

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 Notice of Proposed
Rulemaking

Docket No. FDA-2011-F-0172

Preliminary Regulatory Impact Analysis

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 certain nutrition information for standard menu items in certain chain restaurants and similar retail food establishments to implement the menu 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), among other things, to require restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Under provisions of the Affordable Care Act, restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to the Federal requirements by registering every other year with FDA. Providing calorie and other nutrition information in restaurants and similar retail food establishments 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 notice of proposed rulemaking for the Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments proposed rule, Docket # FDA-2011-F-0172.

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I. Introduction

FDA has examined the impacts of the proposed rule under Executive Orders 12866 and 13563, 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 (both quantitative and qualitative) 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 rule has been designated an “economically” significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

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) definitions of small for industrial subsectors in accommodations, food service, recreation, and retail food stores (NAICS 72, 71, 445), FDA tentatively concludes that a significant number of firms affected by this proposed rule are small businesses.

Section 4205 of the Affordable Care Act and the proposed requirements apply to chain retail food establishments, as that term is used in this document (i.e., a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items), and establishments that voluntarily

register with FDA to become subject to the requirements of section 4205. Some chain retail food establishments may meet the SBA definitions of: less than \$7 million in annual sales for most accommodation and food service or recreation subsectors (NAICS 72, 71); less than \$20.5 million in annual sales for Food Service Contractors (NAICS 722310); or less than \$27 million in annual sales for supermarkets and convenience store chains (NAICS 44510 and 445120). In addition, some chain retail food establishments are owned or operated by entities, including franchisees or cooperative members that may meet the SBA definitions described above.

Establishments that voluntarily register to be subject to the Federal requirements, which may be individually owned or part of a firm that controls establishments within a chain of less than 20 locations, may meet the SBA definition described above. While the voluntary nature of the registration implies that these latter firms see a positive net benefit from becoming subject to the Federal requirements, this does constitute a potentially significant economic impact. Therefore, the agency tentatively concludes that the rule will have a significant economic impact on a substantial number of small entities. This conclusion is discussed further in section V.

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 expects this

proposed rule to result in 1-year expenditures that would meet or exceed this amount.

This conclusion is discussed further in section VI.

FDA asks for comments about the data and the methods used for estimating the regulatory impact of the proposed rule.

A. Need for This Regulation

This proposed rule is necessary to implement Section 4205 of the Affordable Care Act, which amends sections 403(q)(5) and 403A of the FFDCFA, and requires disclosure of calorie and other nutrition information by covered establishments. These nutrition labeling requirements should help consumers to make more informed choices about the nutritional content of the food they purchase. The provision of calorie and other nutrition information for restaurant and restaurant-type foods, as those terms are used in this document, offered for sale by covered establishments should help consumers limit excess calorie intake and understand how the foods that they purchase at these establishments fit within their daily caloric and other nutritional needs. FDA notes as well that Executive Order 13563 specifically directs agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include . . . disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.”

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. In the case of restaurant and restaurant-type foods, the private market is particularly robust and competitive. Hundreds of thousands of retail food establishments and tens of thousands of individual firms vie for consumer dollars across the United States. High estimates of failure rates for restaurants (Ref. 1), with

relatively steady growth rates in number of establishments (Ref. 2) indicate that entry in the industry occurs often, and survival is hard fought: restaurants must be responsive to consumer needs and desires in order to survive. The competitiveness of the industry suggests that if a sizable fraction of consumers were willing to pay for – and discriminate based on – the availability of nutrition information, then the industry would provide it to them. In fact, many retail food establishments do provide nutrition information for at least a fraction of their offerings, either through available brochures, or, increasingly, on the Internet. A 2006 study found that 34 percent of the top 300 chain restaurants (by sales volume) had nutrition information available to consumers in some form (Ref. 3).

Notwithstanding this point, and although many of the usual market failures that justify regulatory action, such as the existence of market power or public goods, cannot be found here (Refs. 4 and 5), the primary support for government intervention is an absence of sufficient nutritional information, produced by an inadequate incentive for restaurants to produce that information on their own. An absence of adequate information is of course a standard market failure, justifying disclosure requirements or provision of information in many contexts.

In terms of explaining the inadequate incentive for restaurants to provide sufficient nutrition information, a central reason involves consumer demand. There are systematic biases in how consumers weigh current or immediate benefits (from eating more, or higher calorie, foods) against future or long term costs (higher probability of obesity and its co-morbidities). These biases are directly related to the proposed requirements: the temporal disconnect inherent between food consumption choices and their potential health costs may work against an efficient provision of nutrition

information for food (Ref. 6). A primary issue here is that long-term risks may not be sufficiently salient to produce adequate consumer demand for relevant information disclosure. And without that information, consumers may fail to make informed choices and may undervalue the future costs of excessive calorie consumption, relative to the current benefits from such consumption (Refs. 6, 7 and 8).

Studies suggest that one problem involves the fact that because food decisions are made so often, and the marginal effect of any one meal on future obesity is small, the cumulative costs of a large number of relevant decisions may be neglected. These studies suggest that some or many consumers will not demand calorie information, because the issue of calories 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 latter date. This tendency may explain why consumers have not generally demanded calorie and other nutrition information for restaurant and restaurant-type food, although they do, at a later point in time, value that information. Furthermore, restaurants and similar retail establishments have costs of providing calorie and other nutrition information, including opportunity costs of limited time and space in which to convey information to the consumer. That is, just as a firm has to decide which possible menu items to leave off a menu board with limited space (thus giving up the opportunity to sell those items), it must choose which pieces of information about its menu items it wants to convey. Adding an additional piece of information means that a firm may need to downplay or remove some other valuable piece of information. In addition, providing calorie information may have complex and unintended effects on revenue and profits as consumers respond to that information. Given the costs and the uncertain reception of

displayed calorie information most restaurants have chosen not to display this information at the point of purchase.

The proposed requirements respond to the apparent market failure in information provision stemming from existing restaurant incentives and present-biased preferences. Specifically, the proposed requirements provide that calorie information for standard menu items must be posted in covered establishments. Providing this nutrition information will likely increase the salience of the information and promote informed choice as well. It will also likely raise consumer awareness regarding the number of calories in restaurant and restaurant-type foods, and thus may serve to highlight the potential future costs of additional calorie consumption. This increased attention to the number of calories in food offered for sale by covered establishments 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 Preliminary Regulatory Impact Analysis (PRIA).

Benefits in response to the proposed requirements Obesity and overweight are major public health concerns in the United States and among the top leading health indicators addressed by the United States Healthy People 2020 goals. Nationally representative data have consistently exhibited a steady increase in the prevalence of obesity over the past three decades (Ref. 9). As noted in section I. A., 34 percent of the adult U.S. population is

obese and 34 percent is overweight (Ref. 10). In addition, about 31 percent of children and adolescents, aged 2 to 19, are overweight or obese (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 disease has been documented to rise simultaneously with the increased prevalence of obesity (Ref. 12). The economic impact is especially evident for health-care costs in terms of greater health-care utilization and higher medical expenditures (Ref. 18). More specifically, as noted, medical expenditures attributable to overweight and obesity accounted for more than 9 percent of the total U.S. medical expenditures in 1998, or between \$86 billion, and \$147 billion (Ref. 18). Another estimate indicates that obesity costs American families, businesses and government approximately \$117 billion in 2010 (Ref. 19).

The primary risk factors for overweight and obesity in the general population are overconsumption of calories (i.e., eating more calories than are needed to maintain body weight) and physical inactivity (i.e., getting an amount of exercise below the amount required to burn excess calories consumed over the amount needed to maintain body weight (Ref. 20).

One contributor out of the complex and multi-facet set of factors is food offered for sale by restaurants and similar retail food establishments. The proportion of total food expenditure spent on such foods increased from 34 percent during the 1970s up to approximately 50 percent by 2004, where it has remained through 2009 (Ref. 21). These foods are generally high in calories, fat and portion size (Ref. 22), and they tend to be

lower in fiber and other essential nutrients such as calcium as compared to home-prepared foods (Ref. 23).

Restaurant food and restaurant-type food form a significant and increasing part of U.S. diets. According to one study, “food away from home” (this term is roughly comparable to restaurant and restaurant-type foods) constituted about a third of calories consumed annually by the average adult or child in the United States in the most recent comprehensive published study (Ref. 23). Another study of adults found that “food away from home” adds an additional 130 calories per meal, on average, relative to a similar meal prepared at home (Ref. 24). The difference in calorie consumption between “food away from home” and food prepared at home was greater for study participants who were overweight or obese; among those individuals, the away-from-home meals had 240 more calories per meal relative to meals prepared at home (Ref. 24).

Although many factors contribute to obesity, to the extent that the proposed requirements would mitigate the prevalence of obesity and of co-morbidities, society would gain the opportunity cost of the averted medical expenditures and an increase in productivity from averted debilitation and death. In addition to informing consumers about the calorie content for restaurant and restaurant-type foods offered for sale by covered food establishments, major predicted elements of the consumer and industry response to this proposed rule may include:

1. Increased awareness regarding the caloric content for foods offered for sale by covered establishments, 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 regarding calorie content of menu items, which may give firms an incentive to:
 - a. Reduce the calorie content of existing items through reformulation or by decreasing portion size.
 - b. Provide additional items with lower calorie formulations.

These changes may reduce consumers' caloric intake from foods sold in covered establishments, and this reduction in caloric intake may in turn contribute to a reduction in obesity in the U.S. population. 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. This substitution of one calorie source for another has been demonstrated in the context of menu labeling (Ref. 25) and in the context of other attempts to modify food choices (Ref. 26). Because FDA lacks data on how consumers will substitute between caloric sources, as well as specific information on the responsiveness of calorie demand to new information, the benefit estimations given here may be higher or lower than those that will be realized if the rule is finalized as proposed. Finally, there may be additional benefits to the extent that consumers use the written nutrition information to make food selections.

Industry and consumer costs in response to the proposed requirements

Meeting the proposed requirements will have costs for both the industry and consumers. Typically, new costs to an industry are borne by both consumers and firms: prices rise to reflect new costs, but generally not by enough to completely offset them. If the expense of meeting the proposed requirements cause prices to increase for some or all restaurant and restaurant-type foods offered for sale by covered establishments, then the

consumption of these foods will fall, further reducing profits for some, or all, of these establishments. Consumers would need to pay more for this food, requiring some reduction in other, valued, consumption.

One difficulty in determining the cost burden stems from the relatively complicated ownership structures in some of the covered sectors. Restaurants and similar retail food establishments can be corporate-owned, franchised as part of a large or small independent chain, or cooperatively-organized and doing business under the same name. Data for separate firms operating under the same name, such as franchises of a particular brand or corporate name, are difficult or impossible to acquire. Therefore, for this analysis FDA counts affected establishments and chains, which may in fact serve one, several, or many, underlying firms. Except for some potential costs of nutrition analysis, the costs of the proposed rule are analyzed at either the chain or the establishment level, so that the overall costs are not primarily a function of the actual number of firms affected.

The major elements of cost for this proposed rule are:

1. Collecting and managing records of nutritional analysis for each standard menu item.
2. Revising or replacing existing menus, menu boards and other affected displays.
3. Training employees to understand nutrition information in order to help ensure compliance with the proposed requirements.

Although not required by the proposed requirements, some chains or establishments may respond to increased consumer interest on caloric content of restaurant and restaurant-type food by reformulating existing menu items or by

introducing new, lower calorie items. While the costs associated with formulating these items have not been included in the cost estimation, FDA has included the cost associated with analyzing new or reformulated items. Because the rate at which these items are introduced may be affected by the proposed requirements, FDA requests comment and data on whether the proposed requirements will accelerate the rate of new item introduction and how the cost of these items may be affected by the proposed requirements.

Finally, because they are not required by the proposal, FDA has not included any costs associated with developing online or other electronic calorie calculators for variable menu items. FDA requests comment and data on the costs of these kinds of calorie tools.

Summary of benefits and costs We summarize the estimated costs and benefits of the proposed requirements and some regulatory options in Tables 1a-1b. Costs of complying with the proposed requirements have been estimated for three major areas: cost of nutrition analysis, cost of menu and menu board replacement, and costs of training. These costs have been aggregated across an estimate of the total number of chains and establishments that would be defined as covered under the proposed rule. In the case of the proposed rule, FDA estimates that there would be approximately 278,600 covered establishments organized under 1,640 chains. The initial mean estimated cost of complying with the proposed requirements is \$315.1 million, with an estimated mean ongoing cost of \$44.2 million. Annualized over 10 years, the mean estimated annual cost of the proposed requirements is \$76.8 million at a 3 percent discount rate, and \$82.3 million at a 7 percent discount rate. FDA has estimated low and high annualized cost

estimates for the proposed requirements of \$33.4 million and \$120.5 million with a 3 percent discount rate, and \$34.9 million and \$130.1 million with a 7 percent discount rate. The bases for this wide range of cost estimates and the main drivers of this uncertainty are collected and discussed in the full, detailed PRIA.

Initial costs are estimated to be \$1,100 per covered establishment. Note however, that this figure combines the average per establishment cost of \$1,800 per limited service eating establishments – i.e. those most likely to have more than one menu board or major display serving as a menu - with full service restaurants averaging less than \$1,000 per establishment. These averages do not show the very wide range of costs that individual establishments and chains will bear, based on their very different approaches to nutrition analysis, menu design and overall market niche.

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 establishment menus. 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 0.06 percent of the adult obese population would need to reach at least this benchmark in order for the rule to break even on the primary, or mean annualized cost.

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

	Primary Estimate	Low Estimate	High Estimate	Year Dollar	Discount Rate	Period Covered
Benefits						
Annualized Monetized (\$millions/year)	Not Quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.06 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%)						
Costs						
Annualized Monetized (\$millions/year)	\$82.3	\$34.9	\$130.1	2009	7%	10
	\$76.8	\$33.4	\$120.5	2009	3%	10

C. Regulatory Options

In addition to a baseline, FDA has identified five regulatory options for this proposed rule as required by Executive Order 12866. The estimated benefits and costs of these options relative to the proposed rule are given in Table 1b.

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

(1) Option 1, the proposed rule, the definition of "restaurants or similar retail food establishments," limited to retail establishments that offer for sale restaurant or restaurant type food where the sale of food is the primary business activity of that establishment. This option encompasses limited- and full-service restaurants, snack bars (including coffee shops, pastry shops, sandwich counters and similar establishments), cafeterias, drinking places, convenience stores and grocery stores that are chain retail food establishments as defined in this proposed rule. The proposed rule has an effective date of six months after the publication of the final rule.

(2) Option 2, with requirements similar to the proposed rule, but with "restaurant or similar retail food establishment" limited to retail establishments where the sale of restaurant food or restaurant-type food is the primary business activity. This option covers all establishments included in Option 1, with the exception that grocery and convenience stores would not be subject to the proposed requirements.

(3) Option 3, with requirements similar to the proposed rule, but with scope broadened to include a wide variety of establishments that serve restaurant or restaurant-type food.

(4) Option 4, with requirements similar to the proposed rule, but with an effective date starting three months after publication of the final rule instead of six months after publication of the final rule.

(5) Option 5, with requirements similar to the proposed rule, but with an effective date starting 12 months after publication of the final rule instead of six months after publication of the final rule.

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	\$76.8	\$33.4	\$120.5	3%	0.0%	0.0%
	\$82.3	\$34.9	\$130.1	7%		
Option 2: Smaller Scope	\$65.9	\$29.1	\$103.2	3%	-12.5%	-5.0%
	\$72.5	\$31.6	\$113.8	7%		
Option 3: Larger Scope	\$86.9	\$38.2	\$135.5	3%	+13.3%	+11.2%
	\$92.9	\$39.9	\$145.8	7%		
Option 4: Shorter Compliance Time	\$84.2	\$35.8	\$132.4	3%	+9.4%	0.0%
	\$91.0	\$37.8	\$144.0	7%		
Option 5: Longer Compliance Time	\$76.2	\$31.9	\$120.5	3%	-2.4%	0.0%
	\$81.6	\$33.2	\$130.1	7%		

FDA estimates that Option 2, which limits the scope of the proposed requirements to establishments that either present themselves as restaurants or have more than 50 percent of their floor area used for restaurant or restaurant-type food, has a ten-year annualized cost of between \$29.1 million per year and \$103.2 million per year with a 3 percent discount rate, with a primary estimate of \$65.9 million. Averaged over primary, low and high estimates, the costs of Option 2 are 12.5 percent lower than those of the proposed requirements. Although FDA does not have adequate data on the proportion of calories consumed at different types of establishments, as a rough estimate of the coverage of Option 2 relative to the proposed requirements, we use the proportion of dollar sales of restaurant or restaurant type food relative to the establishments covered by

the proposed rule. In the case of Option 2, limiting the scope of covered establishments would reduce the coverage of restaurant or restaurant-type food sales by 5.0 percent.

These changes are discussed more fully in the detailed analysis.

Option 3 which considers a wider set of establishments that service restaurant or restaurant-type foods, including lodging, transport, entertainment, general retail and other establishments, has costs that are 13.3 percent higher than those of the proposed requirements and coverage of sales that is 11.2 percent higher. Option 4, which shortens the compliance time to 3 months, has costs that are 9.4 percent higher than the proposed, and Option 5, which lengthens compliance time to 12 months has costs that are estimated to be 2.4 percent lower. These options do not change the set of covered establishments relative to the proposed rule.

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 is only likely to occur to the extent that the costs of registration and compliance with federal regulation is lower than that of State or local regulation, this registration constitutes a collection of information under the Paperwork Reduction Act of 1995. Therefore, FDA has also estimated the burden associated with this collection of information in sections V.D. and VI of this document.

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 for the purpose of analysis – No new federal regulatory action

Imposing no new federal nutrition labeling requirements for restaurant or restaurant-type foods is the baseline in our analysis. Section 4205 requires that FDA issue menu labeling regulations, so this is not a legally viable option. However, OMB Circular A-4 recommends discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity costs of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. All options will be measured for assessing costs and benefits against this baseline. Before the enactment of the Affordable Care Act, some restaurants and similar retail food establishments were subject to State and local menu labeling laws. Further, many restaurant and similar retail food establishment chains had to deal with an increasing number of different nutrition disclosure requirements because their establishments were not all located in the same jurisdiction. Because of different requirements among jurisdictions, these establishments needed to develop and track multiple approaches for disclosing nutrition information in order to meet each jurisdiction's requirements. Consequently, the potential cost to industry in the absence of this new federal regulatory policy (legislation and FDA regulation combined) could have been several times the cost of the proposed rule, which proposes national uniform requirements.

FDA cannot predict the number of regulations that the industry would have had to comply with if the Affordable Care Act had not been enacted. Therefore FDA is unable to estimate the total cost and benefit for the baseline. Instead, we take a conservative approach by counting only those costs that would have been incurred by covered under

State and local laws that would have been in effect if the Affordable Care Act had not been enacted, and that would be applicable to meeting the proposed requirements.

Although these State and local menu labeling laws differed, all imposed requirements on stand-alone full-and-limited-service eating places. Using data from 2007 County Business Patterns, (Ref. 2), FDA estimates that approximately 27 percent of chain retail food establishments would have been in jurisdictions with State and local nutrition labeling laws if the Affordable Care Act had not been enacted. These establishments would have had to acquire nutrition analysis for their menu items and train employees. In order to account for these baseline costs, 27 percent of the nutrition analysis costs and employee training costs have been subtracted from the costs incurred by full and limited service eating places as calculated in the analysis of the options.

Chain retail food establishments that were subject to pre-existing State or local laws will likely need to redesign and replace some of their menus and menu boards to comply with the proposed requirements. The expenses that these establishments incurred to comply with State and local laws will not reduce the cost of complying with the proposed requirements because the proposed requirements differ from the State and local laws.

B. Option 1, the Proposed Rule

Under this, and all other options, FDA proposes that covered establishments are required to disclose in a clear and conspicuous manner:

a. on menus and menu boards: (1) the number of calories for each standard menu item; (2) a succinct statement concerning daily caloric intake; and (3) a statement indicating that additional nutrition information is available upon request;

b. in a written form, available on the premises of the establishment, and to the consumer upon request, additional nutrition information for standard menu items; and

c. for standard menu items that are food on display or for self-service, the number of calories contained in each item or per serving.

The proposed rule specifies how restaurants and similar retail food establishments not subject to the requirements of section 4205 can voluntarily register with FDA to become subject to the Federal requirements. The primary benefit for restaurants and similar retail food establishments that voluntarily register with FDA is the preemption of State and local nutrition labeling laws that are not identical to the Federal requirements. By registering, a restaurant or similar retail food establishment need only comply with the Federal requirements, and any identical State or local requirements. Costs borne by restaurants and similar retail food establishments that voluntarily register to be subject to section 4205 will be lower than the costs of complying with preempted State and local laws because otherwise no firm would voluntarily do so. Therefore, the registration is taken to have positive net benefit. To the extent that these establishments register, the estimates presented here may underestimate the total net benefit of the proposed rule.

We note that although voluntary registration under section 4205 has been available to restaurants and similar retail food establishments that are not subject to the requirements of section 4205 since July 23, 2010; as of March 7, 2011, no firms have attempted to register with FDA. Note that implementation of the proposed requirements, and the resulting attention to the calorie content of restaurant and restaurant-type foods, may give non-covered establishments an incentive to voluntarily disclose calorie and other nutrition information. However, this incentive does not imply that establishments

would voluntarily restrict their options for disclosure by registering under the proposed requirements.

Finally, the proposed rule tentatively sets an effective date of six months after the publication of the final rule. Option 4 analyzes the benefits and costs under a three-month effective date and Option 5 analyzes the benefits and costs under a 12 month effective date. A shorter timeframe will primarily impact the costs of updating or replacing menus and menu boards.

The proposed rule covers chain retail food establishments and other restaurants and similar retail food establishments that voluntarily register with FDA to become subject to the Federal requirements. A “restaurant or similar retail food establishment” is defined in the proposed rule as an establishment that offers for sale restaurant or restaurant-type food whose primary business activity is the sale of food.

For the purposes of this analysis, the universe of chain retail food establishments as defined in the proposed rule is drawn from the industry sectors listed in Table 2 as classified by the North American Industry Classification System (NAICS) (Ref. 27), including eating and drinking places such as full- and limited-service restaurants, snack bars (including, for example, ice cream, donut, and bagel shops and similar establishments), cafeterias and drinking places.^{1,2} Chain retail food establishments may also include some grocery stores and convenience stores.

□

¹ “[NAICS] is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.” (Ref. 28) Note that businesses self-report their sector.

² This list is not definitive in any legal sense. Its creation and use is in fulfilling the requirements for estimating the benefits and costs of the proposed rule. As such, some covered establishments may be in sectors not listed below, and many establishments in the listed sectors are not covered, because they do not meet the conditions of Section 4205 and the proposed rule.

Table 2: Sectors with Estimated Number of Chain Retail Food Establishments and Associated Chains

Sector	NAICS	Estimated No. of Chain Retail Food Establishments ¹	Estimated No. of Associated Chains ¹
Full Service Restaurants and Drinking Places	7221, 7224	115,000	530
Limited Service Eating Places (including snack bars, ice cream shops and similar establishments)	7222	116,200	540
Grocery (excluding convenience) Stores	4451	11,200	120
Convenience Stores and Gas Stations with Convenience Stores	44711	36,200	450
Total Number of Additional Entities		278,600	1,640

¹Estimates are from the analysis of costs below.

a. Costs

The costs to industry of complying with the proposed requirements include nutrition analysis of standard menu items, menu replacement, and employee training.

Cost estimate for nutrition analysis These costs are summarized in Table 3. In order to comply with the proposed requirements, a chain retail food establishment will need to conduct some type of analysis to determine the nutrient content information for each standard menu item. As noted in subsection V.B., many chains may have already obtained nutrition information for their own purposes, but a 2006 study (Ref. 3) found that only 34 percent of the largest 300 restaurant chains (by sales volume) had substantial nutrition information available to consumers in some form. Although anecdotal evidence suggests that this number is currently much larger for the largest restaurant chains, the proposed requirements apply to many smaller chain retail food establishments that may be less likely to have existing nutritional analyses. From the analysis for the baseline, FDA estimated that 27 percent of chain retail food establishments already have obtained

nutrition analysis in order to comply with State and local laws that were in effect before the enactment of the Affordable Care Act. Therefore, we take the remaining fraction of the chain retail food establishments (73 percent) and combine it with the fraction of chains with nutrition information prior to the enactment of the Affordable Care Act or State and local menu labeling rules (66 percent is $(100\% - 34\%)$, or the fraction of restaurant chains that already had nutrition information), to get the fraction of restaurant chains that will need new analyses under the proposed rule: 0.48 (0.73×0.66). Note that because of their more expansive geographic coverage, larger chains are more likely to be part of the 27 percent than smaller ones. To the extent that larger chains were also more (or less) likely to have had nutrition information available prior to the enactment of the Affordable Care Act or State and local menu labeling rules than smaller chains, this estimate may be too low (or too high). FDA requests comment on this estimate.

In practice, many food items are manufactured elsewhere and are delivered as complete products (both packaged and unpackaged) – for example, sodas or completed food items from food service distributors – and may thus have nutrition information already available. Because FDA does not have data on how many products are currently shipped with nutrition information to chain retail food establishments, we conservatively estimate costs given that each standard menu item will need analysis. Nutrition analyses for standard menu items with multiple sizes will also be cheaper on a per-item basis because the analyses can be adjusted proportionally up or down based on the size difference; therefore, we estimate the cost of nutrition analysis based on the number of unique items on the menu.

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. FDA's 2003 Labeling Cost Model reports a cost for full NLEA lab analyses of \$560 (Ref. 29). This is higher than the price, \$495 per item, quoted for a lab analysis in fall 2010 (Ref. 30). Lab testing typically requires the shipment of between 10 and 12 replicates of the item to be tested. At an average food and preparation cost of \$5 per item, and an average of 11 replicates sent, the food cost would be \$55 (\$5/replicate x 11 replicates) per menu item tested.³ We estimate the cost of packing and cold shipping to be approximately \$100/menu item.

Database nutrition analysis services quote prices as low as \$25 per item, going up to \$100 per item for more complicated items (Ref. 32). At least one service offers flat rates of \$49 for ten items where the purchaser enters the recipe into a calculator (Ref. 33). A senior dietician or nutritionist earns \$35.91/hour (Ref. 34). Taking into account 50 percent overhead costs, the wage cost to a firm of one hour to enter a recipe is approximately \$54. The total cost per item at this website would be approximately \$59 per item (lower with high volume discounts).

Based on data from FDA's Recordkeeping Cost Model (Ref. 35), we estimate approximately 4 hours in time burden per standard menu item for creating and administering the record of nutrition analysis. Again using the hourly wage plus overhead for dietitians and nutritionists of \$54/hour, we estimate the costs for

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³ Average price (excluding tax and tip) for a meal is approximately \$8 (Ref. 63). Using a 60 percent markup, food costs are approximately \$5. This may be an overestimate given that meals are comprised of individual food items.

administering the records of menu item nutritional analysis to be \$216 per item (4 hours/item x \$54/hour).

The per-item estimated cost of nutrition analysis ranges from \$275 per item (\$59 database +\$216 administrative cost) to \$866/item (\$495 lab work+\$216 administrative cost +\$100 shipping+\$55 food cost), with a mean estimate of \$571 per item.

Restaurants For purposes of this analysis, we are using the term “restaurant” to mean those establishments that self-identify as establishments whose primary business activity is the sale of “meals and beverages for immediate consumption” in economic census surveys, some of which will be chain retail food establishments, as that term is used in this document. The category of restaurants includes full and limited service eating places that have traditionally been thought of as restaurants in that they primarily serve meals and have seating, although they may also have, or be, drive-through or takeout operations. This category also includes establishments serving more limited restaurant or restaurant-type food, such as ice cream or donut shops, coffee bars, and drinking establishments. All of these establishments are defined by the U.S. Census Bureau as belonging under NAICS 7221, 7222 and 7224. FDA estimates that there are 1,070 chains that will need to comply with the proposed requirements, if finalized as proposed (Ref. 36). These establishments serve as the basis in this analysis for the actual “restaurants and similar retail food establishments” that will be covered by the proposed requirements if finalized as proposed.

The 600 largest restaurant chains (by sales) have an average of 80 unique menu items, excluding alcoholic beverages (Ref. 37). If this average holds for all restaurant establishments that are subject to the proposed requirements, the average per chain cost

of analysis ranges from \$22,000 ($\$275/\text{item} \times 80 \text{ items}$) to \$69,300 ($\$866/\text{item} \times 80 \text{ items}$), with a mean estimate of \$45,600. As noted earlier in the analysis, of 1,070 restaurant chains, we estimate that only 48 percent, or 514, will need nutritional analyses because the rest will have already acquired this information. The estimated costs of analysis for restaurant chains range from a low of \$11.3 million (514 chains \times \$22,000/chain) to a high of \$35.6 million (514 chains \times \$69,300/chain), with a mean estimate of \$23.5 million. Again, the variation depends on how heavily the chains rely on database analysis versus laboratory testing.

In addition to nutrition analysis by restaurant chains, individual firms that make up these chains may need to acquire analyses for standard menu items that are subject to the proposed requirements but are specific to certain establishments, and thus not dealt with at the chain level. FDA lacks data both on the number of firms and the number of standard menu items each of these firms would need to analyze. If the number of firms is represented by between 0 and 10 percent of the total number of chain restaurant establishments, then between 0 and 23,100 ($231,200 \text{ establishments} \times .1$) additional firms would need nutrition analysis. Because these firms are likely to have fewer resources than the larger chains, FDA expects these firms to use the less expensive database nutrition analyses, at an estimated cost of \$275 per item. If each of these firms needed analysis for an average of 5 menu items then the cost of these additional nutrition analyses would be between \$0 and \$31.8 million ($23,100 \text{ firms} \times 5 \text{ items/firm} \times \$275/\text{item}$), with a mean of \$15.9 million. FDA requests data and comment on these estimates.

Grocery and convenience stores FDA estimates that there are approximately 120 grocery chains with 20 or more establishments, accounting for approximately 31,000

establishments (Ref. 38 and 39). Not all of these stores sell restaurant or restaurant-type food. The Census Bureau's 2007 Economic Census data reports that 36 percent of total establishments report sales of "meals or beverages for immediate consumption."

Applying this proportion to all establishments that are part of chains of 20 or more, FDA estimates that approximately 36 percent of grocery store establishments, or 11,200 (31,000 establishments x 0.36), would be considered chain retail food establishments under this option, and therefore would be subject to the proposed requirements under this option. Note that this estimate is limited to those establishments serving restaurant or restaurant-type food. All grocery stores are expected to meet the criterion of greater than 50 percent of floor space devoted to food.

Based on firm counts from the 2007 Economic Census, FDA estimates that there are approximately 450 convenience store chains with 20 or more establishments, accounting for approximately 60,000 convenience stores (Refs. 40 and 41). Again using the proportion of total establishments reporting sales of "meals or beverages for immediate consumption" from 2007 Economic Census data on convenience stores, FDA estimates that 60 percent, or 36,200 convenience stores, would be defined as chain retail food establishments under this option. . Again, this estimate is limited to those establishments serving restaurant or restaurant-type food. Most if not all convenience stores are expected to meet the criterion of greater than 50 percent of floor space devoted to food.

Taken together, there would be 47,400 grocery and convenience stores that would need to comply with the proposed requirements, and 570 chains that are made up of these establishments.

Because of the more limited offerings for restaurant or restaurant-type foods at grocery and convenience stores, FDA estimates that these establishments have, on average, approximately one half the number of menu items of an average restaurant, or 40 menu items. FDA requests comment on this estimate. The per item costs, multiplied by the number of items per chain, yield average costs of nutrition analysis per grocery or convenience store chain of between \$11,000 ($\$275/\text{item} \times 40 \text{ items}/\text{chain}$) and \$34,600 ($\$866/\text{item} \times 40 \text{ items}/\text{chain}$), with a mean estimate of \$22,800 per chain. Because nutrition analysis for restaurant or restaurant-type food generally is less common for grocery and convenience store chains, we calculate the total nutrition analysis costs for grocery and convenience store chains for all 570 chains. The estimated cost of nutrition analysis for grocery and convenience store chains ranges from \$6.3 million (570 chains \times \$11,000/chain) to \$19.8 million (570 chains \times \$34,600/chain), with a mean estimate of \$13.0 million.

Individual firms that make up these chains may need to acquire analysis for standard menu items that are subject to the proposed requirements, but are specific to their establishments, and thus not dealt with at the chain level. FDA lacks data both on the number of firms and the number of standard menu items each of these firms would need to analyze. If the number of firms can be represented by between 0 and 10 percent of the total number of chain grocery and convenience store establishments, then between 0 and 4,700 additional firms would need nutrition analysis. If each of these firms needed

analysis for an average of 5 menu items, then the cost of these additional nutrition analyses would add between \$0 and \$6.5 million (4,700 firms x 5 items/firm x \$275/item) to the cost of nutrition analysis, with a mean of \$3.3 million. FDA requests data and comment on these estimates.

In total, the initial costs of nutrition analysis for restaurants and similar retail food establishments are estimated as between \$17.6 million and \$93.7 million, with a mean estimate of \$55.7 million.

Recurring Costs From Mintel Menu Insights data, FDA estimates that restaurant chains introduced, on average, 24 new menu items in 2009 (Ref. 42). Because the proposed requirements do not apply to temporary menu items, daily specials, and foods that are part of a customary market test, only a fraction of these items would need nutrition analysis. FDA requests comment and data on the number of new and reformulated items that would require nutrition analysis under the proposed requirements.

FDA tentatively estimates that existing restaurant chains or establishments would need new nutrition analysis on between 0 and 50 percent, for an average of 25 percent, of new standard menu items, or 6 items per year. If in addition to these new standard menu items, chains need nutrition analysis on 6 reformulated standard menu items, then there would be a total of 12 nutrition analyses per chain needed on an annual basis. With an estimated total of 1,070 chains associated with establishments that could be subject to the proposed requirements, the annually recurring costs of nutrition analysis for restaurant chains would be \$3.5 million (1,070 chains x 12 items/chain x \$275/item) to \$11.1 million (1,070 chains x 12 items/chain x \$866/item), with a mean estimate of \$7.3 million. Based on growth of the number of establishments in the limited and full service eating place sectors from U.S. 2000-2008 County Business Patterns data, FDA estimates

that the number of chains with establishments that would be newly subject to the proposed requirements would be approximately 2 percent per year (Ref. 2).⁴ Given this growth rate, there would be an estimated 20 new restaurant chains (1,070 chains x .02) with establishments that would be subject to the proposed requirements every year. If each new chain has an average of 80 standard menu items, then the recurring costs associated with these new chain retail food establishments is between \$0.4 million (20 chains x 80 items/chain x \$275/item) and \$1.4 million (20 chains x 80 items/chain x \$866/item), with a mean of \$0.9 million each year.

Using the same estimate as for restaurants of 12 new standard menu items per year, FDA estimates that the 570 additional grocery and convenience store chains would have annually recurring costs of nutrition analysis would be of between \$1.9 million (570 chains x 12 items/chain x \$275/item) to \$5.9 million (570 chains x 12 items/chain x \$866/item), with a mean estimate of \$3.9 million.

Based on growth in the covered sectors from U.S. 2000-2008 County Business Patterns data (Ref. 2), FDA estimates that the number of chains with establishments that would be subject to the proposed requirements would grow by approximately 2 percent per year. Given this growth rate, there would be an estimated 10 new chains (570 chains x .02) with establishments that would be subject to the proposed requirements every year. If each new chain has an average of 40 standard menu items, then the recurring costs associated with these new chain retail food establishments is between \$0.1 million (10 chains x 40 items/chain x \$275/item) and \$0.3 million (10 chains x 40 items/chain x \$866/item), with a mean of \$0.2 million each year.

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⁴ Note that any firms that lost establishments, and thus were no longer subject to the proposed requirements would not be able to recoup the costs already incurred.

Including the costs to restaurants, total recurring nutrition analysis costs for the proposed rule are between \$5.9 million and \$18.7 million, with a mean estimate of \$12.3 million.

Annualized Costs Annualized costs are calculated by adding the recurring costs to the initial costs annualized over 10 years at 3 percent and 7 percent discount rates. Using the 3 percent discount rate over 10 years yields an annualizing factor of 8.79 and using 7 percent yields an annualizing factor of 7.52.⁵ With a 3 percent discount rate, the annualized mean cost of nutrition analysis is estimated to be \$18.6 million (\$12.3 million + \$55.7 million/8.79), or between \$7.9 million and \$29.4 million. With a 7 percent discount rate, the annualized mean cost of nutrition analysis is estimated to be \$19.7 million (\$12.3 million + \$55.7 million/7.52), or between \$8.2 million and \$31.2 million.

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⁵ The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year. In mathematical notation this is: $\sum_{t=0}^9 \frac{1}{(1+r)^t}$ where t is the year from zero to 9 and r is the discount rate, either 3 or 7.

Table 3: Costs of Nutrition Analysis, Proposed Requirements

Sector	No. of Entities	No. Menu Items	Low Estimate	Mean Estimate	High Estimate
Restaurant Chains	514	80	\$11.3 million	\$23.5 million	\$35.6 million
Restaurant Firms (within chains)	11,560	5	\$0.0 million	\$15.9 million	\$31.8 million
Grocery Store Chains (excluding convenience)	120	40	\$1.3 million	\$2.7 million	\$4.2 million
Convenience Store Chains	450	40	\$5.0 million	\$10.3 million	\$15.6 million
Grocery and Convenience Store Firms (within chains)	2,350	5	\$0.0 million	\$3.3 million	\$6.5 million
Total Initial Nutrition Analysis Costs			\$17.6 million	\$55.7 million	\$93.7 million
New Items Restaurants	1,070	12	\$3.5 million	\$7.3 million	\$11.1 million
New Items, Grocery and Convenience	570	12	\$1.9 million	\$3.9 million	\$5.9 million
New Restaurant Chains	20	80	\$0.4 million	\$0.9 million	\$1.4 million
New Grocery and Convenience Chains	10	40	\$0.1 million	\$0.2 million	\$0.3 million
Recurring Costs			\$5.9 million	\$12.3 million	\$18.7 million
Total Annualized Nutrition Analysis Costs 3%			\$7.9 million	\$18.6 million	\$29.4 million
Total Annualized Nutrition Analysis Costs 7%			\$8.2 million	\$19.7 million	\$31.2 million

Menu Replacement Costs Menu replacement costs are summarized in Table 4. Chain retail food establishments will need to redesign and replace their existing menus and menu boards in order to comply with the proposed requirements. For full service restaurants and drinking places with only personal menus and no menu boards, this cost will be relatively low. Most menus are replaced frequently as they wear out, are lost, or as prices and menu items change. For many of these establishments, the cost of updating menus to comply with the proposed requirements would be limited to design and associated administrative burdens. However, some establishments have more durable menus, and longer menu design cycles. These firms would need to discard and replace their menus.

Because of the longer lifespan of menu boards, limited-service eating places would likely need both menu/menu board redesign and replacement of one or more menu boards. In addition, some chains would need to update self-serve and display signs.

Because of the wide variation in styles of menu and economies of scale, reprint costs can run from pennies to several dollars per menu. Based on published printing costs, FDA estimates the range of average materials and printing costs to be between \$1 and \$3 per copy, with some individual chains spending much less and others much more. The number of menus that an establishment will keep on hand is also highly variable. A full-service restaurant, where each order is placed using a menu, will need more than a quick-service establishment that uses menus just for takeout orders. The number of menus is also tied to the seating capacity of the restaurant, and whether the menu is laminated or paper. Because paper menus are more fragile and cheaper to print in bulk,

an establishment may keep a large reserve in stock, whereas establishments using more durable and expensive laminated menus may only keep a few extra on hand.

Estimates for the cost of updating menu boards, other major displays that serve as menus – such as electronic displays – or major materials needed to disclose calories for self-serve or displayed foods to comply with the proposed requirements will vary widely across chains and establishments because of different menu board and display types.

Although FDA has no data on the costs of menu board design per se, FDA's Labeling Cost Model uses design and administrative costs ranging from \$2,250 to \$4,690 per label (updated using the latest, 2009 GDP deflator) (Ref. 29). Costs of new menu boards or other major displays may range from \$100 to \$1,000 per menu board or major display depending on the materials, size and format (Ref. 43). FDA estimates that the in-store labor needed to change out menu boards or other major displays will be one hour for managers and one hour for staff-level employees. Establishments that are part of larger chains with more displays and more sophisticated ordering technology estimate that the cost may range between \$1,500 and \$2,500 per establishment; this estimate is in line with FDA's high estimate of per establishment costs (Ref. 44).

Restaurants Of the 1,070 restaurant chains with 20 or more establishments, FDA estimates that 420 are limited-service restaurants that have menu boards, with a total of 91,000 chain retail food establishments. If each of these establishments has, on average, 3 menu boards or major displays, for example a main menu board, a drive-through board and self-service displays, then the cost of replacing menu boards to comply with the proposed requirements will be between \$410 (3 boards x (\$100/board equip + \$36/board labor)) and \$3,110 (3 boards x (\$1000/board equip + \$36/board labor)) per

establishment, with an average cost of \$1,760. The estimated cost for replacing limited service restaurant menu boards is between \$37.3 million (91,000 establishments x \$410/establishments) and \$283.0 million (91,000 establishments x \$3,110/establishments), with a mean estimated cost of \$160.2 million. Each of these chains will also need to redesign their menus and menu boards, at an estimated cost of between \$0.9 million (420 chains x \$2,251/chain and \$2.0 million (420 chains x \$4,695/chain). FDA estimates that the total cost to limited-service restaurants is between \$38.3 million and \$285 million.

In addition to limited-service restaurants, FDA estimates that there are approximately 25,200 snack bars and cafeteria establishments from 120 chains that would need to replace menu boards under the proposed requirements. If each of these establishments has, on average, 1 menu board or major display, then the cost of replacing a menu board to comply with the proposed requirements will be between \$140 (1 board x (\$100/board equip + \$36/board labor)) and \$1,040 (1 board x (\$1000/board equip + \$36/board labor)) per establishment, with an average cost of \$590. The estimated cost for replacing snack bar and cafeteria menu boards is between \$3.5 million (25,200 establishments x \$140/establishment) and \$26.2 million (25,200 establishments x \$1,040/establishment), with a mean estimated cost of \$14.9 million. Each of these chains will also need to redesign their menus and menu boards, at an estimated cost of between \$0.3 million (120 chains x \$2,251/chain and \$0.6 million (120 chains x \$4,695/chain). The total cost to snack bars and cafeterias is estimated to be between \$3.8 million and \$26.8 million, with a mean estimate of \$15.3 million. Total estimated costs for all limited

service eating places are between \$42.1 million and \$311.8 million, with a mean estimate of \$176.9 million.

FDA estimates that 90 chains made up of drinking establishments that are chain retail food establishments would need to redesign their menus, at an estimated cost of between \$0.2 million (90 chains x \$2,251/chain) and \$0.4 million (90 chains x \$4,695/chain) with a mean estimate of \$0.3 million. FDA estimates that 440 chains of full service restaurants would also need to redesign their menus, at an estimated cost of between \$1.0 million (440 chains x \$2,251/chain) and \$2.1 million (440 chains x \$4,695/chain).

FDA lacks data on the distribution of menu durability across the affected sectors. However, if between 0 and 50 percent of full service restaurants need to discard and replace existing menus before the end of their normal lifespan, then between 0 and 47,800 full-service restaurant establishments (95,500 establishments x 50%) would need new menus under the proposed requirements. We focus on full-service restaurants here because they have relatively durable menus. Based on U.S. 2007 Economic Census data, there is an average of 81 seats per establishment for full-service restaurants (Ref. 45). If the average full-service restaurant establishment must discard and reprint one menu for each seat, plus 10 extra, for a total of 91 menus per establishment, then the estimated cost of menu replacement for these restaurants is between \$0 and \$13.0 million (47,800 establishments x 91 menus/establishment x \$3/menu) with a mean estimate of \$4.3 million (23,900 establishments x 91 menus/establishment x \$2/menu). The total cost to full-service restaurants is estimated to be between \$1.0 million and \$15.1 million, with a mean estimate of \$8.0 million. Total estimated costs for full-service restaurants and

drinking places are estimated to be between \$1.2 million and \$15.5 million, with a mean estimate of \$6.1 million

Grocery and convenience stores FDA estimates that grocery and convenience stores will have an average of one menu board per establishment. With approximately 570 chains that would include 47,400 chain retail food establishments under this option, the cost of redesigning and replacing menu boards at these stores is between \$7.9 million (47,400 establishments x \$140/establishment + 570 chains x \$2,250/chain) and \$52.0 million (47,400 establishments x \$1,040/estab + 570 chains x \$4,690/chain), with a mean estimate of \$29.9 million.

The total estimated costs to restaurants and similar retail food establishments for updating menus and menu boards to comply with the proposed requirements are between \$51.2 and \$379.3 million, with a mean of \$212.9 million.

Recurring Costs Recurring changes to menus or menu boards will be tied to new or reformulated standard menu items. In general, these changes will require menu updates independent of the proposed requirements. Therefore, there are no recurring costs specific to new standard menu items.

All chain retail food establishments will need to provide additional written nutrition information. This analysis estimates that there are 278,600 chain retail food establishments under the proposed requirements. If, in complying with the requirement of additional written nutrition information each of these establishments distributed between 10 and 50 written nutrition information documents per month, on average, then the yearly recurring number would be between 33.4 million and 167.1 million documents. At an

estimated cost of \$0.20 per document, the yearly cost would be between \$0.7 million and \$3.4 million, with a mean cost of \$2.1 million.

The estimated recurring costs for chains that expand to include 20 or more locations and, as a result, have establishments that become subject to the proposed requirements, will be between \$0.2 million and \$1.0 million, with a mean of \$0.6 million. This figure uses the estimate of 30 additional chains with establishments that would become subject to the proposed requirements from Table 3 with 20 establishments each, for a total of 600 new chain retail food establishments. Multiplying the number of new chains by the average costs per establishment – \$190 to \$1,420 (mean, \$800) – yields the range of recurring costs. The menu design costs for these newly covered establishments would add an additional \$0.1 million to each of the low, mean and high estimated costs.

Annualized costs Annualized costs are calculated by adding the recurring costs to the initial costs annualized over 10 years at 3 percent and 7 percent discount rates. Using the 3 percent discount rate over 10 years yields an annualizing factor of 8.79 and using 7 percent yields an annualizing factor of 7.52 as noted in the section on nutrition analysis. With a 3 percent discount rate, the annualized mean cost of menu and menu board updates is estimated to be \$26.9 million ($\$2.5 \text{ million} + \$212.9 \text{ million}/8.79$), or between \$6.7 million and \$47.5 million. With a 7 percent discount rate, the annualized mean cost of menu and menu board updates is estimated to be \$31.0 million ($\$2.5 \text{ million} + \$212.9 \text{ million}/7.52$), or between \$7.7 million and \$54.8 million.

Table 4: Cost of Menu/Menu Board Update

Sector	Establishments	Low Estimate	Mean Estimate	High Estimate
Full Service and Drinking Places	115,000	\$1.2 million	\$6.1 million	\$15.5 million
Limited Service Eating Places	91,000	\$42.1 million	\$176.9 million	\$311.8 million
Grocery Store Chains (excluding convenience)	11,200	\$1.8 million	\$7.0 million	\$12.2 million
Convenience Store Chains	36,200	\$6.1 million	\$22.9 million	\$39.8 million
Total Initial Costs		\$51.2 million	\$212.9 million	\$379.3 million
Recurring Costs (New Chains)	600	\$0.2 million	\$0.6 million	\$1.0 million
Recurring Costs Written Nutrition Information	278,600	\$0.7 million	\$2.1 million	\$3.4 million
Total Recurring Costs		\$0.9 million	\$2.7 million	\$4.4 million
Total Annualized Menu Board Costs 3%		\$6.7 million	\$26.9 million	\$47.5 million
Total Annualized Menu Board Costs 7%		\$7.7 million	\$31.0 million	\$54.8 million

Training Costs Training costs are summarized in Table 5. Although the proposed rule does not mandate employee training, establishments will need to be able to, at a minimum, ensure that foods are prepared such that displayed calorie and other nutrient declarations are in compliance. Establishments are unlikely to be able to meet these requirements without some minimal staff training. The analysis does not include the costs of training staff to be able to handle consumer questions about the required information.

Bureau of Labor Statistics data on annual separations in the Accommodations and Food Service sector show an annual turnover rate of approximately 80 percent for the last ten years for all employees (Ref. 46), while a 2007 industry study shows rates for

restaurants of 105 percent for full service restaurants and 150 percent for quick service restaurants (Ref. 47). Based on these turnover rates, and allowing for necessary updates in training even for continuing employees, FDA estimates that 100 percent of employees at the chain retail food establishments will need to be trained annually.

Although data on employee training are scarce, the high rate of turnover means that, typically, formal training times are kept to a minimum. At least one large quick service chain has a three hour formal training program for new employees (Ref. 48). If the proposed rule increases formal training time by between 10 and 30 minutes, this would be an increase of between 5 percent and 16 percent.⁶

In addition to staff-level training, FDA expects managers to need more intensive training in order to be able to ensure compliance at the establishment level, and to acquire the knowledge needed to train retail level employees. Although the Bureau of Labor Statistics does not break out manager turnover by industry, one 2007 study found manager turnover to be 40 percent for limited service restaurants and 26 percent for other restaurants (Ref. 47). Allowing for retraining, FDA estimates that 50 percent of foodservice managers at covered establishments will need training annually. FDA expects managers to need an additional 4 to 8 hours of training based on the availability and length of online nutrition training courses for food service professionals.

Restaurants In order to estimate the number of employees that are directly involved with either the sale or the preparation of food subject to the proposed requirements, we take Bureau of Labor Statistics estimates of the number of “Food Preparation and Serving Related Occupations (SOC code 350000)” in that sector. This

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⁶ Note that while additional training will need to occur on the job, this additional time cost should be offset by lower probationary period wages for beginning workers.

estimate excludes, for example, administrative and janitorial staff. There are 8.1 million food service employees working in eating and drinking places, making an average wage of \$9.64 per hour (Ref. 49).⁷ With 50 percent overhead, the average hourly cost to the establishment is \$14.50. Based on the estimated fraction of restaurants and similar retail food establishments that would be subject to the proposed requirements, 40 percent, there are approximately 3.2 million food service employees at chain retail food establishments. From the analysis for the pre-statute baseline, we estimated that 27 percent of these establishments were subject to pre-existing State or local laws. Therefore, we take 73 percent of the 3.2 million employees to get 2.4 million employees. If each employee receives between 10 and 30 extra minutes of training, then the formal employee training costs for restaurants would be between \$5.8 million (2.4 million x 1/6 hour x \$14.50/hour) and \$17.4 million (2.4 million x 1/2 hour x \$14.50/hour), with an average cost of \$11.6 million.

There are approximately 750,000 food service managers at eating and drinking places (Refs. 50 and 51). Again using 40 percent fraction of chain restaurants and 76 percent not previously covered by other labeling regulations, FDA estimates that there are approximately 220,000 food service managers that will need training. The average cost, including overhead, for these managers is \$25.50 per hour (Refs. 80 and 81). If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$22.4 million (220,000 x 4 hour x \$25.50/hour) and \$44.9 million (220,000 x 8 hour x \$25.50/hour), with an average cost of \$33.7 million. In total, the training costs for restaurants will be \$28.2 million to \$62.3 million, with a mean estimate of \$45.3 million.

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⁷ All estimates of number of employees and wages are drawn from Bureau of Labor Statistics data.

Grocery and convenience stores As with the analysis of restaurants, FDA includes only those employees that are directly involved in the sale or preparation of covered food. This is a small fraction of the total employees at grocery and convenience stores. There are approximately 293,000 food service employees working in grocery stores, at an average cost to the employer of \$16 per hour. Based on the estimated fraction of those establishments within these sectors that would be subject to the proposed requirements under this option – approximately 18 percent – there are 52,000 food service employees at grocery establishments that would need training. If each employee receives between 10 and 30 extra minutes of training, then the formal employee training costs for grocery store establishments would be between \$0.1 million ($52,000 \times 1/6 \text{ hour} \times \$16/\text{hour}$) and \$0.4 million ($72,000 \times 1/2 \text{ hour} \times \$16/\text{hour}$), with an average cost of \$0.3 million.

There are approximately 20,000 convenience store employees that would need training at chain retail food establishments under this option. With an average cost to the employer of \$13 per hour, the formal employee training costs for convenience store establishments would be between \$0.04 million ($20,000 \times 1/6 \text{ hour} \times \$13/\text{hour}$) and \$0.13 million ($20,000 \times 1/2 \text{ hour} \times \$13/\text{hour}$), with an average cost of \$0.085 million.

Again using fractions of establishments given above, FDA estimates that there are approximately 4,800 food service managers that will need training at grocery stores. The average cost of these managers is \$26 per hour. If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$0.5 million ($4,800 \times 4 \text{ hour} \times \$26/\text{hour}$) and \$1.0 million ($4,800 \times 8 \text{ hour} \times \$26/\text{hour}$), with an average cost of \$0.7 million. FDA estimates that there are approximately 1,200 food service managers

that will need training at convenience stores. The average cost of these managers is \$22 per hour. If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$0.1 million (1,200 x 4 hour x \$22/hour) and \$0.2 million (1,200 x 8 hour x \$22/hour), with an average cost of \$0.16 million.

Training costs associated with grocery and convenience establishments would be between \$0.7 million and \$1.7 million, with a mean added cost of \$1.2 million. Added to the initial costs of training for restaurants, the total estimated training costs under the proposed rule are between \$28.9 million and \$64 million, with a mean estimate of \$46.5 million.

Recurring Costs Given the estimated 100 percent turnover rate for restaurant employees, general employee costs will recur annually. With the estimated 50 percent turnover in managers, half of management training costs will recur annually. To the extent that grocery and convenience store employees have higher retention rates, these estimates may be too high. Training costs for employees of new chains are within rounding margins for these estimates.

Annualized costs Because most of the initial costs are also recurring, the annualized costs are calculated by adding the recurring costs to the difference between initial and recurring costs annualized over 10 years at 3 percent and 7 percent discount rates. Using the 3 percent discount rate over 10 years yields an annualizing factor of 8.79 and using 7 percent yields an annualizing factor of 7.52 as noted in the section on nutrition analysis. With a 3 percent discount rate, the annualized mean cost of menu and menu board updates is estimated to be \$26.8 million ($\$2.4 \text{ million} + \$212.9 \text{ million}/8.79$), or between \$6.6 million and \$47.4 million. With a 7 percent discount rate, the annualized

mean cost of training is estimated to be \$30.9 million (\$2.4 million + \$212.9 million/7.52), or between \$7.6 million and \$54.7 million.

Table 5: Labor Costs of Training, Proposed Requirements

Sector	No. Employees	No. Managers	Low Estimate	Mean Estimate	High Estimate
Restaurant Chains	2,400,000	220,000	\$28.2 million	\$45.3 million	\$62.3 million
Grocery Store Chains (excluding convenience)	52,000	4,800	\$0.6 million	\$1.0 million	\$1.4 million
Convenience Store Chains	20,000	1,200	\$0.1 million	\$0.2 million	\$0.3 million
Total Initial Training Costs			\$28.9 million	\$46.5 million	\$64.0 million
Annually Recurring Costs of Training	2,472,000	113,000	\$17.0 million	\$28.5 million	\$39.9 million
Total Annualized Training Costs 3%			\$18.7 million	\$31.3 million	\$43.6 million
Total Annualized Training Costs 7%			\$18.9 million	\$31.6 million	\$44.1 million

Voluntary Registration Costs Establishments that choose to voluntarily register with FDA in order to come under the proposed requirements will incur costs that are relevant to the required burden reporting under the Paperwork Reduction Act of 1995. In section VIII of this document, FDA estimates that voluntary registration will have an initial burden of 1,934 hours and a recurring annual burden of 256 hours. From BLS data, the manager average hourly wage cost to the industry (including 50 percent overhead) in the restaurant sector is \$22 per hour and in the grocery and convenience store sectors, an average of \$23.50 per hour. Multiplying by the number of burden hours yields \$44,000

(\$22/hour x 746 hours + \$23.50/hour x 1,188 hours) in initial costs and, using a weighted average wage of \$23 per hour, \$5,000 (\$23/hour x 256 hours) in recurring costs.

Total Costs for the proposed requirements Table 6 sums up the total estimated costs of the proposed requirements. FDA estimates that implementing the proposed requirements will cost the private sector between \$97.7 million and \$537.0 million, with a mean estimate of \$315.1 million. FDA estimates recurring costs to be between \$24.1 and \$64.0 million, with a mean estimate of \$44.2 million. The final column in Table 6 shows the distribution of costs across sector. Total annualized costs, summed across all activities are estimated as between \$33.4 million and \$120.5 million at a 3 percent discount rate, or between \$34.9 million and \$130.1 million at a 7 percent discount rate.

Table 6: Total Costs, Proposed Requirements

Sector	Low Estimate	Mean Estimate	High Estimate	Proportion of Total Costs
Restaurant Chains	\$82.8 million	\$267.7 million	\$457.0 million	85%
Grocery Store Chains (excluding convenience)	\$3.7 million	\$11.5 million	\$19.3 million	4%
Convenience Store Chains	\$11.2 million	\$35.9 million	\$60.7 million	11%
Total Initial Costs	\$97.7 million	\$315.1 million	\$537.0 million	100%
Total Annually Recurring Costs	\$24.1 million	\$44.2 million	\$64.0 million	
Total Proposed Rule Annualized Costs 3%	\$33.4 million	\$76.8 million	\$120.5 million	
Total Proposed Rule Annualized Costs 7%	\$34.9 million	\$82.3 million	\$130.1 million	

As noted, costs borne by restaurants and similar retail food establishments that voluntarily register to be subject to section 4205 will be lower than the costs of complying with preempted State and local laws because otherwise no firm would voluntarily do so. Therefore, the registration is taken to have positive net benefit. To the extent that these establishments register, the estimates presented here may underestimate the total net benefit of the proposed rule. However, FDA estimates that registration will create approximately 1,934 hours of burden for the registration process by voluntarily registering entities and would cost less than \$45,000.

b. Benefits

The potential benefit from the proposed rule stems from the effect that decreasing the consumption of calories from restaurant and restaurant-type food has on mitigating obesity rates and growth in the U.S. population. While survey data has shown that calorie labeling increases the number of people who see, and claim to use, this information (Ref. 52), the literature has found mixed results on the effect of calorie posting on actual food consumption. Bollinger and colleagues analyzed transaction data in a large number of Starbucks stores for a period of time running from 3 months before until 11 months after calorie posting commenced in New York City (Ref. 53). They found a 6 percent decrease in calories consumed per transaction, and that the decrease resulted from a decline in accompanying food purchases, rather than substitution towards lower calorie beverages. Bassett and colleagues studied consumer food purchasing behavior and calorie information availability at 275 randomly selected locations in New York City of 11 fast food chains such as McDonalds, KFC, Taco Bell, and Subway in the spring of 2007 before New York City's mandatory labeling requirements went into effect (Ref.

54). They found that among the chains included in the study, only Subway had calorie information at the point of purchase. They also found that, during the study period, Subway costumers who did report seeing calorie information purchased an average of 52 fewer calories per transaction than customers who did not see calorie information. In contrast, in three New York City restaurants, Down and colleagues found that calorie posting had a modest impact consumers' food selections. However, because not all consumers use calorie information for the same purpose (some use the information to shift calorie intake between meals, or to increase intake, or to feel like they are getting a better "value") they also found that calorie labeling in some cases induced consumers to purchase higher calorie items (Ref. 55). Similarly, Elbel and colleagues found that calorie labeling did not have a significant effect on food purchase behaviors in low-income minority neighborhoods (Ref. 56). In a study of adolescent fast food consumption, Yamamoto and colleagues found little difference in food choices made by the study participants when the participants made food choices from menus that included calorie information in comparison to menus that did not include calorie information (Ref. 57). These results are consistent with those of Variyam for packaged foods, who found in a study that consumers' use of the Nutrition Facts alone does little to improve dietary intakes (Ref. 58).

Two of the most recent studies of local calorie disclosure laws, one of calorie disclosure use in a taco chain in King County, Washington (Ref. 59) and another studying child and adolescent fast-food choice in New York City (Ref. 60), found no significant change in calorie intake. In another study of restaurant calorie labeling, Tandon and colleagues found that menu labeling of fast food reduced the number of calories in meals

that parents ordered for their children (Ref. 61). In addition, none of these studies examined total diet. This means that consumers may have compensated by increasing calorie intake during other meals or snacks for the observed reduction in calories.

However, it could be that the effect of menu labeling is more likely to manifest in a longer time frame than that measured in these studies. Another long term effect could be producer-driven reductions in calories through portion size reduction and reformulation.

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 chains and establishments would respond to the proposed requirements, FDA has estimated 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. This response may stem from some combination of reformulation or introduction of new menu items with fewer calories or consumer purchase of fewer calories from existing menu items. The benchmark benefits are calculated by summing quality adjusted life years gained and medical costs averted from the benchmark decline in obesity.

Quality adjusted life years (QALYs) QALYs can be used to measure the loss of well-being that an individual suffers due to a disease or condition. QALYs are measured on a range from 0 to 1 where 0 is equivalent to death, 1 is equivalent to perfect health for 1 year, and intermediate values are higher or lower depending on how much a person is suffering over a 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. 62, 63 and 64). In this context, the method uses regression analysis to estimate the effect of particular conditions on overall health status (Ref. 64). The QALYs used in this analysis do not include the value of health expenditures caused by obesity; we estimate health expenditures separately. 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 2005-2008 data are .0410 per adult, for all U.S. adults in all weight categories. Mortality losses in this study are measured as the probability of premature death in a given year multiplied by the sum of QALYs over life expectancy. Approximately 57 percent of this burden comes from disability and activity limitations rather than premature death (Refs. 63 and 64). Based on the U.S. Census Bureau Statistical Abstract of the United States: 2011, the 18 and over population of the U.S. in 2009 was 232,458,000 (Ref. 65). The total estimate of lost QALYs from obesity for adults in the U.S. 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 (VSL) 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 value of a statistical life year (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 million and \$146,624 million in 2008 dollars (Ref. 18). From Flegal and colleagues, 34 percent of adults were obese in 2006 (Ref. 9). 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 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 with 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 2003-2004 National Health and Nutrition Examination Survey (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. 24). NHANES data shows an estimated four meals eaten away from home per week (Ref. 24). This translates to an average of roughly 140 extra calories per day ($239 \text{ cal/meal} \times 4 \text{ meals/week} / 7 \text{ days/week}$).

Because of the complexity of the causes of overweight and obesity, and the complexity of the choices involved in purchasing and preparing restaurant or restaurant-type food, we do not expect the proposed requirements to reduce calorie intake by an amount as large as this. Furthermore, we know from the Mancino study cited in the last paragraph that while individuals who are not overweight also consume more calories when eating restaurant food in comparison to the foods they prepare themselves, the calorie differential is not as great (134 calories per meal versus 239 for obese individuals).

The studies discussed elsewhere in this section found that responses to calorie information on menus 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. 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 suggests that a 10 percent reduction in the additional calories consumed in restaurant or restaurant-type food may be possible for at least some populations, and may be supported by additional changes to the calorie amounts in offered menu items. We therefore base our benchmark on an average decrease in calorie intake of 24 calories per meal (240 calories per meal x 10%). Equivalently, we can characterize this benchmark as 14 calories per day (240 calories per meal x 4 meals per week / 7 days/week x 10%), or about 100 calories per week (14 calories/day x 7 days/week) by obese adults.

Weight and BMI reduction In order to convert this benchmark calorie reduction to U.S. population weight and BMI reductions we use a 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, physical activity level, (Ref. 66). In order to calculate weight loss using NHANES U.S. population we implemented this model using symbolic algebra software.

On the advice of Hall and Jordan, we use 2003-2004 NHANES data rather than the most recent 2007-2008 NHANES data in order to be able to use the dual energy x-ray absorptiometry (DEXA) 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 DEXA data file, we use demography, body measurement and physical activity questionnaire data. The physical activity data is into

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). Individuals with lower levels of background activity are predicted to lose more weight for a given calorie reduction. Therefore, the replacement of missing physical activity levels with a relatively low PAL score means that estimated weight reductions may be slightly higher than if all PAL 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 steady state 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 is not an annual decrease, but the total weight loss that would result from a permanent reduction of calorie intake. 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 2003-2004 data the mean non-obese BMI is 24.7 and the mean obese BMI is 35.4, for a difference of 10.7 BMI units. 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 Because studies on menu disclosure of calories show that in most cases only a fraction of consumers reduce their calorie intake

in response to the information, there may only be a small group of consumers that respond to the new information or purchase newly reformulated or offered lower calorie menu items. As an illustration of the magnitude of the benefits from a reduction in calorie intake we consider the benefit associated with the 4.3 percent reduction in excess BMI, or 100 calorie reduction per week by a small fraction of obese consumers. In particular, we calculate the minimum percentage of obese consumers that would need to reduce calorie intake by at least 100 calories per week in order for the proposed requirements to have positive net benefits.

Given the mean annualized cost estimate for the proposed requirements of approximately \$ 76.8 million at 3 percent discount rate (Table 1a), and the estimated intermediate benefit of a 100 calorie per week reduction in intake by all obese adults of \$133 billion, if at least 0.06 percent ($\$76.8 \text{ million} / \133 billion) of the adult obese population reduced their total calorie intake from restaurant or restaurant-type food by at least 100 calories per week, the proposed requirements would result in a net benefit. Using the low and high estimates of annualized cost for the proposed rule, the break-even estimate of the proportion of obese adults that would need to reduce their total calorie intake from restaurant or restaurant-type food by at least 100 calories per week ranges from 0.03 percent to 0.09 percent. Using the high and low estimates of the cost of obesity developed in this section of \$222 billion and \$91 billion, the break even proportion ranges from 0.03 percent to 0.08 percent, respectively.

It is important to note that this benchmark benefit analysis has been restricted to adults only (age greater than 18). In addition, normal weight and underweight individuals have been excluded because the literature identifies body weight that exceeds

the recommended weight range poses health risks that are directly attributable to the higher medical expenses (Refs. 12). Note that the benefit estimation takes the current prevalence of obesity as fixed, particularly in terms of population size and the demographic distribution of that population.

Although this analysis does not include an estimate of the benefits or costs of obesity in children, reduction in childhood obesity has been linked with educational, social and career outcomes (Ref. 17). It is reasonable to expect that the impact on their adult caregivers of this proposed rule in terms of the reduction in calorie intake due to menu labeling, and any changes toward more balanced nutrient intake, will benefit children and adolescents. Because the estimated reductions in medical expenses discussed in this analysis are only those expenses currently incurred by obese individuals, the benefit estimate of this proposed rule is conservative and actual reduced medical costs may be greater.

C. Option 2: Limited Scope

Option 2 is similar to the proposed rule, but with scope limited from the proposed rule to include establishments whose primary business activity is selling restaurant food or restaurant-type food directly to the consumer. For the purposes of this analysis, this effectively limits the scope to the sectors shown in Table 7.

Table 7: Limited Sectors and Estimated Number of Chain Retail Food Establishments and Associated Chains as included for Option 2

Sector	NAICS	Estimated No. of Chain Retail Food Establishments¹	Estimated No. of Associated Chains¹
Full Service Restaurants and Drinking Places	7221, 7224	115,000	530
Limited Service Eating Places (including snack bars, ice cream shops and similar establishments)	7222	116,200	540
Total Number of Entities		231,200	1,070

¹Estimates are from the analysis of costs below.

a. Costs

Cost estimates for these sectors are organized as in the analysis of the proposed requirements, with estimates for calorie analysis, menu and menu board replacement, and minimal training given for each additional sector. The total costs for Option 2, which are the costs of Option 1 minus the costs associated with covering grocery and convenience establishments are listed in Table 8. FDA estimates that the total initial cost of Option 2 are between \$82.8 million and \$457.0 million, with a mean estimate of \$267.7 million.

Table 8: Total Costs for Option 2, by Type of Cost

Cost Type	Low Estimate	Mean Estimate	High Estimate	Proportion of Total Costs
Nutrition Analysis	\$11.3 million	\$39.4 million	\$67.4 million	14%
Menu and Menu Board Update	\$43.3 million	\$183.0 million	\$327.3 million	64%
Training	\$28.2 million	\$45.3 million	\$62.3 million	22%
Total Initial Costs	\$82.8 million	\$267.7 million	\$457.0 million	100%
Recurring Nutrition Analysis	\$3.9 million	\$8.2 million	\$12.5 million	21%
Recurring Menu and Menu Board Update	\$0.7 million	\$2.0 million	\$3.4 million	5%
Recurring Training	\$17.0 million	\$28.5 million	\$39.9 million	74%
Total Recurring Costs	\$21.6 million	\$38.7 million	\$55.8 million	100%
Total Proposal Rule Annual Costs 3%	\$29.1 million	\$65.9 million	\$103.2 million	
Total Proposal Rule Annual Costs 7%	\$31.6 million	\$72.5 million	\$113.8 million	

b. Benefits

From the 2007 Economic Census estimates of foodservice revenue across sectors (Ref. 67), FDA estimates that grocery and convenience stores account for approximately 5.0 percent (\$17,983,957/\$361,824,164) of “meals, snacks & nonalcoholic beverages prepared for immediate consumption” sales from the limited- and full-service eating places, grocery stores and convenience stores To the extent that this proportion of sales reflects the proportion of calorie intake, and calorie intake reduction, eliminating coverage of grocery and convenience stores could result in a 5.0 percent decrease in benefits relative to the proposed rule. Eliminating these additional establishments

represent an average 12.5 percent decrease relative to the annualized costs of the proposed rule.⁸

This estimate of the changes in potential benefits depends on a uniform response by consumers and firms to the required nutrient information across all sectors. It is likely that different settings result in different responses to the same required information. Therefore, these estimates may be biased up or down depending on how consumer response and chain response varies across sectors. Furthermore, many of the grocery and convenience stores compete directly with restaurant chains. To the extent that this holds, exempting grocery and convenience stores from coverage may contribute to a less competitive environment because they would not be required to comply with the proposed requirements. In addition, restaurant food and restaurant-type food is a growing market for many grocery and convenience store chains.

D. Option 3. Broader Scope

Option 3 is similar to the proposed rule, but considers a broader application to establishments that offer for sale restaurant or restaurant-type food.

For the purposes of the preliminary regulatory impact analysis, FDA has analyzed the costs and benefits associated with covering establishments in a wider range of sectors that may not be commonly understood to be restaurants, but that serve restaurant or restaurant-type food. These include concessions that are embedded within general merchandise stores, lodging places, entertainment, sports or recreation facilities, transportation carriers and facilities generally served by foodservice contractors. The sectors, and the estimates of the number of chains and establishments that might meet the

□

⁸ Average percentage change is calculated by calculating the percent change for low, mean and high estimates, then averaging these averages.

other criteria of section 4205 and the proposed rule if this wider range of establishments were defined as restaurants or similar retail food establishments for purposes of section 4205 are listed in Table 9.

Table 9: Sectors serving Restaurant or Restaurant-Type Food, with Estimated Number of Establishments and Associated Chains

Sector	NAICS	Estimated No. of Chain Retail Food Establishments ¹	Estimated No. of Associated Chains ¹
General Merchandise Stores	452	3,200	90
Accommodation	721	6,200	100
Food Service Contractors with commercial or manufacturing onsite facilities	72231, 72233	4,500	50
Recreation, Performing Arts and Spectator Sports (including foodservice contractors operating in this sector)	7111,7112, 71131, 712,713, 51213	6,100	250
Transport, including foodservice contractors	48	5,200	50
Additional Number of Entities		25,200	540

¹ Estimates are from the analysis of costs below.

a. Costs

Cost estimates for these sectors are organized as in the analysis of the proposed requirements, with estimates for calorie analysis, menu and menu board replacement, and minimal training given for each additional sector.

Nutrition Analysis Nutrition analysis costs are based on the same data as the analysis of the proposed rule and are summarized in Table 10.

General Merchandise Stores FDA estimates that there are approximately 90 general merchandise retail chains with 3,200 establishments that offer for sale restaurant or restaurant-type food. Because of the more limited offerings for restaurant and restaurant-type food at general merchandise stores, FDA estimates that these

establishments would have the same average costs of nutrition analysis as grocery or convenience store chain of between \$11,000 (\$275/item x 40 items/chain) and \$34,600 (\$866/item x 40 items/chain), with a mean estimate of \$22,800 per chain. The estimated cost of nutrition analysis for general merchandise store chains ranges from \$1.0 million (90 chains x \$11,000/chain) to \$3.1 million (90 chains x \$34,600/chain), with a mean estimate of \$2.1 million.

Lodging Using 2007 Economic Census data (Ref. 68), and similar industry patterns of ownership to other sectors, FDA estimates that there are 6,200 lodging establishments associated with 100 chains that would be subject to the proposed requirements under this option, not including establishments that voluntarily register to become subject to the requirements. Although some of these establishments have full-service restaurants, many are limited to basic breakfast offerings. Therefore, FDA estimates that these chains also have an average of one third of the restaurant offerings, or 40 standard menu items. The per item costs, multiplied by the average number of items per chain, would yield average costs of nutrition analysis per lodging chain of between \$11,000 (\$275/item x 40 items/chain) and \$34,600 (\$866/item x 40 items/chain), with a mean estimate of \$22,800 per chain. With 100 chains, the cost of nutritional analysis in the lodging sector would be between \$1.1 million (100 chains x \$11,000/chain) and \$3.5 million (100 chains x \$34,600/chain), with a mean estimate of \$2.3 million.

Entertainment, Sports and Recreation From 2007 Economic Census data, FDA estimates that there are approximately 6,100 entertainment, sports and recreational establishments, associated with 250 chains, that would be chain retail food establishments as the term is used in this option (Refs. 69 and 70). These include approximately 2,800

movie theaters associated with 50 chains and 1,300 performing arts, entertainment or spectator sports establishments associated with 150 chains. In addition, using the National Restaurant Association's data on foodservice contracting revenue from recreation sites (Ref. 71), FDA estimates that an additional 50 chains and 2,000 establishments are run in this sector by foodservice contractors.

Using the more limited set of standard menu items from the analysis of grocery and convenience stores, FDA estimates an average cost of nutrition analysis per chain of between \$11,000 and \$34,600, with a mean estimate of \$22,800 per chain. With 250 chains, this would yield a total cost for these chains of between \$2.8 million (250 chains x \$11,000/chain) and \$8.7 million (250 chains x \$34,600/chain), with a mean estimate of \$5.7 million.

Transport The Air Transport Association 2010 Economic Report counts 6,278 passenger aircraft in 2009 (Ref. 72). Of these, the report estimates that 3,521 are operated by 14 mainline carriers. MIT's Airline Data Project calculates 3,507 by 15 mainline carriers in 2009 (Ref. 73). The Airline Data Project also calculated that the average seat capacity in 2009 was 168 seats per plane for the 15 carriers (Ref. 74). Not all carriers or aircraft operated by these carriers offer restaurant or restaurant-type foods. FDA therefore takes this set of mainline carriers, rounded to 20 carriers and 3,500 aircraft, as an estimate of the number of chains with establishments that sell restaurant or restaurant-type food, and might be defined as chain retail food establishments if they were restaurants or similar retail food establishments. FDA requests data and comment on this estimate.

The Bureau of Transportation Statistics counts 278 Amtrak locomotives (Ref. 75). Amtrak's 2009 Annual Report, cites "up to 300 daily Amtrak trains" (Ref. 76). Although

there are a small number of local or regional lines that may offer for sale restaurant or restaurant-type food, 300 is a likely upper bound to the number of establishments serving restaurant or restaurant-type food and might otherwise be defined as chain retail food establishments if they were restaurants or similar retail food establishments. FDA requests data and comment on this estimate.

The National Census of Ferry Operators, 2008 lists 490 ferries with capacity greater than 100 passengers, operated by 127 different entities that also are likely to have concessions (Ref. 77). Given that in order to be subject to the proposed requirements, a restaurant or similar retail food establishment must be part of a chain with at least 20 locations, some of these ferries will be excluded. If 19 operators of ferry-based establishments that offer for sale restaurant or restaurant-type food at least 20 establishments, doing business under the same name and offering for sale substantially the same menu items, and all other operators have only 1 (19 operators x 20 ferries/operator + 110 ferries=490 ferries), then the 380 ferry-based establishments operated by the 19 ferry operators (19 operators x 20 ferries/operator = 380 ferries) would be subject to the proposed requirements. FDA requests data and comment on this estimate.

Again using NRA's 2010 data on foodservice sales, FDA estimates that an additional 10 food service contractor chains, operating 1,000 establishments, operate in the transport sector. In total, FDA estimates that there are 50 chains, with 5,200 establishments in the transport sector that serve restaurant or restaurant-type food, and might otherwise be defined as chain retail food establishments if they were restaurants or similar retail food establishments.

Using 40 menu items per chain, FDA estimates costs of nutrition analysis per chain to be between \$11,000 and \$34,600, with a mean estimate of \$22,800. With a total of 50 transport chains, this yields a total cost for these chains of between \$0.6 million (50 chains x \$11,000/chain) and \$1.7 million (50 chains x \$34,600/chain), with a mean estimate of \$1.1 million.

Managed Food Service From 2007 Economic Census data, and NRA's 2010 Forecast (Refs.68 and 71), FDA estimates that there are approximately 4,500 establishments, controlled by 50 chains in the general managed food sector. FDA uses the same per-chain estimate of number of menu items as restaurants, 80 per chain. This results in a per chain estimated cost of between \$1.1 million (\$22,000/chain x 50 chains) and \$3.5 million (\$69,300/chain x 50 chains), with a mean estimate of \$2.3 million.

If all of these establishments were restaurants or similar retail food establishments that were subject to the proposed requirements, they would add between \$6.6 million and \$20.5 million, with a mean estimate of \$13.5 million, to the initial costs of nutrition analysis.

Recurring Costs Using the same estimate as for restaurants of 12 new standard menu items per year, FDA estimates that these 530 chains would have annually recurring costs of nutrition analysis cost of between \$1.7 million (530 chains x 12 items/chain x \$275/item) to \$5.5 million (530 chains x 12 items/chain x \$866/item), with a mean estimate of \$3.6 million.

Given the 2 percent growth rate used in other options, there would be an estimated 10 new chains (530 chains x .02) every year. If each new chain has an average of 40 standard menu items, then the recurring costs associated with these new

establishments would be between \$0.1 million (10 chains x 40 items/chain x \$275/item) and \$0.3 million (10 chains x 40 items/chain x \$866/item), with a mean of \$0.2 million each year. Total estimated additional recurring costs for the establishments discussed in this option are between \$1.8 million and \$5.8 million, with a mean of \$3.8 million.

Annualized costs The annualized costs are calculated by adding the recurring costs to initial costs annualized over 10 years at 3 percent and 7 percent discount rates. With a 3 percent discount rate, the annualized mean cost of nutrition analysis for these additional sectors is estimated to be \$5.3 million, or between \$2.6 million and \$8.1 million. With a 7 percent discount rate, the annualized mean cost of nutrition analysis for these additional sectors is estimated to be \$5.6 million or between \$2.7 million and \$8.5 million.

Table 10: Costs of Nutrition Analysis, By Sector for Option 3

Sector	No. of Entities	No. Menu Items/Entity	Low Estimate	Mean Estimate	High Estimate
General Merchandise Chains	90	40	\$1.0 million	\$2.1 million	\$3.1 million
Lodging	100	40	\$1.1 million	\$2.3 million	\$3.5 million
Entertainment, Sports and Recreation	250	40	\$2.8 million	\$5.7 million	\$8.7 million
Transport	40	40	\$0.6 million	\$1.1 million	\$1.7 million
Managed Food Service	50	80	\$1.1 million	\$2.3 million	\$3.5 million
Total Additional Initial Nutrition Analysis Costs for Option 3			\$6.6 million	\$13.5 million	\$20.5 million
New Items	530	12	\$1.7 million	\$3.6 million	\$5.5 million
New Chains	10	40	\$0.1 million	\$0.2 million	\$0.3 million
Additional Recurring Costs for Option 3			\$1.8 million	\$3.8 million	\$5.8 million
Additional Annualized Analysis Costs 3%			\$2.6 million	\$5.3 million	\$8.1 million
Additional Annualized Analysis Costs 7%			\$2.7 million	\$5.6 million	\$8.5 million

Menu Replacement Costs The basis for these costs are discussed more fully in the analysis of the proposed requirements. The menu replacement costs specific to Option 3 are summarized in Table 11.

General Merchandise Stores FDA estimates that general merchandise stores will have an average of one menu board per chain retail food establishment. With approximately 90 chains that include 3,200 establishments serving restaurant food or restaurant-type food, the cost of redesigning and replacing menu boards at these stores is between \$0.7 million (3,200 establishments x \$140/establishment + 90 chains x \$2,250/chain) and \$3.8 million (3,200 establishments x \$1,040/estab + 90 chains x \$4,690/chain), with a mean estimate of \$2.2 million.

Lodging Lodging places generally have menus instead of menu boards; therefore, the menu replacement costs for establishments in the lodging sector would be limited to menu replacement and redesign and administrative costs. With approximately 100 chains, the estimated cost of redesign is between \$0.2 million (100 chains x \$2,250/chain) and \$0.5 million (100 chains x \$4,690/chain), with a mean of \$0.3 million. The 2007 Economic Census data gives an average number of rooms per lodging establishment of 77. If between 0 and 50 percent of these lodging establishment must discard and reprint one menu for each room, plus 10 extra, for a total of 87 menus per establishment, then the estimated cost of menu replacement for lodging establishments is between \$0 and \$0.8 million (3,100 establishments x 87 menus/establishment x \$3/menu) with a mean estimate of \$0.4 million. The total estimated cost for lodging places is between \$0.2 million and \$1.3 million, with a mean estimate of \$0.8 million.

Entertainment, Sports and Recreation FDA estimates that entertainment, sports or recreational facilities have an average of one menu board per establishment. With an estimated 250 chains including 6,100 establishments, the cost of redesigning and replacing menu boards at these establishments is between \$1.4 million (6,100 establishments x \$140/estab + 250 chains x \$2,250/chain) and \$7.5 million (6,100 establishments x \$1,040/estab + 250 chains x \$4,690/chain), with a mean estimate of \$4.5 million.

Transport With an estimated 30 air passenger carriers or food service contractors serving aircraft that serve restaurant or restaurant-type food, the cost of menu redesign for air passenger carriers is estimated to be between \$68,000 (30 chains x \$2,251/chain) and \$141,000 (30 chains x \$4695/chain), with a mean estimate of \$104,000.

For rail and ferry establishments, with an estimated 20 carriers and 700 establishments that serve restaurant or restaurant-type food the cost of replacing menu boards is estimated to be between \$143,000 (700 establishments x \$140/estab + 20 chains x \$2,250/chain) and \$822,000 (700 establishments x \$1,040/estab + 20 chains x \$4,690/chain), with a mean estimate of \$482,000. Total estimated costs to the transport sector of menu and menu board replacement and redesign are between \$0.2 million and \$1.0 million, with a mean estimated cost of \$0.6 million.

Managed Food Service FDA estimates that establishments associated with managed food services will have an average of one menu board per establishment. With approximately 50 chains including 4,500 establishments, the estimated cost of replacing menu boards at these establishments is between \$0.7 million (4,500 establishments x \$140/estab + 50 chains x \$2,250/chain) and \$4.9 million (4,500 establishments x \$1,040/estab + 50 chains x \$4,690/chain), with a mean estimate of \$2.8 million.

In total, these additional establishments would have initial costs of menu and menu board replacement of between \$3.2 million and \$18.5 million, with a mean increase of \$10.9 million.

Recurring Costs All these establishments would need to provide additional nutrition information if they were restaurants or similar retail food establishments. There are 26,200 additional establishments under this option. If each of these establishments distributed between 10 and 50 written nutrition information documents per month, on average, then the yearly recurring number would be between 3.1 million and 15.7 million documents. At an estimated cost of \$0.20 per document, the yearly cost would be between \$0.1 million and \$3.3 million, with a mean cost of \$2.2 million.

Using average, per-establishment costs of between \$120 and \$1330, the recurring costs from the entry of chains growing to include 20 or more establishments would be for 200 establishments (10 new chains x 20 establishments/chain), between \$24,000 (\$120/establishment x 200 establishments) and \$0.3 million (\$1,330/establishment x 200 establishments). Total recurring costs for these establishments is between \$0.1 million and \$0.6 million, with a mean estimate of \$0.2 million.

Annualized costs The annualized costs are calculated by adding the recurring costs to initial costs annualized over 10 years at 3 percent and 7 percent discount rates. With a 3 percent discount rate, the annualized mean cost of menu update for these additional sectors is estimated to be \$1.4 million, or between \$0.5 million and \$2.4 million. With a 7 percent discount rate, the annualized mean cost of menu update for these additional sectors is estimated to be \$1.7 million or between \$0.5 million and \$2.8 million.

Table 11: Costs of Menu Board Update, By Sector for Option 3

Sector	Establishments	Low Estimate	Mean Estimate	High Estimate
General Merchandise Chains	3,200	\$0.7 million	\$2.2 million	\$3.8 million
Lodging	6,200	\$0.2 million	\$0.8 million	\$1.3 million
Entertainment, Sports and Recreation	6,200	\$1.4 million	\$4.5 million	\$7.5 million
Transport	6,100	\$0.2 million	\$0.6 million	\$1.0 million
Managed Food Service	4,500	\$0.7 million	\$2.8 million	\$4.9 million
Additional Costs of Menu Update, Option 3	26,200	\$3.2 million	\$10.9 million	\$18.5 million
New Chains	200	\$0.0 million	\$0.2 million	\$0.3 million
Nutrition Information	26,200	\$0.1 million	\$0.2 million	\$0.3 million
Additional Recurring Menu Update Costs, Option 3		\$0.1 million	\$0.4 million	\$0.6 million
Additional Annualized Menu Update Costs 3%		\$0.5 million	\$1.4 million	\$2.4 million
Additional Annualized Menu Update Costs 7%		\$0.5 million	\$1.7 million	\$2.8 million

Training Costs The basis for training costs are fully discussed in the analysis for the proposed requirements. The training costs specific to Option 3 are summarized in Table 12.

General Merchandise Stores As with grocery stores, we include only those employees that are directly involved in the sale or preparation of restaurant or restaurant-type food. This is a small fraction of the total employees at general merchandise stores. There are approximately 47,000 food service employees working in these stores, at an average cost to the employer of \$16 per hour. Based on the estimated fraction of those establishments serving restaurant and restaurant-type food that are part of a chain with at least 20 locations, approximately 67 percent, there are 31,000 food service employees at

general merchandise stores that would need training.⁹ If each employee receives between 10 and 30 extra minutes of training, then the formal employee training costs for grocery and convenience store establishments would be between \$0.1 million (31,000 x 1/6 hour x \$16/hour) and \$0.2 million (31,000 x 1/2 hour x \$16/hour), with an average cost of \$0.2 million.

There are approximately 4,000 food service managers employed by these general merchandise stores that would need training. The average cost of these managers is \$22 per hour. If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$0.4 million (4,000 x 4 hour x \$26/hour) and \$0.7 million (4,000 x 8 hour x \$226/hour), with an average cost of \$0.5 million. In total, the training costs for general merchandise stores will be \$0.5 million to \$0.9 million, with a mean estimate of \$0 million.

Lodging FDA estimates that there are approximately 440,000 food service employees working in lodging establishments, at an average cost of \$18 per hour. Based on the estimated 9.8 percent of the lodging establishments that are subject to the proposed requirements without having to register with FDA to become subject to the requirements, there are approximately 43,000 food service employees at these lodging establishments. This fraction is derived from the number of establishments estimated in this document, 6,200 divided by the total number of establishments from the 2008 County Business Practices data. If each employee receives between 10 and 30 extra minutes of training, then the formal employee training costs for lodging establishments would be between

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⁹ The percent of covered employees at general merchandise stores is higher than for grocery and convenience stores because food service workers at these latter establishments are less likely to be involved in restaurant foods.

\$0.1 million ($43,000 \times 1/6 \text{ hour} \times \$18/\text{hour}$) and \$0.4 million ($43,000 \times 1/2 \text{ hour} \times \$18/\text{hour}$), with an average cost of \$0.3 million.

There are approximately 29,000 food service managers at lodging establishments. Again using the 9.8 percent of lodging establishments that are subject to the proposed requirements, without having to register with FDA to become subject to the requirements, FDA estimates that there are approximately 2,800 food service managers that will need training. The average cost of these managers is \$31 per hour. If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$0.3 million ($2,800 \times 4 \text{ hour} \times \$31/\text{hour}$) and \$0.7 million ($2,800 \times 8 \text{ hour} \times \$31/\text{hour}$), with an average cost of \$0.5 million. In total, the training costs for lodging places will be \$0.4 million to \$1.1 million, with a mean estimate of \$0.8 million.

Entertainment, Sports and Recreation FDA estimates that there are approximately 43,000 food service employees working in movie theaters, at an average cost of \$14 per hour. 2008 County Business Patterns data shows the total number of theaters to be 5,120. The number of establishments estimated for this analysis is 2,800, accounting for 54 percent of all movie theaters. Based on this fraction there are approximately 23,000 food service employees at these establishments. There are 28,000 food service employees at other entertainment, sports or recreational establishments that are not otherwise counted as employees of food service contractors. Out of roughly 110,000 total establishments in the 2008 County Business Patterns data, only 1 percent sells restaurant or restaurant-type food and are part of chains of twenty or more. Based on this 1 percent, approximately 300 employees would need training. If each employee receives between 10 and 30 extra minutes of training, then the formal employee training

costs for all these establishments would be between \$0.1 million (24,000 x 1/6 hour x \$16/hour) and \$0.2 million (24,000 x 1/2 hour x \$16/hour), with an average cost of \$0.1 million.

Using the same 54 percent and 1 percent for managers, there are approximately 3,000 food service managers at these kinds of establishments. The average cost of these managers is \$36 per hour. If each manager needs four to eight hours of training, then the wage cost to the industry will be between \$0.4 million (3,000 x 4 hour x \$36/hour) and \$0.9 million (3,000 x 8 hour x \$36/hour), with an average cost of \$0.7 million. In total, the estimated training costs for entertainment, sports and recreation establishments will be \$0.5 million to \$1.3 million, with a mean estimate of \$1.0 million.

Transport Because of the way that food service is organized in the transportation sector, almost all of the employees that would need the minimal training discussed in this section would be counted as employees of the managed food service sector. Bureau of Labor Statistics data show only a few hundred direct food service employees in the entire transportation sector. Using NRA's foodservice revenue numbers, approximately 5 percent of managed service sales are in the transport sector. Because FDA estimates that 76 percent of foodservice contractor establishments have at least 20 locations, we take approximately 4 percent of the 423,000 foodservice employees, or 16,000 employees that may need training. This yields training costs between \$50,000 (16,000 x 1/6 hour x \$17/hour) and \$140,000 (91,000 x 1/2 hour x \$17/hour), with an average cost of \$95,000.

Using the 4 percent proportion for managers, FDA estimates that approximately 2,000 managers would need training in this sector. The average cost of these managers is \$29 per hour. If each manager needs four to eight hours of training, then the wage cost to

the industry will be between \$0.2 million (2,000 x 4 hour x \$29/hour) and \$0.5 million (2,000 x 8 hour x \$29/hour), with a mean cost of \$0.4 million.

Managed Food Service Because the 4,500 establishments estimated for this analysis account for 18 percent of the 25,500 total managed food service establishments in 2008 County Business Practices, FDA estimates that approximately 91,000 employees of the 423,000 total food service employees in this sector work at these establishments, at an hourly cost of \$17. If each employee receives between 10 and 30 extra minutes of training, then the formal employee training costs for all these establishments would be between \$0.3 million (91,000 x 1/6 hour x \$17/hour) and \$0.8 million (91,000 x 1/2 hour x \$17/hour), with an average cost of \$0.6 million.

Using the same 18 percent for managers, there are approximately 7,000 food service managers at these kinds of establishments. The average cost of these managers is \$29 per hour. If each manager needs four to eight hours of training, then the wage cost to this sector would be between \$0.8 million (7,000 x 4 hour x \$29/hour) and \$1.6 million (7,000 x 8 hour x \$29/hour), with a mean cost of \$1.2 million.

In total, training costs associated with the additional establishments analyzed in Option 3 would be between \$2.8 million and \$6.3 million, with a mean added cost of \$4.8 million.

Recurring Costs Given the estimated 100 percent turnover rate for restaurant employees, general employee costs would recur annually. With the estimated 50 percent turnover in managers, half of management training costs would recur annually. Training costs for employees of new chains are within rounding margins for these estimates. These recurring costs are between \$1.7 million and \$4.2 million with a mean of \$3.1 million.

Annualized costs Because nearly all the initial training costs are recurring, annualized training costs are calculated by adding the recurring costs to the difference between the initial costs and the recurring costs annualized over 10 years at 3 percent and 7 percent discount rates. With a 3 percent discount rate, the annualized mean cost of training for these additional establishments is estimated to be \$26.8 million (\$2.4 million + \$212.9 million/8.79), or between \$6.6 million and \$47.4 million. With a 7 percent discount rate, the annualized mean cost of training is estimated to be \$30.9 million (\$2.4 million + \$212.9 million/7.52), or between \$7.6 million and \$54.7 million.

Table 12: Training Costs, Option 3 by Sector

Sector	# employees	# managers	Low Estimate	Mean Estimate	High Estimate
General Merchandise Chains	31,000	4,000	\$0.5 million	\$0.7 million	\$0.9 million
Lodging	43,000	4,000	\$0.4 million	\$0.8 million	\$1.1 million
Entertainment, Sports and Recreation	62,000	3,000	\$0.5 million	\$1.0 million	\$1.3 million
Transport	16,000	2,000	\$0.3 million	\$0.5 million	\$0.6 million
Managed Food Service	91,000	7,000	\$1.1 million	\$1.8 million	\$2.4 million
Additional Initial Wage Costs of Training	152,000	13,000	\$2.8 million	\$4.8 million	\$6.3 million
Additional Recurring Training Costs	152,000	7,000	\$1.7 million	\$3.1 million	\$4.2 million
Additional Annualized Training Costs 3%			\$1.8 million	\$3.3 million	\$4.4 million
Additional Annualized Training Costs 7%			\$1.8 million	\$3.3 million	\$4.5 million

The total additional costs of Option 3 are given in Table 13.

Table 13: Total Additional Costs of Option 3, by Sector

Sector	Low Estimate	Mean Estimate	High Estimate
General Merchandise Chains	\$2.2 million	\$5.0 million	\$7.8 million
Lodging	\$1.7 million	\$3.9 million	\$5.9 million
Entertainment, Sports and Recreation	\$4.7 million	\$11.2 million	\$17.5 million
Transport	\$1.1 million	\$2.2 million	\$3.3 million
Managed Food Service	\$2.9 million	\$6.9 million	\$10.8 million
Additional Initial Costs, Option 3	\$12.6 million	\$29.2 million	\$45.3 million
Additional Recurring Costs, Option 3	\$3.6 million	\$7.3 million	\$10.6 million
Additional Annualized Costs, 3 Percent	\$4.8 million	\$10.1 million	\$15.0 million
Additional Annualized Costs, 7 Percent	\$5.1 million	\$10.6 million	\$15.8 million

b. Benefits

Sectors considered under this option account for approximately 11.2 percent (\$40,579,831/\$361,824,164) of “meals, snacks & nonalcoholic beverages prepared for immediate consumption” food sales relative to the establishments covered by the proposed rule, as calculated using 2007 Economic Census Data. The additional costs of Option 3 represent a 13.3 percent increase in annualized costs over those in Option 1. This increase was calculated using the same formula as the cost change for Option 2. .

This estimate depends on a uniform response by consumers and chains to the required nutrient information across all sectors. It is likely that different settings result in different responses to the same required information. Therefore, these estimates may be biased up or down depending on how consumer and chain response varies across sectors. Furthermore, many of these additional do not have food as their primary business activity. In these cases, the cost of compliance on these individual establishments, relative to the importance or size of the food service, may constitute a substantially larger regulatory burden than for the establishments covered in the proposed rule. FDA requests comment and data on these estimates.

E. Option 4. Shorter Compliance Time

Option 4 is similar to the proposed requirements, but with a 3-month time compliance time from the final rule.

With such a short time to compliance, most or all affected chains will need to begin the process of compliance before the final rule has been published, meaning that they may need to change their menus twice in order to comply with any changes made between the proposed rule and the final rule. Because the proposal addresses include issues that are integral to the design of the menu – such as treatment of disclosure for variable menu items – this option would substantially increase the cost of compliance. Such a short compliance time would also require chains with more disposable menus to discard them prematurely, further driving up the cost of the proposed rule.

In addition to the costs estimated for the proposed requirements, FDA estimates that the costs of menu and menu board redesign and replacement would increase by

approximately 25 percent, based on the ability of covered establishments to design in anticipation of issues subject to change.

We estimate the additional costs of discarding and printing new menus for all full service restaurants, or approximately 95,000 establishments. Using the same estimate as in the analysis of the proposed rule, of 91 menus per establishment, the estimated cost of menu replacement for full service restaurants is between \$8.7 million (95,000 establishments x 91 menus/establishment x \$1/menu) and \$26.0 million (95,000 establishments x 91 menus/establishment x \$3/menu) with a mean estimate of \$17.4 million. All other menu or menu board related costs increase by 25 percent, these menu-related costs are given in Table 14.

Annualized costs The annualized costs are calculated by adding the recurring costs to initial costs annualized over 10 years at 3 percent and 7 percent discount rates. With a 3 percent discount rate, the annualized mean cost of menu update for this option is estimated to be \$1.4 million, or between \$0.5 million and \$2.4 million. With a 7 percent discount rate, the annualized mean cost of menu update for these additional sectors is estimated to be \$1.7 million or between \$0.5 million and \$2.8 million.

Table 14: Costs of Menu Update with 3 Month Compliance Time, By Sector

Sector	Establishments	Low Estimate	Mean Estimate	High Estimate
Full Service and Drinking Places	115,000	\$10.2 million	\$19.6 million	\$29.2 million
Limited Service Eating Places	116,200	\$52.6 million	\$221.1 million	\$389.8 million
Grocery Store Chains (excluding convenience)	11,200	\$2.3 million	\$8.8 million	\$15.3 million
Convenience Store Chains	36,200	\$7.6 million	\$28.6 million	\$49.8 million
Total Initial Costs		\$72.7 million	\$278.1 million	\$483.9 million
New Chains	400	\$0.1 million	\$0.4 million	\$0.8 million
Nutrition Information	231,200	\$0.7 million	\$2.1 million	\$3.4 million
Total Recurring Costs		\$0.8 million	\$2.5 million	\$4.2 million
Total Annualized Menu Update Costs, 3%		\$9.1 million	\$34.2 million	\$59.3 million
Total Annualized Menu Update Costs, 7%		\$10.5 million	\$39.6 million	\$68.6 million

Other costs, including recurring costs, would not change. Total and annualized costs for Option 4 are given in Table 15. FDA requests comment on this estimate.

Table 15: Total Estimated Costs with 3 Month Compliance Time, By Activity

Activity	Low Estimate	Mean Estimate	High Estimate	Proportion of Total Costs
Nutrition Analysis	\$17.6 million	\$55.7 million	\$93.7 million	15%
Menu and Menu Board Update	\$72.7 million	\$278.1 million	\$483.9 million	70%
Training	\$28.9 million	\$46.5 million	\$64.0 million	15%
Total Initial Costs	\$119.2 million	\$380.3 million	\$641.6 million	100%
Recurring Nutrition Analysis	\$5.9 million	\$12.3 million	\$18.7 million	27%
Recurring Menu and Menu Board Update	\$0.9 million	\$2.7 million	\$4.4 million	6%
Recurring Training	\$17.4 million	\$29.3 million	\$41.0 million	67%
Total Recurring Costs	\$24.2 million	\$44.3 million	\$64.1 million	100%
Total Option 4 Annualized Costs 3%	\$35.8 million	\$84.2 million	\$132.4 million	
Total Option 4 Annualized Costs 7%	\$37.8 million	\$91.0 million	\$144.0 million	

Under this option, consumers will likely see calorie declarations sooner than under the proposed rule. However, because the benefits associated with weight reduction are long term, FDA estimates that the benefits associated with Option 4 are unchanged from the proposed rule. Therefore, it is likely that the net benefit of this Option is lower than that of Option 1.

F. Option 5. Longer Compliance Time

Option 5 is similar to the proposed requirements, but with a 12-month time compliance time from the final rule.

Under the analysis of the proposed requirements, the only cost that was estimated as dependent on the timing of compliance as the cost of menu replacement for full-service restaurants. Extending the effective date by 6 months relative to the proposed rule would allow more of these restaurants to coordinate menu replacement with an already scheduled menu change. We had estimated in the analysis of the proposed requirements that the cost of menu replacement for these restaurants was between \$0 and \$13.0 million (47,800 establishments x 91 menus/establishment x \$3/menu) with a mean estimate of \$4.3 million (23,900 establishments x 91 menus/establishment x \$2/menu). Extending the effective date to 12 months could then save up to \$13 million. All other costs would still apply. Subtracting these costs from those estimated for the proposed requirements yields annualized costs of \$76.2 million, with low and high estimates of \$31.9 million and \$120.5 million at a 3 percent discount rate or \$81.6 million, with low and high estimates of \$33.2 million and \$130.1 million. FDA recognizes that there may be additional savings from an extension of the effective date from logistical issues. FDA requests comment and data on how a longer time to compliance would affect costs. An increase in the time to compliance is unlikely to substantially affect any ongoing stream of benefits from the proposed requirements. However, because of the attention that menu labeling is currently receiving, to the extent that this attention may be declining over time, delaying compliance may reduce the initial impact of the requirements.

G. Uncertainty Analysis

Table 1a shows that the estimated annualized cost of the proposed requirements range from \$33.4 million to \$130.1 million. FDA has identified several areas of

uncertainty about the costs and benefits of the proposed requirements. Table 16 identifies the primary drivers of uncertainty in each of the cost centers.

Table 16: Main Factors of Uncertainty in Initial Costs: By Activity

	Low	Mean	High
Nutrition Analysis			
Cost of analyses	\$275 per analysis (database)	\$571 (mean)	\$866 pre analysis (lab analysis)
Firms with establishment specific items	0	6,955	13,910
Menu replacement			
Cost of menu board	\$100 per board	\$550	\$1000 per board
Nutrition information use	10 per month per establishment	1 (all others)	50 per month per establishment
Training: time to train			
Staff level	10 minutes	20 minutes	30 minutes
Manager	4 hours	6 hours	8 hours

The uncertainty in the cost of nutrition analysis is driven primarily (nearly 80 percent of the range) by the wide variety, and thus cost, of available methods for analysis. The wide range in estimated cost of menu placement is driven primarily by the wide range in types and costs of menu boards. In addition, some of this uncertainty is related to the number of requests for written nutrition information that establishments will receive. The uncertainty for training time is driven by uncertainty about the amount of time establishments will devote to training staff. FDA requests comment and data on all these estimates.

We also report the variability underlying the estimate of the value of lost quality adjusted life years associated with obesity. Estimates of the baseline burden of obesity cover a five-fold range. However, because FDA cannot estimate actual effects of the

proposed requirements on obesity reduction, and because the estimated costs of the rule are so small relative to the estimated costs of obesity, the break-even point is not particularly sensitive to the variability in these values.

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