.0 million	\$30.0 million	\$49.0 million
Annualized Costs, 3%	\$15.1 million	\$30.2 million	\$49.4 million
Annualized Costs 7%	\$15.8 million	\$31.0 million	\$50.3 million

ii. Benefits. Because consumer spending on foods sold from bulk vended machines with no selection buttons comprises less than 0.5 percent of all vending expenditure, FDA uses the same estimate of benefits for this option as for the proposed rule. With total initial costs of \$31.7, the break-even point for this option is 0.02 percent of obese adults.

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