I. Analysis of Impacts

A. Introduction

FDA (FDA or we) has examined the impacts of certain nutrition labeling proposed rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The nutrition labeling proposed rules (collectively, the nutrition labeling proposed rules) include the following:

1. Title: Food Labeling: Revision of the Nutrition and Supplement Facts Labels. (Insert Docket No.)

2. Title: Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments. (Docket No. FDA-2004-N-0258).

See the ADDRESSEES section of the nutrition labeling proposed rules for information on how to submit comments on these documents. Please submit your comments to the appropriate docket.

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We are publishing two proposed rules on nutrition labeling in the Federal Register. We have developed one comprehensive Preliminary Regulatory Impact Analysis (PRIA) that presents the benefits and costs of the two proposed nutrition labeling rules taken together. We believe that the cumulative impact of the

proposed rules on nutrition labeling, taken as a whole, represents a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity from the proposed rules are small, but not negligible, and as a result we conclude that the proposed rules on nutrition labeling, taken as a whole, would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that we 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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed rules on nutrition labeling, taken as a whole, meet this threshold.

B. Summary of the Proposed Rules

In this section, we provide a summary of the nutrition labeling proposed rules. Detailed descriptions are provided in each of the proposed rules published in the Federal Register.

Proposed Rule 1 – Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Nutrition Facts Label)

The purpose of this proposed rule is to amend our labeling regulations for foods to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. As such, we are proposing to -

- Update the list of nutrients that are required or permitted to be declared.
- Update the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs) based on current dietary recommendations from consensus reports.
- Establish DRVs and RDIs for nutrients in foods[1] purported for infants (7 through 12 months), young children (1 through 3 years), and pregnant and lactating women.
- Modify the categorization of subpopulation children ages 2 through 4 years to children 1 through 3 years of age.
- Require that under certain circumstances manufacturers make and keep records sufficient to verify the label declaration for the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid in products and provide these records upon request by FDA, during an inspection, for official review and photocopying or other means of reproduction.
- Increase the prominence of calories and the serving size information; reverse the order of the "Serving Size" declaration and the "Servings Per Container" declaration; right-justify the quantitative amounts of the serving size information; change the "Amount Per Serving" declaration to "Amount Per ___" with the blank filled in with the serving size provided in common household measures, e.g. "Amount per 2/3 cup"; remove the declaration of "Calories from fat"; declare "Added Sugars" as an indented listing directly beneath the listing for "Sugars"; declare the quantitative amounts - in addition to percent Daily Values (DVs) - of mandatory and, when declared, voluntary vitamins and minerals; modify the footnote; require that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and

[1] Unless otherwise specified, the word food or foods refers to conventional foods and dietary supplements.

regular type; modify the presentation of the "% DV" information by changing its position on the label and separating it from the list of nutrients with a vertical line; and, add a horizontal line directly beneath the "Nutrition Facts" heading.

Proposed Rule 2 - Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments (Serving Size)

The purpose of this proposed rule is to amend our regulations on serving sizes based on newer consumption data and other current scientific evidence. As such, we are proposing that –

- A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered a single-serving container, and the entire content of the product be labeled as one serving including products that have reference amounts customarily consumed (RACCs) of 100 g (or 100 mL) or larger.
- Products that are packaged and sold individually and contain at least 200 percent and up to and including 400 percent of the applicable reference amount, as well as discrete units in multi-serving packages that contain at least 200 percent and up to and including 400 percent of the applicable reference amount, provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire package or discrete unit as applicable, as well as the preexisting columns listing the quantitative amounts and percent DVs for a serving that is less than the entire package or discrete unit as applicable (i.e., the serving size derived from the RACC).

- RACCs for certain food product categories be updated based on newer food consumption data available from the National Health and Nutrition Examination Survey, and that additional RACCs be modified or established where appropriate.
- The label serving size for breath mints be "1 unit."
- A number of technical revisions be made to help clarify the serving size requirements in §101.9 and §101.12.

C. Need for Regulation

With the goal of providing information to consumers to help them maintain healthy dietary practices, the proposed rules would affect consumers by: (i) better aligning the information provided in the Nutrition and Supplement Facts labels with new data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic diseases, (ii) improving the design and content of the Nutrition Facts label such that relevant information is more salient and easy to understand for the purpose of informing consumer consumption decisions, and (iii) by potentially prompting industry to reformulate products to maintain health claims and nutrient content claims, and to reformulate products that may appear less attractive to consumers under the provisions of the proposed rules.

Information failure, a well-established type of market failure, can provide an economic rationale for the mandatory disclosure of nutrition information. The government does not necessarily have to intervene to address a market failure from a lack of information. However, when individuals find collecting information costly, time-consuming, or both, the revealed private demand for information may differ from the socially optimal level of information. Before NLEA, consumers lacked access to nutrition information for specific product categories. With the implementation of NLEA (effective 1994), FDA began using mandatory nutrition

information disclosure as a regulatory tool to address information asymmetries regarding the nutritional content of packaged foods. Given that consumers have limited time, attention, and resources for seeking out new information, the Nutrition Facts label attempts to convey relevant nutrition information to better inform choices at the point of purchase.

To the extent that there are information constraints with respect to nutrition information, the proposed revisions to the Nutrition Facts label may relieve some of the information constraints. If the proposed revised labels provide few constraints to receiving nutrition information, it may bring about healthier food choices by reducing uncertainty about the underlying nutrient amounts in prepackaged foods because labels now reflect current science, and the proposed rules may reduce market failure arising from incomplete information.

Changes in labeling may also assist consumers by making the long-term health consequences of consumer food choices more salient and by providing contextual cues of food consumption. We note that the behavioral economics literature suggests that distortions internal to consumers (or internalities) due to time-inconsistent preferences, myopia or present-biased preferences, visceral factors (e.g., hunger), or lack of self-control, can also create the potential for policy intervention to improve consumer welfare (Refs. 1 - 4).[2] In a study that examines one of the possible factors that drive obesity, Ruhm (2012) finds that standard economic models of rational preferences and optimal consumption, which emphasize changes in the price of calorie consumption and expenditure as the primary causes of obesity, have a limited ability to explain the rapid and continuing increase in the prevalence of obesity (Ref. 1). The author suggests that we can characterize decisions related to eating and body weight as an interaction between a

[2] An individual has time inconsistent preferences if his or her welfare-maximizing choice is different when considered at different times. For example, an individual has time inconsistent preferences when making food choices if they choose to consume a relatively unhealthy but highly palatable item at lunchtime in spite of having packed, in the morning, a healthier and less palatable alternative.

"deliberative system," where individuals trade off the "utility from current food intake against the associated monetary expense and disutility of future weight gains to achieve a constrained optimum," and an "affective system," which "responds to cues and stimuli but does not consider long-term effects of current actions (Ref. 1)."[3] Akerlof (1991) proposes that when consumers face repeated decisions with a short span of time in between each decision, e.g., choosing food items or meals, and consumers give the present benefits of consumption undue salience relative to their future costs, then small deviations from the utility maximizing (rational) level of consumption can quickly accumulate into large mistakes (Ref. 5).[4]

Consistent with predictions based on models of bounded rationality, consumers can systematically make suboptimal dietary choices because they discount future health consequences relative to immediate benefits more than they would if they chose according to their underlying or true preferences, leading them to regret their decisions at a later date.[5] To the extent that some form of intrapersonal market failure characterizes diet-related decisions, changes in labeling may assist consumers by making the long-term health consequences of consumer food choices more salient and by providing contextual cues of food consumption. For example, the dual-column labeling ("DCL") format cues the consumer into the caloric consequences of consuming the entire package. Similarly, the DCL format and the added sugars declaration may encourage individuals to consume less energy dense and nutrient poor foods by

[3] In the behavioral economics and psychology literatures the dual decision maker systems are also referred to as the reflective and automatic, long-run and short-run, or cold and hot systems (or selves).

[4] Several other behavioral economics or bounded rationality models exist. These models can account for the seemingly irrational behaviors of over eating and continually postponing efforts at weight loss by incorporating the effects of visceral factors, present-biased preferences, heuristics, and other factors that influence decision making (Refs. 1;3 - 6).

[5] Bounded rationality refers to models of decision making that take the cognitive constraints of the decision maker, e.g., present biased preferences, into account. Individuals use heuristics or rules of thumb to simplify the decision making process, but they often sacrifice judgment accuracy for the reduction in cognitive effort in systematic ways (Ref. 7).

making the nutritional attributes of these products more salient and reducing the undue salience consumers place on the utility of consuming these products.

Consumer research supports the importance of salience and cues in immediate consumption decisions. For example, some research has found evidence that increased portion sizes of food products may have contributed to the obesity epidemic (Ref. 8). Over the last twenty years portion sizes have increased by 60 percent for salty snacks and 52 percent for soft drinks (Refs. 9 - 10). Because larger package and portion sizes have been shown to be correlated with increased food consumption, the "supersizing" trend may represent one of the drivers of the obesity epidemic. The literature suggests that package and portion size influence consumers' intake of food products and that consumers need assistance in deciding and monitoring how much they consume in a single eating occasion (Ref. 11). Some argue that current labeling practices, which allow packages containing multiple servings per container to only list the nutrient content per serving, confuse consumers who think that the nutrition information on the product label refers to the entire package (Refs. 9; 11 - 12). The DCL provision of the proposed Serving Size rule, which requires that certain packages and discrete units of food present the nutrition information per serving as well as based on the nutrition information for the entire package or discrete unit, as applicable, would aid consumers in calculating the amount of calories and nutrients in a particular package, while increasing the salience of the caloric content of the foods. Increasing the font size of and bolding the word "Calories" may also increase the salience of the caloric content of foods. Thus, the DCL format and larger font would increase the usefulness of nutrition information on packaged foods. Additionally, given that the Nutrition Facts Label proposed rule, if finalized, would require the declaration of added sugars and that the

2010 DGA recommends reducing calories from solid fats and added sugars, we expect that some producers may reformulate their products to reduce added sugars.

Overall, major predicted elements of the consumer and industry response to the nutrition labeling proposed rules include:

- Increased knowledge of the nutrient content of packaged foods, which may help consumers make healthier food choices;
- Increased ease of nutrition label use from the decreased need to do arithmetic for products that bear DCLs;
- Greater disclosure of the nutrient content of existing packaged foods, which may give firms an incentive to provide additional items with healthier formulations; and,
- Potential reformulation of products to reduce added sugars or change amounts of added vitamins and minerals based on current recommendations.

The effects together would help reduce the information failure and increase the salience of the information on food packages, assisting consumers to make healthy decisions in their diet.

D. Single Analysis for the Two Proposed Rules

We prepared this PRIA for the two proposed rules together, since the two proposed rules involve some form of a label change. Making all of the proposed changes together would allow the manufacturers to undertake all of the proposed revisions to the Nutrition Facts label under one label re-design. For example, for manufacturers that would be required to make label changes under Proposed Rule 2 (Serving Size) and Proposed Rule 1 (Nutrition Facts Label), it would be more efficient to make changes to their product's serving size and to the other information on the Nutrition Facts label at the same time. If undertaken at different points in time, these proposed rules could result in two label re-designs for such manufacturers, one for

the changes required under the proposed Serving Size rule and one for the changes required under the Nutrition Facts Label proposed rule, which could result in greater cost.

E. Coverage of the Rule and Industry Overview

The nutrition labeling proposed rules, together, cover all manufacturers of foods that are required to provide nutrition labeling. This represents about 60,000 manufacturers and over 700,000 Universal Product Codes (UPCs). In terms of sales, they represent about $236.78 billion sales in grocery stores, drug stores and mass merchandise stores. We estimate that 65 percent of the covered firms are small businesses as defined by the Small Business Administration (SBA). SBA's definition, as it is applied to food manufacturers, includes those entities that have less than 500 employees.

Table 1: Industry Coverage Breakdown by Proposed Rules

Proposed Rule	**Type of Label Change**	**Covered UPCs**
Nutrition Facts Label		
Conventional Food	Minor	436,843
Conventional Food	Major	2,881
Dietary Supplements	Minor	85,172
Dietary Supplements	Major	194
Total Nutrition Facts Label UPCs		***525,090***
Serving Size		
Conventional Food	Minor	0
Conventional Food	Major	216,044
Total Serving Size UPCs		***216,044***
Total UPCs		**741,134**

Table 1 presents the industry coverage breakdown by the two proposed rules separately and the type of label changes or re-designs they entail. A minor label change is defined as a one-color/printing plate change that does not require a label re-design (Ref. 13). Examples include changes to the net quantity statement; minimal changes to the Nutrition or Supplement Facts panel; minimal changes to an ingredient list; the addition of a toll-free number;

and, minimal changes to a claim, caution statement, or disclaimer on the back or side of a package (Ref. 13). A major label change is defined as a multiple color/printing plate change that requires a label redesign (Ref. 13). Examples include changes to the name of the product; changes to the standard of identity or fanciful name for a food product; the addition of a Nutrition or Supplement Facts panel; substantial changes to an ingredient list; substantial changes to or elimination of a claim; the addition of or substantial changes to a caution statement; and, the addition of or substantial changes to a disclaimer (Ref. 13).

Proposed Rule 1 (Nutrition Facts Label) entails primarily minor label changes, and covers the most number of UPCs and manufacturers since this proposed rule affects all food manufacturers. In addition, certain changes in nutrient DVs, as well as the new definition of dietary fiber, will require some products to either reformulate to continue to make a related health or nutrient content claim or to remove the health or nutrient content claim from their label altogether, the latter which entails a major label change. Not all manufacturers are covered under Proposed Rule 2 (Serving Size) because the serving sizes for dietary supplements are not changing and not all food products may be affected by the proposed changes. Certain products would have to undertake minor label changes under this proposed rule. Additionally, for certain products, (i.e., those that are packaged and sold individually, as well as those containing discrete units and that contain at least 200 percent and up to and including 400 percent of the applicable RACC) the DCL provisions of Proposed Rule 2 would require manufacturers to undertake a major re-design of their labels. The proposed DCL provisions would not apply to bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine), multipurpose baking mixes, or products that meet the requirements to use the linear format on the Nutrition Facts label

(§101.9(j)(13)(ii)(A)). These provisions would also not apply to products that require further preparation and voluntarily include two columns of nutrition information on the "as purchased" and "as prepared" forms of the food or to products that are commonly consumed in combination with other foods (e.g., cereal and skim milk) and that include another column with information regarding that combination (§§101.9(e) and 101.9(h)(4)). Additionally, certain changes in RACCs will require some products to either reformulate to continue to make a related health or nutrient content claim or to remove the health or nutrient content claim from their label altogether, the latter which entails a major label change.

It is important to note that there is sufficient overlap in covered establishments (food manufacturers) between these proposed rules. For example, many covered establishments under Proposed Rule 1 are also covered under Proposed Rule 2. Not only do these firms have to update some of the nutrition information for their products, but they also have to update the serving size information for their products. Similarly, food manufacturers covered under Proposed Rule 2 are also covered under Proposed Rule 1. This overlap, as previously mentioned in Section D of this document, allows firms to achieve significant cost savings by undertaking all of the required label changes vis-à-vis one label re-design.

F. Industry and Consumer Costs in Response to the Proposed Rules

Meeting the requirements of the proposed rules would impose costs on both industry and consumers. Most of the costs to industry of the proposed rules are fixed costs. Increases in fixed costs affect market prices through shifts in supply only if there is exit of products or firms. Prices rise to reflect changes in supply, but generally not by enough to completely offset them, unless demand is perfectly inelastic, which is unlikely (Ref. 14). Increased prices would reduce

consumption of certain food items. Consumers would pay more for this food, requiring some reduction in other, valued consumption.

The elements of cost for the proposed Serving Size rule include (1) changing the serving size of certain products, (2) altering the graphic design of certain products that are packaged and sold individually that contain at least 200 percent and up to and including 400 percent of the applicable reference amount, as well as those that contain discrete units that are at least 200 percent and up to and including 400 percent of the applicable reference amount, to provide a second column on the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container or individual unit, as applicable, and (3) certain RACC changes, either reformulation to continue to make a related health or nutrient content claim or relabeling to remove the health or nutrient content claim from the product's label.

The changes necessary for the proposed Nutrition Facts Label rule would be (1) the declaration of the amount of micronutrients per serving of a product, updating the DVs for some nutrients, changes to mandatory vs. voluntary declaration of some nutrients, changes to the units of the measure used when declaring the amount of some nutrients, changes to the information found in the footnote, and changes to the format and appearance of the Nutrition Facts labels to include requiring that both the numeric value and the titles "Calories" and "Servings per Container" be displayed in bold or extra bold type and that the font and numeric value of "Calories" be increased, (2) associated with certain DV changes, as well as the new definition of dietary fiber, either reformulation to continue to make a related health or nutrient content claim or relabeling to remove the health or nutrient content claim from the product's label, and (3) associated with the proposed disclosure of added sugars, reformulation in response to the increased visibility of this nutrient.

G. Summary of Cost and Benefits

In this section, we describe the bases of costs and benefits of the proposed rules and summarize the results of the detailed analysis.

Summary of Costs

Costs of complying with the proposed rules include undertaking a major redesign of the labels of certain products for some food manufacturers, while, for others, the requirements would entail undertaking a minor label change. Some manufacturers may also need to reformulate their product to continue to make certain health claims and nutrient content claims, or choose to reformulate in response to new information appearing on the label. Each is discussed in turn.

Labeling costs have been aggregated across an estimate of the total number of products that would be covered under the proposed rules using FDA's Labeling Cost Model (Ref. 13), developed by Research Triangle Institute (RTI). We estimate that there would be approximately 60,000 manufacturers and over 700,000 UPCs covered by the proposed rules. The initial estimated labeling cost associated with complying with the proposed rules, assuming both a 2 year compliance time and that the rules have the same compliance dates, ranges from $1,073 million to $3,083 million, with an estimated midrange cost of $1,876 million (2011$). The uncertainty in the estimates is due largely to the highly variable costs of printing methods utilized by the firms (Ref. 13). Annualized over 20 years, the labeling cost associated with the proposed rules is $122 million per year at a 3 percent discount rate and $165 million per year at a 7 percent discount rate (2011$). We estimated low and high annualized labeling cost estimates for the proposed rules of $70 million per year and $201 million per year at a 3 percent discount rate, and $95 million per year and $272 million per year at a 7 percent discount rate (2011$). Related recordkeeping costs are estimated to be $27.7 million at a 3 percent discount rate and

$26.6 million at a 7 percent discount rate (2011$). Annualized over 20 years, recordkeeping costs are estimated to be $1.8 million per year at a 3 percent discount rate and $2.3 million per year at a 7 percent discount rate (2011$).

We also evaluate the costs of reformulating food products motivated by the proposed rules changing the potential eligibility of products currently making health or nutrient content claims on their label, as well as increasing the visibility of nutrients that, based on the 2010 DGA consumers should limit. We estimate total reformulation costs of $103 million to $905 million, with a mid-range estimate of $440 million (2011$). Uncertainty in the estimates associated with reformulation arises because some reformulations prove to be more difficult than others, requiring several candidate formulas before a suitable one is found (Ref. 15). In addition, different formulas even within a specific product group (e.g. entrees), use different ingredients in a variety of different ways, including assorted quantities and levels of importance in creating specific flavors, providing certain nutritional values, maintaining structural integrity, creating visual appeal, and preserving shelf life and inhibiting pathogen growth.

Summary of Benefits

Organization and Considerations in Estimating Benefits

The detailed analysis contains a description of the motivation for the proposed rules, the expected changes in consumer behavior as a result of the proposed rules, the methodology FDA used to estimate the benefits of the proposed rules, a discussion of the unquantified benefits from reduced medical expenditures and increased quality of life, and finally, an analysis of the sensitivity and uncertainty of our estimates. To quantify the benefits of the proposed rules, FDA extrapolated from the welfare effects estimated in a retrospective study on the impact of NLEA by Abaluck (2011) (Ref. 16). Abaluck (2011) measured the consumer welfare gains as the

willingness-to-pay (WTP) for nutrient content based on revealed preference data, i.e., food consumption and prices.

Summary of Primary Benefits Estimate

The Nutrition Facts label contains nutrient content information that can help people follow healthy dietary practices. The growth in the prevalence of obesity and diabetes and the high rates of chronic diseases such as heart disease and stroke in the United States has elevated the treatment and prevention of these diseases to a top public health concern and a national priority. With the goal of providing information to help people maintain healthy dietary practices, the proposed rules would: (i) better align the information provided in the Nutrition Facts label with new data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic disease, (ii) improve the design and content of the Nutrition Facts label to make relevant label information more salient and easy to understand so that consumers may make more informed consumption decisions, and (iii) potentially prompt industry to reformulate products to maintain health claims and nutrient content claims, and reformulate products that may appear less attractive to consumers under the provisions of the proposed rules.

Based on the WTP estimates from Abaluck (2011), we estimate that the present value (PV) of the stream of benefits associated with the proposed rules for the total US population over the next 20 years ranges (90 percent confidence interval (CI)) from $1.9 to $47.1 billion, with a mean estimate of $21.1 billion (2011$) at a discount rate of 7 percent (refer to second row of Table 2). Annualized over 20 years, we estimate that the benefits of the proposed rules equal

$2.0 billion per year (2011$) assuming a 3 percent discount rate and $1.9 billion per year (2011$) assuming a 7 percent discount rate.[6]

Table 2. Summary of Costs and Benefits Over 20 Years
(in billions of 2011$)

		Benefits	Costs	Net Benefits
Present Value (PV)				
	3%	$31.4	$2.3	$29.1
	7%	$21.1	$2.3	$18.8
Annualized (3% PV Amount)				
	3%	$2.0	$0.2	$1.8
Annualized (7% PV Amount)				
	7%	$1.9	$0.2	$1.7

Notes: Compliance period is 24 months. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

H. **Costs and Benefits of Regulatory Options – Detailed Analysis**

We have identified five regulatory options for these proposed rules:

1.) No New Federal Regulatory Action;

2.) The proposed rules that would give manufacturers 2 years for compliance;

3.) The proposed rules, but with a 3 year compliance time;

4.) The proposed rules, but with a 4 year compliance time; and

5.) The proposed rules, but with DVs for sodium of 1,500 mg or 1,900 mg.

Requiring different compliance dates for the Nutrition Facts label rule and the Serving Size rule is a theoretical policy choice and a potential consequence of unforeseen circumstances

[6] We believe that 20 years is an appropriate time frame to show the likely implications of the regulations. A ten year time horizon might under-represent the full effects of the rule due to limited or no benefits accruing prior to the compliance date. A time frame of more than 20 years begins to be rather speculative. After twenty years, it is likely that food, drug, and supplement technologies, as well as medical treatments will have changed enough so that the potential benefits derived from these rules may be less impactful. Moreover, even though only 20 years' worth of changed consumption behavior is included in the analysis, the projected health impacts of the rule extend over the entire lives of the affected consumers, and technology will likely have changed even further over that overall time horizon than over the first two decades following rule finalization.

in the regulatory process. Therefore, in our discussions of regulatory alternatives (2) through (5), we present impact estimates with both sub-options: same and differing compliance dates.

1. Option 1: No New Federal Regulatory Action

Nutrition labeling has been mandated by Congress (NLEA 1990), with FDA only defining details of implementation by regulation. Although existing food labels have been found to generate substantial benefits for consumers, the absence of the proposed rules would mean that the Nutrition Facts label would not be revised based on the latest data, nutrition research, and changes in our understanding of consumer behavior.

2. Option 2: The Proposed Rules that would give manufacturers 2 years for compliance

Under this option, some manufacturers would be required to undertake a major re-design of their labels due to the provisions of DCL for certain food packages, or to remove a health or nutrient content claim in response to certain changes in the DVs, RACCs, or definition of dietary fiber, while others would need to undertake a minor label change due to changes in the nutrition information that must be declared on the Nutrition and Supplement Facts labels. Some manufacturers may choose to reformulate their product to continue to make certain health claims and nutrient content claims, or in reaction to new nutrient declarations. The proposed requirements are described in greater detail in the individual proposed rules published in the Federal Register.

a. Costs

i) <u>Relabeling Costs</u>

In order to comply with the proposed rules, some firms would have to change some of their labels for the second proposed rule, whereas all covered firms would have to make changes to all of their labels for the first proposed rule related to increasing the prominence of calories and the serving size information, reversing the order of the "Serving Size" declaration and the "Servings Per Container" declaration, right-justifying the quantitative amounts of the serving size information, changing the "Amount Per Serving" declaration to "Amount Per ___" with the blank filled in with the serving size provided in common household measures, removing the declaration of "Calories from fat," updating the declarations and %DVs of some nutrients, changing the units of measure for some nutrients, declaring "Added Sugars" as an indented listing directly beneath the listing for "Sugars," declaring the quantitative amounts (in addition to percent DVs) of mandatory and, when declared, voluntary vitamins and minerals, modifying the footnote, requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular type, modifying the presentation of the "% DV" information by changing its position on the label and separating it from the list of nutrients with a vertical line, and adding a horizontal line directly beneath the "Nutrition Facts" heading. Because of the number of steps involved in changing the information on food packaging and labeling, the entire process generally takes several months (Ref. 13). Although some food manufacturers of branded products change their labeling information several times a year, other food manufacturers, particularly for private label products,[7] change their labeling information only every few years, mostly scheduled to coincide with the uniform compliance date for new food labeling requirements that we announce periodically. Depending

[7] Branded products make their way to store shelves by way of branded food manufacturers and distributors (e.g., Hunt's ketchup, French's mustard). Private label products make their way to store shelves either by way of in-house manufacturing or manufacturers who specialize in the manufacture of private label products (e.g., Wal-Mart's "Great Value" product line).

on when the required labeling change is announced, food manufacturers may or may not be able to coordinate the required change with a scheduled labeling change. If they can coordinate, then the incremental costs of making the required change would be substantially less than if they made the change separately.

Relabeling costs were estimated using FDA's Label Cost Model (Ref. 13). The label cost model, which was built based on discussions with trade associations and product manufacturers, provides estimates of the costs of making labeling changes for a range of food products. Label costs are first calculated on a per-UPC basis and then aggregated across each product category, and are calculated separately as low, midrange, and high cost estimates.

To determine the UPC counts in each product category, the model utilizes 2008 Nielsen Scantrack data (2008 was the most recent calendar year for which data were available when the model was updated by RTI in 2011). The model allows us to select the types of products that would be covered under any specific regulation, the type of label change (major or minor) that would be required under the regulation, and the compliance period. Our estimate of the covered products was obtained by selecting the types of products that we think fall under each of the proposed rules. However, it is important to note that within the data on broad categories of food, there are products that are regulated by USDA (e.g., Salisbury steak frozen dinner) (Ref. 17). We are not able to separate out from the total number of UPCs in each category the number of UPCs that are regulated by USDA, and which therefore are not covered by the proposed rules. Based on a random sample of UPCs taken from Nielsen Weekly Scanner data, we estimate the percentage of UPCs which fall under USDA jurisdiction to be 5 percent and build this into our analysis.[8] We invite comments on this estimate.

[8] Nielsen Weekly Scanner data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

The parameters of the label cost model include:

- Manufacturers who can coordinate a required labeling change with a planned labeling change would incur lower costs than they would if they had to undertake multiple separate label changes.
- Even if manufacturers can coordinate a required labeling change, the model is designed to include administrative and recordkeeping costs associated with labeling changes, as manufacturers still incur costs associated with understanding the regulation, determining their response, tracking the required change through the label change process, and reviewing and updating their records of product labels.
- Other types of costs, such as prepress, graphic design, and engraving plates or cylinders, are not attributable to the regulation if the required labeling change is coordinated with a planned change.

With a 2 year compliance time period, the label cost model estimates that 74 percent of private label food products would have to undertake an uncoordinated label change. For branded food products there would be no uncoordinated label changes. For dietary supplements, 78 percent of branded products and 84 percent of private label products would have to undertake an uncoordinated label change. The number of UPCs that would have to undertake coordinated versus uncoordinated label changes for each of the proposed rules is provided in Table 3. Table 3 also shows the number of UPCs per rule that can undertake one label change to satisfy the requirements of all of the proposed rules. The proposed Nutrition Facts Label rule covers all packaged food, so the total UPC count of 741,134 reflects that. As described earlier, all UPCs will have to undergo various changes to the Nutrition Facts label. Based on analyses conducted using a combination of Gladson and Mintel data, we estimate that some baked goods, some

baking ingredients, some beverages, some breakfast foods, some candy and gum, some condiments/dips/spreads, some dairy foods, some dressings and sauces, some entrees, some fats and oils, some fruits and vegetables, some pizza, some seafood, some side dishes and starches, some snack foods, some soups, and some dietary supplements will need to re-label to remove a health or nutrient content claim in response to certain DV changes and some baked goods, some baking ingredients, some beverages, some breakfast foods, some candy and gum, some dietary supplements, some condiments/dips/spreads, some dairy foods, some desserts, some dressings and sauces, some entrees, some fats and oils, some fruits and vegetables, some infant foods, some pizza, some seafood, some side dishes and starches, some snack foods, some soups, and some sweeteners will need to re-label to remove a health or nutrient content claim in response to the new definition of dietary fiber.[9] We invite comments on this. The Serving Size proposed rule, in part, applies to foods that would need to have DCL (products in packages that are at least two times the RACC and up to and including four times the RACC). We estimate that some of the UPCs under each of the following food product categories would have to undertake DCL – baked goods, beverages, breakfast foods, desserts, entrees, snack foods, and soups. We invite comments on this selection of product categories. In addition, based on an analysis conducted using Gladson and Mintel data, we estimate that 15 percent of candy and gum UPCs, excluding those that meet the requirements to use the liner format, would have to undergo DCL. We invite comments on this estimate. The Serving Size proposed rule also applies to foods for which RACCs would change, foods that would change in response to the changes in the single serving size requirement, and foods that would require changes to their labels in response to the technical

[9] The Gladson Nutrition Database and the Mintel Global New Products Database are commercial label databases which contain information gathered since approximately the year 2000 on product type, brand, ingredients, and verbatim wording manufacturers use on product labels. For more information, see http://www.mintel.com and http://www.gladson.com.

amendments. We estimate that manufacturers making some of the UPCs under each of the following food product categories would have to undertake a labeling change related to these proposed changes – baked goods, beverages, breakfast foods, candy and gum, condiments/dips/spreads, dairy foods, desserts, entrees, fruits and vegetables, infant foods, pizza, seafood, side dishes and starches, and sweeteners. We invite comments on this selection of product categories. Finally, based on an analysis conducted using a combination of Gladson and Mintel data, we estimate that some of the UPCs under each of the following food product categories will need to relabel to remove a health or nutrient content claim in response to certain RACC changes – baked goods, baking ingredients, beverages, candy and gum, condiments/dips/spreads, dairy foods, dressings and sauces, entrees, fats and oils, fruits and vegetables, pizza, seafood, and side dishes and starches. We invite comments on this list of product categories.

Table 3: Industry Coverage by Proposed Rule – Coordinated vs Uncoordinated

Proposed Rule	**Source of Label Change**	**Type of Label Change**	**Covered UPCs**		**Covered UPCs**	
			Different Compliance Dates		*Same Compliance Date*	
			Uncoordinated	*Coordinated*	*Uncoordinated*	*Coordinated*
Nutrition Facts Label (NFL)						
Conventional Food	Various Changes to the NFL	Minor	188,956	461,510	126,221	310,622
Conventional Food	Claim Removal Related to DV Change	Major	535	947	335	535
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	1,229	2,591	700	1,311
Dietary Supplements	Various Changes to the NFL	Minor	68,876	16,296	68,876	16,296
Dietary	Claim	Major	61	14	61	14

Supplements	Removal Related to DV Change					
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	93	26	93	26
Total Nutrition Facts Label UPCs			**741,134**		**525,090**	
Serving Size						
Conventional Food	Dual-Column Labeling	Major	63,382	152,356	63,382	152,356
Conventional Food	Claim Removal Related to RACC Change	Major	82	224	82	224
Conventional Food	Changes Due to RACC Proposals	Minor	26,468	102,729	-	-
Total Serving Size UPCs			**345,241**		**216,044**	
Total			**1,086,375**		**741,134**	

Notes: Compliance period is 24 months. UPC counts have been rounded to the nearest whole number amount.

From Table 3 we can see that if the rules have different compliance dates, then the covered products under the proposed Serving Size rule (345,241 UPCs) would have to undergo two label changes – one for the proposed Nutrition Facts label rule and one for the proposed Serving Size rule. However, a UPC subject to multiple *within rule* label changes only has to undergo one rule-specific label change. For example, under the Nutrition Facts label rule, a UPC subject to both various minor changes to the Nutrition Facts label and claim removal related to the new dietary fiber definition was counted only under the latter change, because we considered major label changes to subsume minor label changes for the purpose of this economic analysis. When all of the proposed rules have the same compliance date, the covered products under the proposed Serving Size rule can satisfy the requirements of both the proposed Nutrition Facts Label rule and the proposed Serving Size rule under one label change. For example, a UPC subject to both various minor changes to the Nutrition Facts label under the Nutrition Facts label

rule and dual-column labeling under the Serving Size rule was counted only under the latter change because, again, we considered major label changes to subsume minor label changes for the purpose of this economic analysis.

Label cost estimates in 2011 USD are presented in Table 4. We first compare the cost of the proposed rules if they have different compliance dates with the cost under the same compliance date. Such a comparison illustrates the reduction in label costs that firms would experience if they undertook all of the proposed label changes under one label re-design. The labeling cost of the proposed rules, if they had different compliance dates, would be approximately $2.4 billion at the midrange estimate. This translates into per UPC costs (at the midrange) of about $6,188 per uncoordinated UPC and roughly $367 per coordinated UPC.

If, instead, the proposed rules have the same compliance date, the cost savings are substantial – looking at the "Same Compliance Date" columns in Table 4, the one-time labeling cost of the proposed rules would be reduced by 21 percent, to $1.9 billion, at the midrange estimate. This translates into per UPC costs (at the midrange) of approximately $6,479 per uncoordinated UPC and roughly $401 per coordinated UPC. These cost savings arise because firms that are covered by both of the proposed rules are now able to undertake just one label change to comply with the requirements of the two proposed rules.

Table 4: Label Cost Comparison – Different Compliance Dates vs. Same Compliance Date (in millions of 2011 USD)

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$588	$1,075	$1,782	$377	$693	$1,152
Conventional Food	Claim Removal Related to	Major	$4	$7	$12	$3	$4	$7

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
	DV Change							
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$11	$18	$28	$5	$9	$14
Dietary Supplements	Various Changes to the NFL	Minor	$184	$341	$589	$184	$341	$589
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.4	$0.6	$1	$0.4	$0.6	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.9	$2	$3	$0.9	$2	$3
Total Nutrition Facts Label			**$788**	**$1,444**	**$2,415**	**$570**	**$1,050**	**$1,766**
Serving Size								
Conventional Food	Dual-Column Labeling	Major	$502	$824	$1,315	$502	$824	$1,315
Conventional Food	Claim Removal Related to RACC Change	Major	$0.9	$2	$2	$0.9	$2	$2
Conventional Food	Changes Due to RACC Proposals	Minor	$89	$166	$274	-	-	-
Total Serving Size			**$592**	**$992**	**$1,591**	**$503**	**$826**	**$1,317**
TOTAL ALL			**$1,380**	**$2,436**	**$4,006**	**$1,073**	**$1,876**	**$3,083**
Annualized (3%)			$90	$159	$261	$70	$122	$201
Annualized (7%)			$122	$215	$353	$95	$165	$272

Notes: Compliance period is 24 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

With the same compliance date, it can be seen that the one-time labeling cost estimates of the proposed rules under the 2 year compliance time period range from $1.1 billion to $3.1

billion. The uncertainty in the estimates is due largely to different printing methods utilized by the firms (Ref. 13). Table 4 also presents annualized labeling costs. With a 3 percent discount rate, the annualized labeling cost is estimated to be between $70 million and $201 million. With a 7 percent discount rate, the annualized labeling cost is estimated to lie between $95 million and $272 million.

Proposed rule 1 requires that under certain circumstances manufacturers make and keep records to verify the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E and folate/folic acid in products. Thus, manufacturers must maintain records sufficient to verify the label declaration for these nutrients for at least 2 years after introduction or delivery for introduction of the food into interstate commerce and, as well, provide these records upon request by FDA, during an inspection, for official review and photocopying or other means of reproduction. The records required to be retained could be nutrient database analyses, recipes or formulations, batch records, or any other information that a manufacturer has that verifies the nutrient content in the final product. For yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and non-malt beverage beers, all of which undergo fermentation during food processing, sugars added before and during fermentation may be reduced in quantity during the process. Thus, the amount of added sugars in the finished food product may be uncertain. While some manufacturers of these products may be able to determine the amount of added sugars in their finished food products by either conducting laboratory analyses or relying on a scientific document, manufacturers of such foods will be permitted to declare the amount of added sugars present in the food product *prior* to fermentation, with that number not exceeding the amount of total sugars declared. We assume that most manufacturers of these products will choose to declare the amount of added sugars present in the food product *prior* to fermentation.

We assume that manufacturers currently maintain the abovementioned records in the normal course of doing business. Thus, the time burden to the covered food manufacturer would be to maintain these records to verify the amount of such nutrients in a food and to make such records available to appropriate regulatory officials upon request. Maintaining database analyses, formulation records, batch records, or other records of the amount of nutrients in the final product is within the scope of normal business operations for food manufacturers and, thus, imposes additional costs associated only with the time required to identify and assemble the records for copying and retention. Referring to the Paperwork Reduction Act analysis in Section IV of the PRIA, we estimate that manufacturers will incur 359,252 recordkeeping hours initially and 216 recordkeeping hours on an annual recurring basis. According to the Bureau of Labor Statistics National Industry-Specific Occupational Employment and Wage Estimates, the mean hourly wage of an operations manager in the food manufacturing industry is $53.56. We increase this cost by 50 percent to account for benefits and overhead, making the total cost of time $80.34 (= $53.56 × 1.50). Thus, total recordkeeping costs, discounted over 20 years and in 2011 dollars, are estimated to be approximately $27.7 million using a 3 percent discount rate and roughly $26.6 million using a 7 percent discount rate. We invite comment on whether most manufacturers of yeast-leavened bakery products, wines with less than 7 percent alcohol, and non-malt beverage beers will choose to declare the amount of added sugars present in the food product *prior* to fermentation. We also invite comment on whether or not maintaining database analyses, formulation records, batch records, or other records of the amount of nutrients in the final product is within the scope of normal business operations for food manufacturers.

ii) Reformulation Costs

The proposed rules could motivate food manufacturers to reformulate their products in response to future changes in consumer preferences. Incentives to reformulate can be categorized into two groups: (i) reformulations to maintain health and nutrient content claims motivated by DV and RACC changes and changes in the definition of dietary fiber and (ii) reformulations motivated by the increased visibility of added sugars. We estimate reformulation costs associated with each group in turn.

Cost of Reformulation of Food to Maintain Health Claims and Nutrient Content Claims

The proposed rules could affect producers of food products who currently make certain nutrient content claims or health claims authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act) on their product's label. The use of a claim may add value to a product's brand by providing both additional nutritional information and a health signal that may positively differentiate their product from competitors. Under the FD&C Act, RACCs are to be used to determine whether a product meets the criteria for a nutrient content claim or health claim. The changes the proposed rules make to product label requirements (specifically, changes in the RACCs and changes in the DVs leading to changes in the declared percent DV and changes in the definition of dietary fiber so as to exclude certain isolated and synthetic fibers from the definition) could cause a product currently making a health or nutrient content claim to become ineligible to make the claim. This would force manufacturers of these products to either remove the claim from their product's label or reformulate in order to continue to make the claim.[10] It is

[10] To illustrate, consider these examples:

1) Brand X Low-fat Ice Cream – Brand X currently sells in pint-sized cartons, with 3 grams of fat per ½ cup. The proposed rules would double the RACC of ice cream from ½ cup to 1 cup. According to the Food Labeling Guide (Ref. 18), this product is currently eligible to make a "low fat" claim on its label since it contains 3 grams or less of total fat per RACC. By doubling the RACC, Brand X would now contain 6 grams of fat per RACC, rendering it ineligible to keep the "low fat" claim.

2) Brand Y Greek Yogurt – Brand Y currently sells yogurt in 24-oz packages, with 8 oz. per serving. It also contains 22 percent of DV of calcium and currently qualifies for the nutrient content claim "excellent source of calcium" since it contains 20 percent or more of the DV per RACC. The proposed rules decrease the serving size of

difficult to predict how the requirements of the proposed rules would influence manufacturers' incentives to reformulate versus remove the claim from the product label. We therefore assume that some manufacturers would reformulate while others would remove the claim from their product's label. We attempt to estimate reformulation costs by linking the proposed rules' labeling changes to specific formulas whose label claims would most likely be affected. Then, the cost of reformulating these individual formulas can be estimated.

To estimate reformulation costs, we gathered data to provide a representative sample of the total number of food products from the Gladson and Mintel databases. To determine which UPCs would need to either reformulate to continue to make health or nutrient content claims or relabel to remove such claims from their label related to RACC changes, the data were refined to identify UPCs with new or changing RACCs. Label data were aggregated for each food/nutrient category specifically targeted by the proposed rules through either a change in RACC or a change in DV. For each product, the current nutrition and serving size data were used to calculate new hypothetical nutrition data if the proposed RACC changes were to occur. The data were then filtered down to only products with label health claims (excluding qualified health claims) and nutrient content claims as stated in Appendices A-D of the FDA Food Labeling Guide (Ref. 18) (e.g., "good source of…," "low sodium," "Vitamin C added," etc.). We then assessed whether the specific claims could still be used if the labeling changes were enacted.

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yogurt to 6 oz., which brings the percent DV of calcium down to 17 percent. Brand Y can no longer claim "excellent source," and must either reformulate to keep the claim, or downgrade the claim to "good source" of calcium.

3) Brand Z Breakfast Bar – According to the Food Labeling Guide (Ref. 18), in order to make an "Excellent Source of Fiber" claim, Brand Z breakfast bars must contain 20 percent or more of the DV of fiber (DV = 25 grams) per RACC (RACC = 40 grams). Brand Z breakfast bars currently contain 6 grams of dietary fiber per 40 gram bar (24 percent of DV per RACC) and, thus, are currently eligible to make the "Excellent Source of Fiber" claim on their label. The source of this dietary fiber, however, is a fiber known as Fiber A, an isolated/synthetic fiber which does not meet the definition of dietary fiber under the proposed rules. Thus, under the proposed rules, Brand Z breakfast bars must either reformulate their breakfast bars using natural dietary fiber or an isolated/synthetic dietary fiber that meets the definition of dietary fiber to continue to make the "Excellent Source of Fiber" claim, or remove the claim from the breakfast bar label.

Products currently making label claims but rendered ineligible after the introduction of the RACC changes were flagged as needing either label modifications or reformulation. An identical refinement methodology was used to determine which UPCs would need to reformulate to continue to make health or nutrient content claims related to DV changes or re-label to remove such claims from their label. This part of the analysis captured products that currently have label claims that would no longer be eligible on the packaging after the proposed DV changes. These products were aggregated by food category and added to the previous list of affected products.

To determine which UPCs would need to reformulate to continue to make health or nutrient content claims related to the new definition of dietary fiber or relabel to remove such claims from their label, the data were refined to identify UPCs containing at least one isolated or synthetic fiber. The data were then further refined to identify which among these UPCs contain a fiber related health or nutrient content claim. Because of data limitations, we conservatively assume that all UPCs that both contain at least one isolated or synthetic fiber and that carry a fiber related health or nutrient content claim will need to reformulate to continue to make such a claim or relabel to remove such a claim from their label.

The Gladson and Mintel databases do not provide formula counts. Thus, to convert the above UPC counts to formula counts, we relied on UPC and formula count data from the FDA Labeling Cost Model (Ref. 13). The FDA Labeling Cost Model estimates both total UPCs as well as total formulas for each of the relevant food product groups. For each product group, we multiply the ratio of Formulas to UPCs obtained from the FDA Labeling Cost Model by the UPC counts obtained from the Gladson and Mintel databases. This is illustrated in Tables 5 and 6. In this way, we are able to impute a formula count from each UPC count obtained from the Gladson and Mintel databases.

Table 5. UPC & Formula Counts for Claim Related Reformulations and Claim Removals Motivated by RACC and DV Changes

Category	UPCs	Formula/UPC Ratio	Formulas
Appetizers	30	0.853	26
Baked Goods	400	0.850	340
Baking Kits	80	0.893	71
Beverages	500	0.468	234
Beverages, Mixer	100	0.788	79
Beverages, Mixer for Milk	40	0.694	28
Bread	100	0.884	88
Canned Seafood	150	0.822	123
Cereal	500	0.562	281
Cereal Bars	500	0.752	376
Cheese	250	0.851	213
Cocoa Powder/Carob Powder	5	0.757	4
Cookies/Crackers	100	0.769	77
Dried Veg.	25	0.756	19
Frozen Meals	75	0.893	67
Fruit Snacks	50	0.767	38
Ice Cream	100	0.865	87
Juice	300	0.678	203
Nuts	250	0.793	198
Other Candies	100	0.762	76
Packaged Veg.	200	0.833	167
Pasta Sauce	30	0.926	28
Pasta/Rice	150	0.833	125
Pizza, Burritos, Sandwiches	40	0.888	36
Seasoning Oils/Sauces	20	0.814	16
Soup	75	0.857	64
Vitamins and Other Supplements	144	0.849	122
Yogurt	500	0.798	399
Total	**4,814**		**3,585**

Notes: UPCs × Formula/UPC Ratio = Estimate of Formulas.

Table 6. UPC & Formula Counts for Claim Related Reformulations and Claim Removals Motivated by the New Definition of Dietary Fiber

Category	UPCs	Formula/UPC Ratio	Formulas

Baby Food/Formula	198	0.928	184
Baked Good Mixes/Ingredients	129	0.799	103
Bakery Sweets	10	0.752	8
Beverages - Dairy and Dairy Substitutes	104	0.609	63
Beverages - Dry Mix	165	0.694	115
Beverages - Juice & Juice Drinks	180	0.706	127
Beverages - Other (Soda, Enhanced Water, etc.)	491	0.492	242
Beverages - Tea	104	0.823	86
Breads/Bagels/Wraps	1,188	0.861	1,022
Butter/Margarine/Spread	8	0.728	6
Candy	123	0.736	91
Canned Fish	4	0.822	3
Cereal/Granola/Nutrition Bars	663	0.883	585
Cheese	82	0.851	70
Condiments/Dips/Sauces	35	0.872	31
Cookies	123	0.758	93
Crackers	132	0.805	106
Cream/Creamer	1	0.724	1
Dessert Topping	-	0.842	0
Dry Dinner Mix	139	0.886	123
Dry Rice/Pasta/Potato	194	0.828	161
Fresh Produce Snacks/Salads	16	0.784	13
Frozen Baked Goods	99	0.868	86
Frozen Fish/Seafood	49	0.739	36
Frozen Meals	464	0.893	414
Frozen Pizza	61	0.874	53
Frozen Snacks/Appetizers	20	0.869	17
Frozen Vegetables	24	0.837	20
Fruit Snacks	35	0.767	27
Gum/Mints	10	0.605	6
Ice Cream/Frozen Desserts	394	0.873	344
Jelly/Preserves	32	0.883	28
Nuts/Trail Mix	119	0.795	95
Other Dry Mixes	32	0.808	26

Pasta Sauce	9	0.926	8
Pickles/Olives	2	0.813	2
Protein/Nutrition Powder	238	0.802	191
Pudding/Gelatin/Pie Filling	29	0.752	22
Refrigerated Prepared Meals	21	0.848	18
RTE Cereal, Instant Cereal, and Toaster Pastries	1,418	0.663	940
Salad Dressing	67	0.792	53
Shelf Stable Vegetables	34	0.789	27
Snack Cakes	41	0.808	33
Snacks (Chips/Pretzels/Popcorn)	407	0.699	285
Soup	211	0.857	181
Sour Cream	3	0.555	2
Spices/Seasoning	4	0.853	3
Syrup	5	0.709	4
Yogurt	359	0.798	286
Total	**8,276**	**-**	**6,440**

Notes: UPCs × Formula/UPC Ratio = Estimate of Formulas.

Reformulation costs are computed by multiplying the estimated number of formulas by estimates of per-formula costs. Per-formula cost estimates, illustrated in Table 7, are obtained from the FDA Reformulation Cost Model, which allows the incorporation of a variety of potential reformulation costs associated with idea generation, product research and process development, coordinating activities, product testing, packaging development, market testing, and production/manufacturing (Ref. 15). Since the ingredients in question generally play a non-critical, minor role in product formulation, we consider the only relevant cost inputs should correspond to idea generation, product research and process development, coordinating activities, product testing, and production/manufacturing. We invite comment on this approach. Idea generation involves the costs of deciding how the manufacturer chooses to approach the reformulation problem, specifically whether the target ingredients need to be added, subtracted,

or substituted, and to what degree. Product research and process development is responsible for developing the new formula and coordinating testing and support activities. Coordinating activities involves purchasing, legal, marketing, and quality control issues. Product testing will most likely involve shelf-life studies to measure the response of products to conditions experienced in handling and storage. Finally, the production/manufacturing stage ensures the proper people, equipment, and logistics are in place to manufacture the reformulated product. Per-formula reformulation costs range from $11,626/formula to $102,365/formula, with a midrange value of $49,716/formula.[11]

Table 7. Reformulation Costs per Formula (in 2011 USD)

Cost Input	Low	Med	High
Idea Generation	$526	$2,630	$6,312
Product Research and Process Development	$6,067	$28,850	$59,837
Coordinating Activities	$2,838	$8,511	$14,185
Product Testing	$803	$2,765	$6,686
Production/Manufacturing	$1,392	$6,960	$15,345
Total	**$11,626**	**$49,716**	**$102,365**

If we apply the per-formula costs in Table 7 to the formula counts in Tables 5 and 6, we will likely overestimate the cost of reformulation. First, the estimates of the number of affected formulas are likely high. More detailed data would allow us to better refine our estimate of the number of affected formulas, but we are not aware of any such data. Second, not all manufacturers would choose to reformulate their product to continue to make the health or nutrient content claim, but rather might instead choose to remove the health or nutrient content claim from their product's label. If a manufacturer decided to remove a claim instead of

[11] Product reformulation may result in higher ongoing production costs for food manufacturers. Such costs can only partially be passed along to consumers, as demand for food is not perfectly inelastic (Ref. 14). However, due to data limitations, we are unable to quantify either the total costs or how the costs are distributed across manufacturers and consumers. We invite comment on this.

reformulating, we assume that any loss in sales directly attributable to the removal of the claim would simply be transferred to a substitute product, with negligible value lost to society. We invite comment on this assumption. Thus, in such a case, the relevant cost to consider is the relabeling cost associated with printing new labels that do not contain the claim (which is captured already in the relabeling cost estimation section). In lieu of reliable data regarding manufacturers' response to the proposed rules, we assume that 50 percent of affected UPCs would choose to reformulate and 50 percent would choose to relabel (again, this is captured already in the relabeling cost estimation section). We invite comment on this approach. This brings the total formula count to 5,013 (0.5 × 3,585 + 0.5 × 6,440).

Reformulation costs depend on the mandated compliance period, with coordination costs decreasing as the compliance period increases. A built-in assumption of the FDA Reformulation Cost Model is that to the extent a manufacturer can coordinate a required reformulation with a scheduled reformulation, reformulation costs will be smaller than they otherwise would be.[12] Given a compliance period of 24 months, 20 percent of formulas can coordinate. Given compliance periods of 36 months and 48 months, respectively, 30 percent and 40 percent of formulas can coordinate. Under a 24 month compliance period, the total formula count reduces to 4,010 (5,013 - 0.2 × 5,013). Multiplying this formula count by the per-formula reformulation costs in Table 7 yields total reformulation costs (in 2011 USD) associated with reformulating to maintain a health or nutrient content claim due to changes in RACC, DV, and the definition of dietary fiber of between $47 million ($11,626 × 4,010) and $410 million ($102,365 × 4,010), with a midrange estimate of $199 million ($49,716 × 4,010).

[12] Based on reviews of published material on the reformulation process, as well as interviews with manufacturers, the FDA Reformulation Cost Model assumes that if manufacturers can coordinate a required reformulation with a scheduled reformulation, the costs associated with compliance are negligible. Where they are not, reformulation costs will be underestimated. We invite comment on this.

Cost of Reformulation of Foods That Significantly Contribute Added Sugars to Diets

We recognize that the proposed rules increase the visibility of nutrients that, based on the 2010 DGA, consumers should limit, particularly the proposed label disclosure of added sugars. These label changes may motivate some food manufacturers to reformulate existing products. In order to estimate the number of formulas that would be reformulated as a result of these changes, we use a similar methodology to that which was used in the previous section.

To identify product categories that significantly contribute added sugars to diets, we relied on the 2010 DGA, as well as the Gladson and Mintel databases. This resulted in the product categories listed in Table 8. We estimate reformulation costs using both the FDA Labeling Cost Model and the FDA Reformulation Cost Model. The FDA Labeling Cost Model provides formula counts for each of the identified product categories, which are reported in Table 8. A total of 109,938 formulas were identified as significantly contributing added sugars to diets. The FDA Reformulation Cost Model provides per-formula estimates of reformulation costs. These were illustrated earlier in Table 7. Reformulation costs are computed by multiplying the per-formula reformulation costs by the formula counts.

Table 8. Formula Counts for Product Groups That Significantly Contribute Added Sugars to Diets

Product Subcategory	Total Formulas	5% Reformulated	6% Reformulated
Carbonated beverages	6,439	322	386
Fruit drinks	16,409	820	985
Flavored Milk	1,450	73	87
Isotonic Drinks (e.g., sports drinks)	594	30	36
Cereal - ready to eat	4,610	231	277
Condiments	3,627	181	218
Jams/jellies/spreads	5,918	296	355
Frozen novelties	5,685	284	341
Ice cream	12,561	628	754
Yogurt	6,682	334	401

Salad dressing – liquid	3,892	195	234
Sauce/gravy/glaze	7,622	381	457
Entrees – frozen	9,726	486	584
Baby food	1,449	72	87
Juices – baby	157	8	9
Grain based desserts	20,072	1,004	1,204
Pizza – frozen	3,045	152	183
Total	**109,938**	**5,497**	**6,598**
	Average:	**6,048**	

The proposed labeling changes for added sugars would likely have varying degrees of effectiveness[13] in providing an incentive for manufacturers to reformulate voluntarily. The required disclosure of added sugars on the Nutrition Facts label under the proposed rules is new, and so would require an entirely new line-item, providing a set of information that was not previously available.

We assume that 5 to 6 percent of products that significantly contribute added sugars to diets will be reformulated. Again, in lieu of reliable data to precisely predict the extent of such reformulation, we acknowledge that the actual rate of reformulation may be higher or lower than this range. Referring back to Table 8, an estimated range of 5 to 6 percent reformulation yields total formula counts of 5,497 to 6,598 and an average count of 6,048 ([5,497 + 6,598]/2) formulas. We use this average count to compute reformulation costs. We invite comments regarding this estimation approach.

As stated previously, reformulation costs depend on the mandated compliance period, with coordination costs decreasing as the compliance period increases. A built-in assumption of the FDA Reformulation Cost Model is that to the extent a manufacturer can coordinate a

[13] FDA acknowledges that the proposed requirement to embolden calorie content on package labels may have an impact. There are studies that suggest that increasing or emboldening the font size could lead to increases in attention of readers (Ref. 19). However, a study by Lando and Lo (2013) (Ref. 20) with FDA/CFSAN consumer studies concludes that enlarged font size for calories did not independently affect label usability. Without further study, it is unclear how large the impact of increasing prominence of calories on the label will be, hence we do not attribute costs or benefits to reformulation based on calorie emboldening alone.

required reformulation with a scheduled reformulation, reformulation costs will be smaller than they otherwise would be. Given a compliance period of 24 months, 20 percent of formulas can coordinate. Given compliance periods of 36 months and 48 months, respectively, 30 percent and 40 percent of formulas can coordinate. Under a 24 month compliance period, the total formula count reduces to 4,838 (6,048 - .2 × 6,048). Multiplying this formula count by the per-formula reformulation costs in Table 7 yields total reformulation costs (in 2011 USD) of between $56 million ($11,626 × 4,838) and $495 million ($102,365 × 4,838), with a mid-range estimate of $241 million ($49,716 × 4,838).

Cost of Reformulation of Foods Associated With Reduction in Vitamin B_{12} DV

Under the proposed rules, the DV for vitamin B_{12} is being reduced from 6.0 mcg to 2.4 mcg. This new DV may incent some manufacturers who currently fortify their products with vitamin B_{12} to reformulate their products to reduce B_{12} amounts, for two reasons. First, those manufacturers who currently fortify their products to 100 percent of the DV will be able to do so under the proposed rules for less cost by using 3.6 mcg per serving less of vitamin B_{12}. Second, those manufacturers who currently fortify their products to 100 percent of the DV, at 6.0 mcg per serving, will have a DV of 250 percent (= 6.0 mcg / 2.4 mcg) if they continue to fortify at 6.0 mcg per serving under the proposed rules. Some consumers may find this unappealing. Manufacturers of ready-to-eat breakfast cereals are those most likely to fortify their products with vitamin B_{12} (Ref. 21) and, thus, reformulate their products to reduce B_{12} amounts. However, because limited data are available to quantify B_{12} reformulation costs, we do not quantify the potential costs from B_{12} reformulation. Such costs would likely be small, though, as ready-to-eat breakfast cereals represent just 1 percent of all food products (Ref. 13). Considering that not all ready-to-eat breakfast cereals would necessarily choose or need to reformulate, the percentage of affected food products is likely much smaller than 1 percent. In addition, such

costs would be at least partially offset by the cost savings enjoyed by manufacturers mentioned above. Third, some vitamin B_{12} deficient individuals may not rely solely on fortified foods such as cereal to supplement their diet with vitamin B_{12}, but rather rely on dietary supplements in pill form. The majority of dietary supplements contain levels of vitamin B_{12} well in excess of 100 percent of the DV and, thus, are unlikely to be reformulated. However, we also recognize that ready-to-eat cereals are the third-ranked food source of vitamin B_{12} for US adults age 51 and older (Ref. 22). Ready-to eat cereals contribute 15% of the mean 5.1 mcg per day intake for vitamin B_{12}. This contributes about 0.75 mcg per day of crystalline vitamin B_{12}. The IOM recommends that adults age 51 and older obtain 100% of the RDA, which is 2.4 mcg per day, from crystalline vitamin B_{12} (Ref. 23). We invite comment on this issue.

Summary of Reformulation Costs

Table 9 presents a summary of estimated reformulation costs. We estimate total reformulation costs (in 2011 USD) of between $103 million and $905 million, with a mid-range estimate of $440 million. Table 9 also presents annualized reformulation costs, at 3 percent and 7 percent, over a 20 year period.

Table 9. Summary of Total Reformulation Costs (in millions of 2011 USD)

	Low	**Medium**	**High**
Claims	$47	$199	$410
Added Sugars	$56	$241	$495
Total	**$103**	**$440**	**$905**
Annualized at 3%	**$7**	**$29**	**$59**
Annualized at 7%	**$9**	**$39**	**$80**

Notes: Compliance period is 24 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

Summary of Total Cost of the Proposed Rules

Table 10 summarizes the relabeling and reformulation cost of the proposed rules and the total cost of the proposed rules, as well as the total cost of the proposed rules annualized over 20 years at both 3 percent and 7 percent.

Table 10. Summary of Total Cost of the Proposed Rules (in millions of 2011 USD)

	Low	Med	High
Present Value (3%)			
Relabeling	$1,073	$1,876	$3,083
Recordkeeping	$28	$28	$28
Reformulation	$103	$440	$905
Total	$1,204	$2,344	$4,016
Present Value (7%)			
Relabeling	$1,073	$1,876	$3,083
Recordkeeping	$27	$27	$27
Reformulation	$103	$440	$905
Total	$1,203	$2,343	$4,015
Annualized at 3%	$79	$153	$262
Annualized at 7%	$106	$207	$354

Notes: Compliance period is 24 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate.

b. Benefits

Organization

This section is organized by first describing the motivation and need for the proposed rules and discussing the potential effects of the rules. Next we describe the study by Abaluck (2011) (Ref. 16) that estimated the increase in consumer welfare from the Nutrition Labeling and Education Act of 1990. We describe how we extrapolate from and make adjustments to Abaluck (2011) and use his findings to estimate the benefits of the proposed rules. As discussed in the summary above, our primary estimate of the benefits of the proposed rules is based on Abaluck's

WTP welfare gain estimate. Following this, we consider other sources of benefits from the proposed rules. We conclude with a sensitivity analysis and discussion of sources of uncertainty in our analysis.

Background

A large body of scientific research has consistently confirmed the significant effect of diet on health, quality of life, and longevity (Refs. 24 - 25; Ref. 26). In the United States, high intakes of total energy (kilocalories), saturated fat, trans-fat, and sodium, and low intakes of fruits, vegetables, whole gains, and dairy products correlate with an increased risk of various chronic health conditions (such as CVD, obesity, diabetes, and osteoporosis) that can impair the quality of life and decrease longevity. Treating these health conditions comes at a considerable expense (Refs. 24 - 25; Ref. 26). Chronic diseases, such as heart disease, cancer and stroke are the leading causes of death and disability in the United States, and account for 70 percent of all deaths in the United States (Ref. 24). In 2005, 133 million Americans, almost one out of every two adults, had at least one chronic illness (Ref. 24). An estimated 37 percent of Americans suffer from CVD (Ref. 25), 11 percent of individuals 20 years and older have diabetes, 35 percent of adults have pre-diabetes (Ref. 27), and an estimated 41 percent of the population will receive a diagnosis of cancer during their lifetime (Ref. 28). While the causes of these chronic diseases are multifactorial, having a poor diet contributes to excess morbidity and mortality (Ref. 29) and numerous nutrients affect chronic disease risk.

Although many sources of nutrition information currently exist, nutrition labeling gives consumers a combination of information and reminders that accompany foods at the points of purchase and consumption. For that reason, nutrition information represents an important tool for providing information to assist with dietary choices. The proposed rules would: (1) better align

the information provided in the Nutrition Facts label with new data on consumption, dietary recommendations, and scientific evidence on the relationship between nutrition and chronic diseases; (2) improve the design and content of the Nutrition Facts label such that relevant information is more salient and easy to understand for the purpose of informing consumption decisions; and (3) potentially prompt industry to reformulate products to maintain health claims and nutrient content claims, and reformulate products that may appear less attractive to consumers under the provisions of the proposed rules.

In addition to alerting consumers to calorie and nutrient content, major predicted elements of the consumer and industry response to the nutrition labeling proposed rules include:

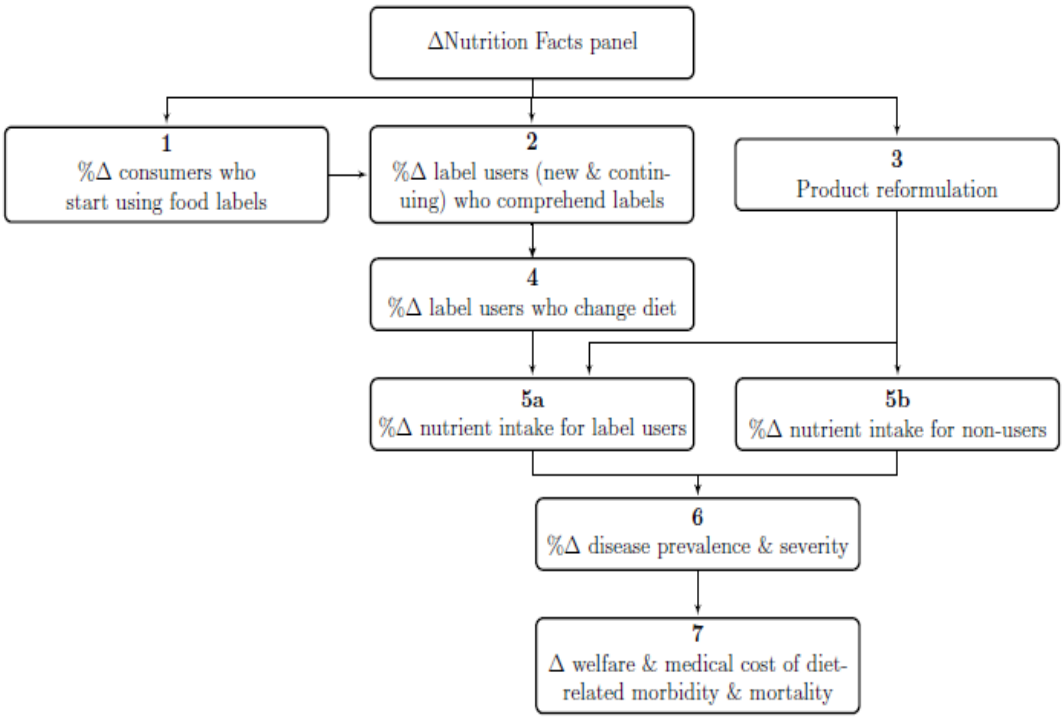
- Increased knowledge by consumers of the nutrient content of packaged foods, which may help them make healthier food choices;
- Increased ease of nutrition label use from the decreased need to do arithmetic for products that bear DCLs;
- Greater transparency in the nutrient content of existing packaged foods, which may give firms an incentive to provide additional items with healthier formulations; and
- Potential reformulation of products to reduce sodium and added sugars or increase other vitamins and minerals.

These responses could potentially reduce consumption of food products that do not contribute to a healthful diet. Note that consumers may offset any reduction in their consumption of unhealthy items with consumption of unlabeled or unhealthy meals or snacks. Consumers substitute between nutrient sources when attempting to modify their food choices (Ref. 30). Because we lack any data or information on how consumers would substitute between

foods in response to the labeling changes, the benefit estimates in this analysis may over- or understate the effects realized if we finalize the nutrition labeling proposals as proposed.

Nutrition labeling provides consumers with information they can use to compare products and build a healthy diet that conforms to federal dietary recommendations, their nutritional preferences, or both. The costs of consuming a poor diet include the value of the quality of life lost to illness and other sources of disutility, such as taking medications every day, as well as the value of years-of-life-lost (YLL) from premature death. The costs of consuming a poor diet also include the net lifetime cost of treating the diseases caused or exacerbated by poor diet. As illustrated in Figure 1, we expect that the proposed changes to nutrition labeling would lead to changes in the prevalence and intensity of label use, as well as some product reformulation, which would result in changes in nutrient intake. The benefits of the proposed rule would come from consumer welfare gains primarily due to increases in health and longevity generated by improvements in overall diet.

Figure 1. Links Between Nutrition Labeling, Health Outcomes, and Value of Health Improvements



Welfare Estimates: Nutrition Labeling

Using the parameters and assumptions discussed in the following sections, FDA estimates the welfare gain (benefit) from the proposed changes in the information content of the Nutrition Facts label, B_t^{Label}, using the formula

$$B_t^{Label} = POP_t \times s_1 \times \Delta W^{Label} \times USE \times (1 - USDA), \quad (1)$$

where s_1 represents the ratio of the welfare gain attributable to the proposed rules to the welfare gain attributable to the NLEA, ΔW^{Label} equals the change in consumer welfare from the NLEA, *USE* represents the ratio of estimated use of the Nutrition Facts label under the proposed rules to estimated use of the Nutrition Facts label under NLEA, *USDA* is the percent of labeled food regulated by the USDA Food Safety Inspection Service (FSIS), and POP_t is the (adult or child and adolescent) population of the United States in period *t*.

Equation (1) captures the welfare gain from consumers using the information that is provided to them by the updated Nutrition Facts label. The larger s_1, the larger the welfare gains associated with the proposed rules. Equation (1) serves as the basis for FDA's primary estimate of the benefits stemming from the proposed rules.

Changes in Consumer Welfare from NLEA ("ΔW^{Label}")

To obtain estimates of the effect of the proposed rules on consumer welfare, we extrapolate from the welfare effects estimated in a retrospective study on the impact brought about by NLEA. Using data on women of 19 to 50 years of age on the prevalence of package labels, label use, and food intake from the FDA Food Labeling and Package Survey (FLAPS), the Diet and Health Knowledge Survey (DHKS), and the Continuing Survey of Food Intake by Individuals (CSFII), Abaluck (2011) identified the change in nutrient intake attributable to differential changes brought about by NLEA in nutritional information content across foods.[14] Abaluck (2011) based his estimates on a structural model of food demand that accounts for substitution effects in food consumption, differences in demand elasticities across products, and heterogeneity in the use and knowledge of nutrition information.

[14] Abaluck (2011) uses the estimated percent of annual sales of packaged foods that labeled foods represent from the report "Status of Nutrition Labeling of Processed Foods: 1995" by O'Brien (1995) (Ref. 31), who used the FLAPS survey for various years. The FLAPS survey is created using a multistage sampling plan to select a representative sample of food products from the retail packaged food supply. The FLAPS data provide comprehensive labeling information for food products in the United States. Despite the fact that the FLAPS data set was created using a sampling scheme biased towards the highest selling products within a product category, thus creating a not completely random sample of products in the marketplace, this data set is the most robust, nationally representative data set to measure the increase in labeling over the time period prior to and directly following the implementation of NLEA. However, due to the collection methods of FLAPS, the estimated change in the prevalence of labeling due to NLEA may be over- or understated. Further information about FLAPS can be found in Brecher et al. (2000) (Ref. 32) and Ferguson (2013) (Ref. 33).

Abaluck (2011) measured the consumer welfare gains as the willingness to pay for nutrient content based on revealed preference data, i.e., food consumption and prices. This hinges on the idea that when labeling reveals the true marginal cost of consumption, an individual responds to that information by internalizing the health costs as if they have experienced a change in the price of that good. Then one can compare the change in nutrient intake based on changes attributable to NLEA to the equivalent price change that would have to occur to produce the same response given that preferences and tastes also influence the demand for food. One can then use the difference in the perceived price of consumption before and after receipt of the information to value the measured change in nutrient intake. We refer to these estimates as the willingness-to-pay (WTP) estimates. In Table 11, we summarize these estimates and convert them to current (2011) dollars. Abaluck (2011) found that NLEA led to an average increase in consumer welfare of $58 (in 2011 dollars) per year per label user.

Table 11. Annual welfare gains per person based on Abaluck (2011)

		Annual welfare gain per person					
		1990			2011		
NLEA		Model 1	Model 2		Model 1	Model 2	Mean
WTP		$41	$33		$64	$52	$58

Notes: We use the Gross Domestic Product (GDP) deflator from the U.S. Bureau of Economic Analysis to scale the benefits to 2011$. These estimates can be found in Table 11 of Abaluck (2011). Models 1 and 2 are different specifications of Abaluck's model of willingness-to-pay for nutrient content. Model 1 estimates the willingness-to-pay for calories, sodium, and cholesterol and Model 2 disaggregates calories into protein, non-fiber carbohydrate (e.g., sugars), dietary fiber, and total fat. The annual welfare gains per person presented here are the same for children and adults.

Calibrating Welfare Effects of NLEA to Welfare Effects of the Proposed Rules

The estimates generated by Abaluck (2011) represent welfare gains and thus are the appropriate form for estimated benefits of the proposed rules (i.e., the mean WTP estimates of welfare gains from NLEA, $58). However, we must calibrate the estimates to the expected

effects of the proposed rules. For example, the proposed changes to the Nutrition Facts label would increase the available nutrition information on food labels, but by an amount much smaller than the changes brought about by NLEA.

We can use the estimated welfare gains from NLEA found in Table 11 as the basis of the benefits from the proposed rules. The WTP estimates tie directly to revealed preference data and represent a plausible lower bound for the welfare gains from NLEA. We adjust the welfare gain estimates for the considerations outlined below. If we assume that these factors imply a zero net effect then we could directly apply the estimated welfare gains to the proposed rules.

Effect of Proposed Rules Relative to the 1993 Rules that Implemented NLEA ("s_1")

We cannot use the estimated welfare gains associated with NLEA in Abaluck (2011) for the estimation of the benefits of the nutrition labeling proposed rules *directly* because the NLEA estimate would overstate the incremental effects of the nutrition labeling proposed rules. First, the estimated welfare gains associated with NLEA in Abaluck (2011) do not take into account label use since the implementation of NLEA. Also, whereas the 1993 rules that implemented NLEA added nutrition labels to previously unlabeled products, the nutrition labeling proposed rules involve only modifications to the existing label. That is, the estimated welfare gain from Abaluck (2011) represents a 100 percent increase in label content and the proposed rules represent something less than that.

The proposed rules represent a significant modification of the existing Nutrition Facts label. Significant proposed changes to the Nutrition Facts label include:

- Increasing the prominence of calories and the serving size information
- Reversing the order of the "Serving Size" declaration and the "Servings Per Container" declaration
- Right-justifying the quantitative amounts of the serving size information

- Changing the "Amount Per Serving" declaration to "Amount Per ___" with the blank filled in with the serving size provided in common household measures, e.g. "Amount per 2/3 cup"
- Removing the declaration of "Calories from fat"
- Changing the nutrient declarations and %DV declarations on some products for some nutrients
- Declaring "Added Sugars" as an indented listing directly beneath the listing for "Sugars"
- Changing the units of measure for some nutrients
- Declaring the quantitative amounts (in addition to percent DVs) of mandatory and, when declared, voluntary vitamins and minerals
- Modifying the footnote
- Requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular type
- Modifying the presentation of the "% DV" information by changing its position on the label and separating it from the list of nutrients with a vertical line
- Adding a horizontal line directly beneath the "Nutrition Facts" heading
- Changing some of the RACCs
- Changing the criteria for single-serving packages
- Adding requirements for DCL

Increasing the prominence of calories may benefit consumers in weight control and maintenance, as noted by the FDA's Obesity Work Group in its final report entitled "Calories Count" (Ref. 34) and research on food labels with two servings per container that found that labeling changes that highlighted the number of servings per container (via text or a dual column) served as cues to consumers that the product contained more than one serving and helped them more accurately determine the number of calories per container (Ref. 20). Reversing the order of the declarations of "Servings Per Container" and "Serving Size" would help consumers more readily observe and comprehend the nutrition information appearing in the Nutrition Facts label, allow consumers to search for information with a minimum of effort, and assist consumers in their food purchasing decisions and in maintaining healthy dietary practices. Keeping the proposed "Serving size" declaration left-justified while right-justifying the corresponding numerical values would create white space on the Nutrition Facts label that would

result in a less cluttered appearance, heightened focus and emphasis, and improved readability (Ref. 35). This design feature would provide enhanced emphasis of the information about serving size, allowing this information to be more noticeable and thereby facilitating its access and use by consumers. Studies suggest that consumers are often confused by serving size information as it is currently presented on the Nutrition Facts label (Refs. 36 - 37). Therefore, specifying the actual serving size in the listing of "Amount per " declaration would be expected to help consumers more readily observe and comprehend the nutrition information appearing in the label. Consumer research (Ref. 20), which evaluated a label format that did not contain the "Calories from fat" statement, found that the lack of this information had no effect on consumers' judgments of product healthfulness, accuracy in identifying nutrient contents of products, or perceptions of the label.

DVs are intended to help consumers to understand nutrient levels in the context of the total daily diet, to compare foods, and to plan general diets and are being proposed to be revised by FDA so as to reflect the most current science. Nutrient declaration revisions are being proposed to assist consumers in maintaining healthy dietary practices. FDA is proposing to add the declarations of added sugars, potassium, and Vitamin D and no longer require the declarations of Vitamin A and Vitamin C. Both the American Heart Association and American Academy of Pediatrics recommendations point out that added sugars intake is associated with a greater intake of calories and a lower intake of essential nutrients, whereas the 1990 World Health Organization recommendation for decreasing added sugars is based on dental caries and that excessive consumption of these sugars can displace nutrient-containing foods in the diet (Refs. 38 - 40).

Regarding changes in units of measure, requiring mg instead of g for sodium, potassium, copper, and chloride could be beneficial because it better facilitates comparisons of amounts - amounts, say, declared as 0.2g and 0.5g may not seem as significantly different as 200 mg and 500 mg – and consumers may be already familiar with the units used on the label. For folate, versus the proposed unit of measure, mcg DFE, or micrograms dietary folate equivalents, the current unit of measure, mcg, does not take into account the difference in the bioavailability of folate and folic acid. In addition, the mcg DFE declaration would provide a more accurate representation of the amount of folate in foods that contain both naturally occurring folate and added folic acid. For vitamins A, D, and E, IUs, or international units, are being proposed to be replaced with units that are consistent with the DRIs, or dietary reference intakes, because DRIs form the basis for the proposed RDIs, or reference daily intakes, for these vitamins.

In a report on labeling and fortification, the Institute of Medicine recommended listing both absolute amounts (e.g., mg/serving) and percent DVs to assist consumers who have difficulty understanding how to interpret the percent DV declaration (Ref. 41). This report also stated that the absolute amounts declaration for all micronutrients would maintain consistency in how nutrients are declared on the Nutrition Facts label. Regarding the Nutrition Facts label footnote, FDA is proposing to modify the footnote and is planning to propose a new footnote statement containing informational text to help consumers interpret the meaning of the percent DV and use the DVs. Regarding requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular type, based on design considerations of highlighting information in Bold type (Ref. 42), this would help differentiate the name of the nutrient from its absolute amount and sets nutrients apart from other information that appears in the Nutrition Facts label.

Based on the graphic design principles of primacy (which asserts that initial items in a list are stored more efficiently in memory than items listed later), proximity (which asserts that elements positioned close together are perceived as a single group), the importance of white space (which, among other things, is used by designers to isolate an element that demands attention) (Refs. 35 and 42), and chunking (a technique for combining multiple units of information into a limited number of units or chunks so that the information is easier to process and remember) (Ref. 42), proposing to position the %DV to the left of the label and to add a vertical hairline to the right of the %DV column should increase consumers' focus on the %DV. The addition of a hairline rule immediately below the Nutrition Facts heading would direct the reader's eye to the serving size information, further emphasizes the information about servings, and helps break the information into small chunks, thus making it easier to process and remember the information (Ref. 42).

FDA established RACCs, or Reference Amounts Customarily Consumed, in 1993 based in part on data from Nationwide Food Consumption Surveys (1977-1978 and 1987-1988) conducted by the U.S. Department of Agriculture. However, over the last decade, there has been general recognition that consumption patterns have changed. RACC changes proposed by FDA are based primarily on recent food consumption data from the 2003 – 2008 National Health and Nutrition Examination Surveys (NHANES). A recent study comparing three types of labels – listing two servings per container with a single column ("two-serving single-column labels"), listing two servings per container with a dual-column that lists the nutrients in both "per serving" and "per container" columns ("dual-column labels"), and declaring the entire package as one serving and listing all of the nutrients as a single serving ("single serving per container labels") – found that single serving per container labels and dual-column labels resulted in more

participants correctly identifying the number of calories per container and the amount of other nutrients per container and per serving compared to two-serving single-column labels (such as the current label) (Ref. 20). In addition, participants in the study reported more positive attitudes toward single-serving and dual-column labels in comparison to two-serving single-column formats (Ref. 20).

The 1993 rules that implemented NLEA represented a 100 percent change in label content. The proposed rules would change approximately 33 percent of the label content on products with a single-column label (SCL), which represent approximately 88 percent of UPCs (Ref. 13), and approximately 25 percent of the label content for products with DCL formats, which represent roughly 29 percent of UPCs (Ref. 13).[15] We assume that the change in label content associated with SCL products is uniformly distributed between 15 percent and 50 percent, with a mean of 33 percent (= [15 +50] / 2). The DCL format, which adds a second column of information to the Nutrition Facts label, comprises approximately one-half of the label. Thus, the DCL format can be viewed as a 50 percent change in label content. Therefore, we assume that the change in label content associated with DCL products is a maximum of 50 percent, and is uniformly distributed between 0 percent and 50 percent, with a mean of 25 percent (= [0 + 50] / 2)..

The estimated welfare gains associated with NLEA in Abaluck (2011) do not take into account label use. Thus, we assume that the welfare effects of the proposed rules relative to the 1993 rules that implemented NLEA are proportional to the use of the Nutrition Facts label following NLEA, but scaled down to reflect the fact that the proposed rules involve only modifications to the existing label, versus NLEA which added nutrition labels to previously

[15] In computing the percentage of UPCs with SCL and DCL formats, we excluded dietary supplements, as we believe that the benefits from the proposed rules are overwhelmingly attributable to changes in the consumption of conventional food. We invite comment on this.

unlabeled products. Results from the DHKS indicate that 65 percent of respondents reported using the Nutrition Facts label at least "Sometimes" following the introduction of NLEA.

The information presented above suggests that for SCL products, the mean effect of the proposed rules is 33 percent (= 33 / 100) of the effect of NLEA and for DCL products, the mean effect of the proposed rules is 25 percent (= 25 / 100) of the effect of NLEA. Weighting these amounts by label use following the introduction of NLEA, as well as by the share of total UPCs that SCL and DCL products represent, produces a mean effect of the proposed rules of 23.6 percent (= [0.65 × 0.33 × 0.88] + [0.65 × 0.25 × 0.29]) of the estimated welfare gains associated with NLEA in Abaluck (2011).

Given the evidence presented above, we will scale the estimated welfare gain associated with NLEA in Abaluck (2011) by a range of values (denoted s_1) to both account for label use and to capture the fact that the proposed rules represent something less than a 100 percent increase in the labeling of packaged food. We will use a uniform distribution with a minimum of 0, an expected maximum of 0.236, and a mean of 0.118 (= [0 + 0.236] / 2) for s_1, which implies that the effect of the proposed rules lies between 0 and 23.6 percent of the estimated welfare gains associated with NLEA in Abaluck (2011). Our choice of zero as a lower bound is intended to reflect the uncertainty surrounding the impact of the proposed rules relative to NLEA. However, we do not expect that this rule will have zero impact on consumer behavior. In fact, Abaluck (2011) demonstrates that new or improved information on the label of food products can result in a substantial change to consumer behavior. We use zero as an absolute minimum to capture the entire range of uncertainty inherent in this estimate, to allow for the possibility of even a very small effect.

Increased Prevalence of Food Label Use ("USE")

Label use has increased over time from 65 percent just after the introduction of NLEA. For example, from the data in the 2009-2010 National Health and Nutrition Examination Survey (NHANES 2009-2010), FDA estimates that 77 percent of respondents used the Nutrition Facts label at least "Sometimes." In addition, there is evidence to suggest that a change in labeling regulations (and the educational messages that accompany it) vis-à-vis the proposed rules will increase both label use and the share of label users who change their intake based on the nutrition information from labels. For example, for the analysis of the proposed rules, the DCL and updated RACC and serving size criteria may increase label use (Ref. 16). Along these lines, Antonuk and Block (2006) found a 13.9 percent increase in attention to the label when switching from a SCL to DCL format (Ref. 30). We estimate that under the proposed rules approximately 28 percent of universal product codes (UPCs) would switch to the DCL format (Ref. 13). Thus, if 28 percent of products switch to a DCL format and the DCL format increases label use by 13.9 percent, then FDA expects at least a 4 percent (= 0.28 × 0.139) increase in overall label use as a result of the proposed rules.

As stated earlier, we estimate that 77 percent of respondents in the NHANES 2009-2010 used the Nutrition Facts label. Following the implementation of the proposed rules, then, we estimate that the prevalence of label use would equal 80 percent (= 1.04 × 0.77). Thus, the ratio of use of the Nutrition Facts label under the proposed rules to the use of the Nutrition Facts label under NLEA is 1.23 (= 0.80 / 0.65). Therefore, in the model, USE = 1.23.

USDA Regulated Food Labels ("USDA")

The estimated welfare effects of NLEA from Abaluck (2011) may also capture the effect of labeling regulations simultaneously issued by USDA. The USDA FSIS regulates the labeling of certain meat, certain poultry, and certain egg products (Guide to Federal Food Labeling Requirements for Meat and Poultry Products). The USDA labeling regulations for packaged foods mirror the FDA regulations almost exactly. Using Table 2-2 (p. 12) of the 2010 DGA, we estimate that approximately 353 of the 2,157 calories (16.4 percent) an average American consumes daily come from foods regulated by the USDA. These products include chicken and chicken mixed dishes, beef and beef mixed dishes, burgers, sausage, franks, bacon, ribs, certain egg products and egg mixed dishes, and cold cuts. Therefore, to accommodate for the possibility that the welfare estimates capture the benefits of labeling on USDA regulated products, we scaled the benefits from nutrition labeling to reflect the fact that between zero and 32.8 percent of daily calories come from products that would not be affected by the proposed rules. That is, USDA = U(0, 0.328), with a mean of 0.164 (= [0 + 0.328] / 2), or (1 – USDA) = U(0.672, 1), with a mean of 0.836 (= [0.672 + 1] / 2).

Stream of Benefits ("B_t")

The WTP estimates implicitly capture and reflect the fact that individuals discount the benefits stemming from the effects of their current diet on their future health status. In other words, the full measured benefits of the proposed rules are summarized in a value (WTP) that is simultaneous with the timing when manufacturers comply with the proposed rules. We adjust the annual stream of benefits from the proposed rules for the projected growth in the total

population in the United States from 2013 to 2032[16] from the U.S. Census Bureau International Data Base.[17]

Compliance Time ("c_t")

The welfare gains from the proposed rules estimated above reflect the full annual impact of the regulations. However, industry would need time to comply with the regulations and reformulate products. Thus, it would take several years after the publication date of the final version of the proposed rules, depending on the compliance date, for consumers to realize the full annual welfare gains. A compliance date further in the future would slightly delay consumers in reaching the maximum annual welfare gains, but because the benefits continue to accrue for the rest of the lifespan, the present value (PV) of total lifetime welfare gains roughly equates in the long run. However, over the next 20 years, changing the compliance time may change the PV of the stream of benefits from the proposed rules.

We assume that the percentage of UPCs in compliance at time t, denoted c_t, equals 100 percent if time t falls on or after the compliance date or equals the percentage of UPCs which can coordinate a scheduled label change with a required label change (Ref. 13) if time t falls before the compliance date. Table 12 illustrates the relationship between the compliance period and the percentage of UPCs which are able to coordinate a scheduled label change with a required label change. Using this information and assuming a two year compliance period, $c_t = 0$ in 2013, the first year of the proposed rules, $c_t = 0.08$ in 2014, the second year of the proposed rules, and $c_t = 1$ in 2015 through 2032, the third year of the proposed rules through the twentieth year. Assuming a three year compliance period, $c_t = 0$ in 2013, $c_t = 0.08$ in 2014, $c_t = 0.65$ in 2015, and

[16] Impacts that are labeled as occurring in 2013 – 2032 actually occur in the first twenty years after the proposed rules are finalized and, thus, might be slightly underestimated due to population growth since 2013.
[17] Available at: http://www.census.gov/population/international/data/idb/informationGateway.php.

c_t = 1 in 2016 through 2032. Assuming a four year compliance period, c_t = 0 in 2013, c_t = 0.08 in 2014, c_t = 0.65 in 2015, c_t = 0.78 in 2016, and c_t = 1 in 2017 through 2032.

Table 12 – Percentage of UPCs Able to Coordinate a Scheduled Label Change with a Required Label Change by Compliance Period

Compliance Period	% Who Can Coordinate
0 Months	0%
12 Months	8%
24 Months	65%
36 Months	78%
48 Months	97%

The following equation gives the formula for the PV of this stream of benefits, *B*, discounted at a rate of *r* percent per year with, again, the percent of UPCs in compliance at time *t* equal to c_t.[18]

$$PV(B) = \sum c_t [B_t / (1 + r)^t] \quad (2)$$

Benefits Estimates

Using the @Risk software (Ref. 43), we carried out a simulation with 10,000 iterations to estimate the PV of the benefits from the proposed nutrition labeling rules over the next 20 years. Each iteration of the simulation randomly draws a value for s_1[19] and (1 – USDA), which each have a uniform distribution with their respective minima and maxima, and calculates the PV of

[18] FDA takes t = 1 to be the first year of the rule, t = 2 to be the second year of the rule, and so on.
[19] Each iteration of the simulation also randomly draws a value for the change in label content associated with SCL and DCL products, each of which are components of the s_1 calculation and are assumed to have a uniform distribution with their respective minima and maxima.

the stream of benefits over the next 20 years using Equations (1) and (2). Table 13 displays the results of this simulation assuming a 2 year compliance period.

Table 13. Estimated Present Value of Benefits from Proposed Nutrition Labeling Rules 2013-2032 (in billions of 2011 dollars)

				90% Confidence Interval	
Benefits:	Discount Rate	Mean		Lower Bound	Upper Bound
WTP[a]					
	3%	$31.4		$2.8	$69.9
	7%	$21.1		$1.9	$47.1

Notes: Compliance period = 24 months. Estimates reflect total U.S. population (children and adults).
[a] Based on Abaluck (2011) willingness-to-pay or revealed preference estimates.

Depending on the values the parameters s_1 and (1 – USDA) take, and based on the WTP welfare gain estimate and other modeling assumptions, the present value of the stream of benefits from the changes in food labeling attributable to the nutrition labeling proposed rules for the total US population over the next 20 years ranges (90 percent CI) from $1.9 to $47.1 billion, with a mean estimate of $21.1 billion at a 7 percent discount rate.

Other Sources of Benefits

Re-Evaluated Benefits Estimates

Estimates of WTP based on revealed preference data may underestimate the full welfare gain from improved diets because revealed preference captures only the misinformation and time-inconsistent preferences that consumers themselves *recognize*. The WTP for better nutrition reflects only the nutrition effects that consumers can internalize, and may not fully reflect their underlying preferences because of time-inconsistent behavior, problems with self-control,

addiction, or poor information.[20] However, by reducing the intake of certain nutrients, consumers realize these existing, but uninternalized benefits nonetheless. These additional nutrition related improvements in health are proportional to the level of market failure generated by consumer internalities and can be thought of as estimates of the full welfare gain (internalized and uninternalized), i.e., the amount (in dollars) that consumers value the new information. (Such value is, presumably, mostly due to improvements in the consumers' health and longevity, including avoided medical costs, and net of any offsetting effects, such as lost utility due to eating less palatable foods.) Abaluck (2011) re-evaluates the welfare effects of NLEA based on the relationship between changes in nutrient intake and health and longevity and a benchmark value of statistical life (VSL) to capture these additional gains. We will refer to these estimates, which are summarized in Table 14, as the Re-Evaluated estimates.

Table 14. Annual welfare gains per person based on Abaluck (2011)

		Annual welfare gain per person					
		1990			2011		
NLEA		Model 1	Model 2		Model 1	Model 2	Mean
Re-Evaluated		$159	$172		$250	$270	$260

Notes: We use the GDP deflator from the U.S. Bureau of Economic Analysis to scale the benefits to 2011$. These estimates can be found in Table 11 of Abaluck (2011). Models 1 and 2 are different specifications of Abaluck's model of willingness-to-pay for nutrient content. Model 1 estimates the willingness-to-pay for calories, sodium, and cholesterol and Model 2 disaggregates calories into protein, non-fiber carbohydrate (e.g., sugars), dietary fiber, and total fat.

In addition to scaling the welfare effects as described in the previous section, we make several initial adjustments to the Re-Evaluated estimates, which depend on the choice of a value of a statistical life year (VSLY) and discount rate, to conform to the parameters typically used by FDA in regulatory impact analyses. We also extrapolate from the welfare gains estimated for the adult population to estimate welfare gains for children. Table 15 displays the estimated annual

[20] See footnote 2.

Re-Evaluated welfare gains after scaling for the FDA preferred parameters, which allows us to estimate benefits using a primary VSLY of $219,626 (in 2011 dollars) and discount rates of 3 percent and 7 percent. Appendix A contains the details of the methodology used to scale these gains.

Table 15. Annual welfare gains per person scaled for preferred FDA parameters (in 2011 $)

			Adults			Children	
			3%	7%		3%	7%
NLEA – Re-Evaluated Welfare Gains			$217	$53		$336	$23

Notes: Scaled for FDA preferred VSLY, income growth, and discount rates.

Table 16 contains our estimate of the welfare gains of the proposed rules based on the Re-Evaluated estimates. Using an identical methodology to that which was used in the previous section, FDA estimates that the present value of the Re-Evaluated benefits from the proposed nutrition labeling rules ranges (90 percent CI) from $1.5 to $38.1 billion, with a mean estimate of $17.1 billion, at a 7 percent discount rate.[21]

Table 16. Estimated Present Value of Re-Evaluated Benefits from Proposed Nutrition Labeling Rules 2013–2032 (billions 2011$)

		90% Confidence Interval	
Benefits:	Mean	Lower bound	Upper bound
Re-Evaluated [a]			
Discount Rate = 3%	$129.9	$11.7	$288.8
Discount Rate = 7%	$17.1	$1.5	$38.1

Notes:
Compliance period = 24 months. Estimates reflect total U.S. population (children and adults).
[a] Based on Abaluck (2011) "re-evaluated" estimates. Represents the full (internalized and uninternalized) welfare gain.

Reformulation

[21] At a 3 percent discount rate, the Re-Evaluated benefits are higher than the WTP benefits, while at a 7 percent discount rate, the Re-Evaluated benefits are lower than the WTP benefits. This is because the 3 percent (7 percent) scaled Re-Evaluated per person per year welfare gains presented in Table 15, upon which the Re-Evaluated benefits are based, are larger (smaller) than the WTP welfare gains per person per year in Table 11, upon which the WTP benefits are based. This is in turn due to the effect of the VSLY adjustment used to scale the re-evaluated NLEA estimates generated by Abaluck (2011) to reflect the FDA preferred VSLY and discount rates. Details of the VSLY adjustment are provided in Appendix A.

We expect consumers to benefit from the provisions of the proposed rules if manufacturers reduce the amount of added sugars in their products in response to the proposed rules. Manufacturers may reformulate to reduce the amounts of added sugars because, if finalized, the proposed rules would require manufacturers to list added sugars on the Nutrition Facts label. For example, Walmart has pledged to decrease the added sugars content of foods sold at Walmart by 10 percent by 2015 (Ref. 44). Also, between 2005 and 2011, cereal manufacturers reduced added sugars by 7.6 percent (Ref. 45). Literature suggests that reduced consumption of sugar-sweetened beverages that contain added sugars is associated with decreases in body weight, blood pressure, measures of inflammation, increases in HDL cholesterol, and a decreased risk of developing metabolic syndrome, Type II diabetes, coronary heart disease (CHD), and stroke (Refs. 46 - 52). However, limited data are available to quantify the effect of reformulation to reduce added sugars on measures of health. Thus, we do not quantify the potential benefits from reformulation to reduce added sugars.

Under the proposed rule, the DV for vitamin B_{12} is being reduced from 6.0 mcg to 2.4 mcg. This new DV may incent manufacturers who currently fortify their products with vitamin B_{12} to reformulate to reduce B_{12} amounts. The risk of developing a vitamin B_{12} deficiency increases with age, with the elderly more likely to develop a vitamin B_{12} deficiency because they are at risk for both malabsorption and malnutrition (Ref. 53). Because vitamin B_{12} deficiency may contribute to certain health problems (Refs. 53 - 54), reformulation to reduce the amount of vitamin B_{12} per serving may potentially have a negative health impact on a small portion of the elderly population. However, there is limited data to quantify the effect of vitamin B_{12} reformulation on health outcomes. Thus, we do not quantify the potential negative effect on benefits from vitamin B_{12} reformulation. Such an effect on benefits would likely be very small,

though, for several reasons. First, only approximately 3.2 percent of persons aged 51 years or older currently has a vitamin B_{12} deficiency (Ref. 53), which translates into an even lower percentage of the United States population as a whole. Second, manufacturers of ready-to-eat breakfast cereals are those most likely to fortify their products with vitamin B_{12} (Ref. 21) and, thus, those most likely to reformulate their products to reduce B_{12} amounts. However, ready-to-eat breakfast cereals represent just a tiny fraction of all food products – roughly 1 percent (Ref. 13). Considering that not all manufacturers of ready-to-eat breakfast cereals would necessarily choose or need to reformulate, the percentage of affected food products is likely much smaller than 1 percent. Third, it is unlikely that vitamin B_{12} deficient individuals rely solely on fortified foods such as cereal to supplement their diet with vitamin B_{12}, but rather rely on dietary supplements in pill form, the majority of which contain levels of vitamin B_{12} well in excess of 100 percent of the DV and, thus, are unlikely themselves to reformulate. We invite comment on this issue.

Finally, manufacturers may also reformulate in response to certain RACC changes, certain DV changes, and changes in the definition of dietary fiber so that they can continue to make certain nutrient content claims or health claims authorized under the FD&C Act. Such reformulations may generate benefits to society. For example, the proposed rules would double the RACC for ice cream, from ½ cup to 1 cup. Ice cream products that currently make a low fat claim must contain 3 g or less of total fat per RACC (½ cup). Thus, products which currently contain, say, 3 g of fat per ½ cup contain, proportionally, 6 g of fat per 1 cup, requiring such producers to lower the amount of total fat in their ice cream by at least 3 g per cup in order to continue to make a low fat claim under the proposed rules. Reductions in fat, especially saturated fat, are associated with a reduced risk of cardiovascular disease (Ref. 55). In addition,

under the proposed rule, only dietary fibers which have physiological effects that are beneficial to human health may be declared on the Nutrition Facts label. Thus, under the proposed rules, manufacturers of products which both contain dietary fibers that have not been shown to have beneficial physiological effects, and which make fiber-related health or nutrient content claims that they wish to keep making, will need to reformulate their products so as to contain amounts of dietary fiber that have been shown to have beneficial physiological effects (the actual amount of such dietary fiber called for depends on the claim in question). Limited data, however, are available to quantify the effects of such reformulations on measures of health. Thus, we do not quantify the potential benefits from such reformulations.

Benefits of Reduced Morbidity

Changes in label use and nutrient intake could reduce the risk of morbidity and prolong life by reducing the incidence and severity of chronic diseases associated with consuming a poor diet. Unlike the WTP estimates, the "re-evaluated" welfare gain estimates only reflect the benefits from the reduction in the risk of early mortality, rather than any reduction in morbidity. However, as one recent report illustrates, obesity prevention programs that reduce morbidity generate substantial long-run savings, especially for children (Ref. 56).[22]

Research has demonstrated links between diet and excess body weight (overweight and obesity), CVD (which includes CHD, heart attack, stroke and high blood pressure), type 2 diabetes (or non-insulin dependent diabetes mellitus), some cancers, cognitive decline,

[22] The Study by Brill (2013) uses a 75 year (long-run) time horizon to evaluate the return to federal obesity prevention programs. The greatest returns to prevention come from preventing obesity in children, who realize the benefits of prevention as adults through higher wages and reduced morbidity, mortality, and medical expenditures. One drawback to the study, however, is that it doesn't consider potential offsetting utility impacts, such as those due to consumers eating less palatable foods.

osteoporosis, and dental disease (Ref. 26; Ref. 40; Refs. 57 - 58). Each of these diseases may cause some degree of disability, impairment, discomfort, and anxiety among sufferers, and may also involve a significant amount of time for daily treatment or management. We could quantify and value these costs using an estimate of the quality adjusted life years (QALYs) lost to a particular disease and a VSLY if we could predict the number of cases of each diet-related disease the proposed rule would prevent. For example, on a scale from 0 (death) to 1 (perfect health), individuals with diabetes lose 0.11 QALY per year, for a 12.6 percent reduction in QALY relative to the average individual who has 0.87 QALYs (Ref. 59), which equates to a loss of $24,119 (= $219,262 × [0.11]) per diabetic per year, using a VSLY of $219,262. Thus, for example, if the proposed labeling rules prevented 10,000 new cases of type 2 diabetes per year (i.e., reduced the incidence of diabetes), then the proposed rules would generate an additional $241.2 million (= 10,000 × $24,119) in benefits the first year, $482.4 million (= $241.2 + $241.2) in benefits the second year, and so on (pre-discounting).

Decreases in the prevalence and severity of diet-related morbidities such as diabetes and CVD will improve the quality of life of individuals who use food labels to choose healthier food products and construct a better diet; one potential aspect of improved quality of life is an increase in productivity. For instance, a recent study estimates that preventing obesity in women would increase annual wages by $2,192 (2012$) per person per year in the long-run (Ref. 56). Thus, to the extent that we have not quantified the value of the expected increases in quality of life from the proposed rules through reductions in morbidity, we could use productivity estimates to assess these benefits (though we note that the resulting estimates would be conservative relative to the results produced by the preferred VSLY approach described in the preceding paragraph).

Medical Costs

We have not fully quantified the effects of the proposed rules on medical spending in this analysis because we have not attempted to estimate the effect of the proposed rules on the incidence of diet-related disease. If the requirements in the proposed rules improve diet quality and reduce the prevalence of chronic diet-related diseases, then consumers and other payers would spend less on medical treatment of these diseases. (The portion consumers spend on themselves is included in our WTP estimates, but not in the "re-evaluated" estimates; any portion borne by the rest of the society has not been quantified in either case.) Preventing obesity, and avoiding the increased medical costs associated with it, could generate significant long-run savings for publicly funded programs like Medicare, Medicaid, and Social Security Insurance (disability). One study estimates that preventing obesity would save $663 (2012$) per Medicaid recipient per year and $1,964 per Medicare recipient per year (Ref. 56). These programs' savings would likely represent some combination of societal benefits and transfers between members of society.

Individuals with diet related diseases incur considerable monetary costs for prescription drugs, medical treatments, exams, consultations, lab work, and so on. The top-five diet-related chronic conditions according to the Centers for Disease Control and Prevention (CDC) are CHD, stroke, type 2 diabetes, obesity, and hypertension (high blood pressure). The estimated medical cost associated with these diseases ranges from $19 billion to $190 billion per year, with the medical costs associated with CHD and obesity being considerably higher than those of stroke or hypertension (Refs. 60 - 62). Given that over the next 20 to 40 years the prevalence of type 2 diabetes and CVD will likely continue to increase, the costs of treating these diseases will also likely increase (Refs. 63 - 65).

The medical costs associated with these diseases and conditions increase medical spending for persons of a given age and gender. These diseases, however, also reduce life expectancy. Persons with longer life expectancy incur medical costs for more years, and may incur very large expenses. Therefore, we do not know in advance if the present value of lifetime medical expenses is on average higher for individuals with diet-related conditions.

If we could quantify the net effects on lifetime discounted medical costs, then we could attribute them to the changes in behavior caused by the proposed rules and include the value in the estimated costs or benefits.

Offsetting Utility Loss

As with morbidity effects and medical savings borne by consumers themselves, there is a potential impact of the proposed labeling changes that is theoretically captured in the WTP estimates but not in the "re-evaluated" estimates: offsetting loss of utility (which is an economics term sometimes described as enjoyment, usefulness or satisfaction). Consumers may prefer the taste of relatively unhealthy foods, so when they switch consumption to other products or reformulated versions of the same products, utility loss will offset some portion of their health and longevity gains. Similarly, healthy food may require greater preparation time than unhealthy food, in which case there would be a time cost attributable to the proposed rules.

Sensitivity Analysis

The primary source of variation in the benefits presented in this analysis stems from the uncertainty surrounding the parameter s_1, which translates the welfare gain estimates associated with NLEA in Abaluck (2011) into the estimated welfare gains from the proposed rules, to include the change in label content associated with single column label (SCL) and DCL

products, each of which are parameters of the s_1 calculation, and the parameter (1 – USDA), which ensures that we are only capturing the benefits of labeling associated with FDA regulated products. As described in detail above, we assume that each of these parameters takes a range of equally likely values (that each parameter has a uniform distribution over some range).

Another source of uncertainty in the benefits estimated by FDA comes from the fact that Abaluck (2011) generates his WTP estimates of welfare gains from a data set that contains only women of 19 to 50 years of age from the Diet and Health Knowledge and Continuing Survey of Food Intake by Individuals Surveys. Using an identical methodology to that which is used above, we estimate the benefits from the proposed rules for adult women only. This exercise estimates the benefits from the proposed rules assuming that benefits accrue only to the sub-population which Abaluck (2011) used to estimate the welfare gains of NLEA. Table 17 contains our estimates of the benefits from the proposed rules if only adult women received benefits and assuming a 2 year compliance time. We estimate that the present value of the stream of benefits from the proposed nutrition labeling rules for adult women ranges (90 percent CI) from $0.8 to $19.4 billion, with a mean estimate of $8.7 billion (2011$) at a 7 percent discount rate.

Table 17. Estimated Present Value of Benefits from Proposed Nutrition Labeling Rules for Women 2013-2032 (in billions of 2011 dollars)

				90% Confidence Interval	
Benefits:	Discount Rate (%)	Mean		Lower Bound	Upper Bound
		(billions 2011$)			
WTP[a]	3%	$12.9		$1.2	$28.8
	7%	$8.7		$0.8	$19.4

Notes: Compliance period = 24 months.
[a] Based on Abaluck (2011) willingness to pay or revealed preference estimates (means only).

3. Option 3: The Proposed Rules, but with a 3 year compliance time

a. Costs

Relabeling Costs

Increasing the compliance time to 3 years would give all firms more time to comply with the proposed regulations, and would thus decrease the labeling costs associated with the proposed rules. This decrease in costs would result from firms having to undertake fewer uncoordinated label changes. That is to say, firms would be able to coordinate a greater number of their scheduled label changes with changes associated with the proposed rules. The FDA's Labeling Cost Model estimates that with a 3 year compliance time, 43 percent of private label food products would have to undertake an uncoordinated label change. For branded food products there would be no uncoordinated label change. For dietary supplements, 55 percent of branded products and 69 percent of private label products would have to undertake an uncoordinated label change.

Label costs under this scenario are summarized in Table 18. With the same compliance date, it can be seen that the one-time labeling cost estimates of the proposed rules under the 3 year compliance period range from $694 million to $2,027 million. With a 3 percent discount rate, the annualized labeling cost is estimated to be between $45 million and $132 million. With a 7 percent discount rate, the annualized labeling cost is estimated to lie between $61 million and $179 million.

Table 18: Label Cost Comparison – Different Compliance Dates vs. Same Compliance Date (in millions of 2011 USD)

Proposed Rule	**Source of Label Change**	**Type of Label Change**	**Different Compliance Dates**			**Same Compliance Date**		
			Low	Midrange	High	Low	Midrange	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$358	$672	$1,112	$232	$436	$722
Conventional Food	Claim	Major	$3	$5	$7	$2	$3	$4

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
	Removal Related to DV Change							
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$7	$11	$18	$3	$6	$9
Dietary Supplements	Various Changes to the NFL	Minor	$142	$265	$457	$142	$265	$457
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.3	$0.5	$0.8	$0.3	$0.5	$0.8
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.7	$1	$2	$0.7	$1	$2
Total Nutrition Facts Label			**$511**	**$955**	**$1,597**	**$380**	**$712**	**$1,195**
Serving Size								
Conventional Food	Dual-Column Labeling	Major	$313	$523	$830	$313	$523	$830
Conventional Food	Claim Removal Related to RACC Change	Major	$0.6	$1	$2	$0.6	$1	$2
Conventional Food	Changes Due to RACC Proposals	Minor	$58	$110	$179	-	-	-
Total Serving Size			**$372**	**$634**	**$1,011**	**$314**	**$524**	**$832**
TOTAL ALL			**$883**	**$1,589**	**$2,608**	**$694**	**$1,236**	**$2,027**
Annualized (3%)			$58	$104	$170	$45	$81	$132
Annualized (7%)			$78	$140	$230	$61	$109	$179

Notes: Compliance period is 36 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

Related recordkeeping costs are estimated to be $27.7 million at a 3 percent discount rate and $26.6 million at a 7 percent discount rate (2011$). Annualized over 20 years, recordkeeping costs are estimated to be $1.8 million per year at a 3 percent discount rate and $2.3 million per year at a 7 percent discount rate (2011$).

Reformulation Costs

Reformulation costs under a 3 year compliance period are summarized in Table 19. Reformulation costs under a 3 year compliance period are lower than under a 2 year compliance period because, as discussed in the Reformulation Costs section under Option 2 in the PRIA, with greater time to comply manufacturers are more able to coordinate a required reformulation with a scheduled reformulation. Total costs of reformulation due to health claims and nutrient content claims and voluntary reformulation due to increased visibility of added sugars range from $64 million to $561 million. With a 3 percent discount rate, the annualized reformulation cost is estimated to be between $4 million and $37 million. With a 7 percent discount rate, the annualized reformulation cost is estimated to lie between $6 million and $49 million.

Table 19. Summary of Total Reformulation Costs (in millions of 2011 USD)

	Low	Medium	High
Claims	$15	$62	$128
Added Sugars	$49	$210	$433
Total	**$64**	**$272**	**$561**
Annualized at 3%	$4	$18	$37
Annualized at 7%	$6	$24	$49

Notes: Compliance period is 36 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

b. Benefits

We estimate that the present value of the stream of probable benefits from the proposed rules for the total US population over the next 20 years (i.e., between 2013 and 2032) would equal $30.6 billion at a 3 percent discount rate and in 2011$ or $20.5 billion at a 7 percent discount rate and in 2011$ if we used a compliance time of 3 years.

4. Option 4: The Proposed Rules, but with a 4 year compliance time

a. Costs

Relabeling Costs

Increasing the compliance time to 4 years would give all firms even more time to comply with the proposed regulations, and would thus decrease the labeling costs associated with the proposed rules even further. As described above, this decrease in costs would result from firms having to undertake fewer uncoordinated label changes. The FDA's Label Cost Model estimates that with a 4 year compliance time, no food products (private label and branded) would have to undertake an uncoordinated label change. For dietary supplements, no branded products and 49 percent of private label products would have to undertake an uncoordinated label change.

Label costs under this scenario are summarized in Table 20. With the same compliance date, it can be seen that the one-time labeling cost estimates of the proposed rules under the 4 year compliance period range from $208 million to $587 million. With a 3 percent discount rate, the annualized labeling cost is estimated to be between $14 million and $38 million. With a 7 percent discount rate, the annualized labeling cost is estimated to lie between $18 million and $52 million.

Table 20: Label Cost Comparison – Different Compliance Dates vs. Same Compliance Date (in millions of 2011 USD)

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
Nutrition Facts								

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$101	$195	$281	$66	$128	$185
Conventional Food	Claim Removal Related to DV Change	Major	$0.6	$1	$2	$0.3	$0.6	$0.8
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$2	$3	$4	$0.7	$1	$2
Dietary Supplements	Various Changes to the NFL	Minor	$63	$119	$200	$63	$119	$200
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.1	$0.2	$0.4	$0.1	$0.2	$0.4
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.1	$0.2	$0.3	$0.1	$0.2	$0.3
Total Nutrition Facts Label			**$167**	**$318**	**$488**	**$130**	**$249**	**$389**
Serving Size								
Conventional Food	Dual-Column Labeling	Major	$78	$138	$198	$78	$138	$198
Conventional Food	Claim Removal Related to RACC Change	Major	$0.1	$0.2	$0.3	$0.1	$0.2	$0.3
Conventional Food	Changes Due to RACC Proposals	Minor	$20	$39	$56	-	-	-
Total Serving Size			**$98**	**$177**	**$254**	**$78**	**$138**	**$198**
TOTAL ALL			**$265**	**$495**	**$742**	**$208**	**$387**	**$587**
Annualized (3%)			$17	$32	$48	$14	$25	$38
Annualized (7%)			$23	$44	$65	$18	$34	$52

Notes: Compliance period is 48 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

Related recordkeeping costs are estimated to be $27.7 million at a 3 percent discount rate and $26.6 million at a 7 percent discount rate (2011$). Annualized over 20 years, recordkeeping costs are estimated to be $1.8 million per year at a 3 percent discount rate and $2.3 million per year at a 7 percent discount rate (2011$).

Reformulation Costs

Reformulation costs under a 4 year compliance period are summarized in Table 21. Total costs of reformulation due to health claims and nutrient content claims and voluntary reformulation due to increased visibility of added sugars range from $55 million to $481 million. With a 3 percent discount rate, the annualized reformulation cost is estimated to be between $4 million and $31 million. With a 7 percent discount rate, the annualized reformulation cost is estimated to lie between $5 million and $42 million.

Table 21. Summary of Total Reformulation Costs (in millions of 2011 USD)

	Low	Medium	High
Claims	$13	$53	$110
Added Sugars	$42	$180	$371
Total	**$55**	**$233**	**$481**
Annualized at 3%	$4	$15	$31
Annualized at 7%	$5	$21	$42

Notes: Compliance period is 48 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

b. Benefits

We estimate that the present value of the stream of probable benefits from the proposed rules for the total US population over the next 20 years (i.e., between 2013 and 2032) would

equal $30.2 billion at a discount rate of 3 percent and in 2011$ or $20.1 billion at a discount rate of 7 percent and in 2011$ if instead we used a compliance time period of 4 years.

5. Option 5: The Proposed Rules, but with Daily Values for sodium of 1,500mg or 1,900 mg

a. Costs

Relabeling Costs

Whether the DV for sodium is 1,500 mg or 1,900 mg, relabeling costs would remain unchanged from Option 2 and are reproduced below in Table 22.

Table 22: Label Cost Comparison – Different Compliance Dates vs. Same Compliance Date (in millions of 2011 USD)

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$588	$1,075	$1,782	$377	$693	$1,152
Conventional Food	Claim Removal Related to DV Change	Major	$4	$7	$12	$3	$4	$7
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$11	$18	$28	$5	$9	$14
Dietary Supplements	Various Changes to the NFL	Minor	$184	$341	$589	$184	$341	$589
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.4	$0.6	$1	$0.4	$0.6	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.9	$2	$3	$0.9	$2	$3
Total Nutrition Facts Label			**$788**	**$1,444**	**$2,415**	**$570**	**$1,050**	**$1,766**
Serving Size								

Proposed Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Midrange	High	Low	Midrange	High
Conventional Food	Dual-Column Labeling	Major	$502	$824	$1,315	$502	$824	$1,315
Conventional Food	Claim Removal Related to RACC Change	Major	$0.9	$2	$2	$0.9	$2	$2
Conventional Food	Changes Due to RACC Proposals	Minor	$89	$166	$274	-	-	-
Total Serving Size			**$592**	**$992**	**$1,591**	**$503**	**$826**	**$1,317**
TOTAL ALL			**$1,380**	**$2,436**	**$4,006**	**$1,073**	**$1,876**	**$3,083**
Annualized (3%)			$90	$159	$261	$70	$122	$201
Annualized (7%)			$122	$215	$353	$95	$165	$272

Notes: Compliance period is 24 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

Related recordkeeping costs are estimated to be $27.7 million at a 3 percent discount rate and $26.6 million at a 7 percent discount rate (2011$). Annualized over 20 years, recordkeeping costs are estimated to be $1.8 million per year at a 3 percent discount rate and $2.3 million per year at a 7 percent discount rate (2011$).

Reformulation Costs

Reformulation costs under this option comprise those estimated under Option 2, in addition to reformulation costs related to the sodium DV change. A sodium DV change to either 1,500 mg or 1,900 mg could motivate food manufacturers to reformulate their products in response to future changes in consumer preferences. More specifically, food manufacturers might be motivated to reformulate due to the increased visibility of sodium on the Nutrition Facts label (the proposed reduction of the DV for sodium would make sodium content appear

significantly higher in terms of percent DV). We anticipate that reformulation will most likely occur in products high in added sodium. In order to estimate the number of formulas that would be reformulated as a result of the change in sodium DV, we use a similar methodology to that which was used to estimate the number of formulas that would be reformulated as a result of the proposed label disclosure of added sugars.

We qualitatively identified product groups thought to contain significant amounts of added sodium using the product group listing in the FDA Labeling Cost Model. For example, milk generally contains only innate sodium and, therefore, was excluded from our identification. This resulted in the product categories listed in Table 23. Data limitations preclude us from being able to identify a set of affected product categories under the 1,500 mg DV different from a set of affected product categories under the 1,900 mg DV. Thus, we use the same set of product categories for both the 1,500 mg and 1,900 mg DVs. Given the closeness in magnitude of the two DVs, we do not estimate a difference in reformulation costs between these two DVs. We believe this to be a reasonable approach, as reformulation costs under the 1,500 mg DV are unlikely to differ greatly from those under the 1,900 mg DV.

We estimate reformulation costs using both the FDA Labeling Cost Model and the FDA Reformulation Cost Model. The FDA Labeling Cost Model provides formula counts for each of the identified product categories, which are reported in Table 23. A total of 337,013 formulas were identified as being high in sodium. The FDA Reformulation Cost Model provides per-formula estimates of reformulation costs. These were illustrated earlier in Table 7. Reformulation costs are computed by multiplying the per-formula reformulation costs by the formula counts.

Table 23. Formula Counts for Product Groups High in Added Sodium

Product Subcategory	**Total**	**1%**	**2%**

	Formulas	Reformulated	Reformulated
Dairy	25,111	251	502
Fats, Oils, Dress., Sauces, Cond., Dips, & Season.	68,592	686	1,372
Vegetables & Salad	28,695	287	574
Soups	8,842	88	177
Cereals	6,717	67	134
Baked Goods	56,355	564	1,127
Desserts	34,943	349	699
Seafood	8,609	86	172
Snacks, Nuts, & Seeds	37,571	376	751
Entrees & Sides	61,578	616	1,232
Total	**337,013**	**3,370**	**6,740**
	Average:	**5,055**	

Reformulation costs associated with the voluntary reformulation of sodium content are estimated under the assumption that 1 to 2 percent of all formulas high in added sodium will be reformulated to reduce sodium content. This estimate is based on the notion that changing the percent DV will exert some pressure on manufacturers to reformulate (particularly manufacturers who are either conscious about the contents of the label themselves, or have customers sensitive or alert to sodium content levels, e.g., hypertensive individuals). We do not have data to accurately estimate the number of products that are likely to be reformulated as a result of this percent DV change and we acknowledge that the actual rate of reformulation may be higher or lower than the range of 1 to 2 percent. Referring back to Table 23, an estimated range of 1 to 2 percent reformulation for products high in added sodium to be reformulated yields total formula counts of 3,370 to 6,740 and an average count of 5,055 ([3,370 + 6,740]/2). We use this average count to compute reformulation costs. We invite comments regarding this estimation approach.

As stated previously, reformulation costs depend on the mandated compliance period, with coordination costs decreasing as the compliance period increases. A built-in assumption of the FDA Reformulation Cost Model is that to the extent a manufacturer can coordinate a required reformulation with a scheduled reformulation, reformulation costs will be smaller than

they otherwise would be. Given a compliance period of 24 months, 20 percent of formulas can coordinate. Given compliance periods of 36 months and 48 months, respectively, 30 percent and 40 percent of formulas can coordinate. Under a 24 month compliance period, the total formula count reduces to 4,044 (5,055 – [0.2 × 5,055]). Multiplying these formula counts by the per-formula reformulation costs in Table 7 yields total reformulation costs (in 2011 USD) associated with sodium reformulation of between $47 million ($11,626 × 4,044) and $414 million ($102,365 × 4,044), with a mid-range estimate of $201 million ($49,716 × 4,044).

Table 24 presents a summary of total estimated reformulation costs under Option 5, for a DV of either 1,500 mg or 1,900 mg. We estimate total reformulation costs (in 2011 USD) of between $120 million and $1,056 million, with a mid-range estimate of $513 million. Table 24 also presents annualized reformulation costs, at 3 percent and 7 percent, over a 20 year period.

Table 24. Summary of Total Reformulation Costs (in millions of 2011 USD)

	Low	**Medium**	**High**
Claims	$17	$71	$147
Added Sugars	$56	$241	$495
Sodium	$47	$201	$414
Total	**$120**	**$513**	**$1,056**
Annualized at 3%	**$8**	**$33**	**$69**
Annualized at 7%	**$11**	**$45**	**$93**

Notes: Compliance period is 24 months. The annualization period is 20 years. Annualized Amount = Amount/Annualizing Factor. 3 percent annualizing factor = 15.32. 7 percent annualizing factor = 11.34. 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: $\sum_{t=0}^{19} \frac{1}{(1+r)^t}$, where t is the year from 0 to 19 and r is the discount rate, either 3 percent or 7 percent.

b. Benefits

A May 2013 report issued by the Institute of Medicine entitled *Sodium Intake in Populations: Assessment of Evidence* concluded that studies on direct health outcomes (not including studies on blood pressure reduction) are inconsistent in quality and insufficient in

quantity to determine that sodium intakes below 2,300 mg/day either increase or decrease the risk of heart disease, stroke, or all-cause mortality in the general U.S. population (Ref. 66). However, typical consumption of dietary sodium in the U.S. exceeds 3,400 mg per day and many organizations concerned with public health, including the U.S. Department of Health and Human Services, the American Heart Association, and the World Health Organization, have called for reductions in dietary sodium (Ref. 67).

Several studies modeling the effects of reduced dietary sodium in the U.S. predict that it would create substantial benefits (Ref. 28; Refs. 68 - 71), including substantial reductions in medical costs and reduced morbidity and mortality associated with elevated blood pressure and related diseases. However, we are not able to quantify the size of the dietary reductions in sodium that might result from reformulation, and so we do not quantify the additional benefits associated with this option. Therefore, benefits under Option 5, which are presented below in Table 25, are equivalent to those estimated under Option 2. We invite comment on this issue.

Table 25. Present Value of Stream of Benefits from Proposed Nutrition Labeling Rules 2013–2032 (in billions of 2011 dollars)

Benefits:	Discount Rate (%)	Mean
WTP[a]		
	3%	$31.4
	7%	$21.1

Notes: Compliance period = 24 months.
[a] Based on Abaluck (2011) willingness to pay or revealed preference estimates.

6. Summary of Net Benefits by Regulatory Option

Net benefits by regulatory option are summarized below in Table 26 and Table 27. Table 26 presents net benefits assuming that the proposed rules will be enacted together. Table 27 presents net benefits assuming that the proposed rules will be enacted separately.

Table 26. Summary of Net Benefits by Regulatory Option 2013 - 2032 (in billions of 2011$)

Option	Discount Rate	Benefits	Costs	Net Benefits
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$31.4	$2.3	$29.1
	7%	$21.1	$2.3	$18.8
3 – Proposed Rules – 3 Year Compliance Period	3%	$30.6	$1.5	$29.1
	7%	$20.5	$1.5	$19.0
4 – Proposed Rules – 4 Year Compliance Period	3%	$30.2	$0.6	$29.6
	7%	$20.1	$0.6	$19.5
5 – Proposed Rules - DV for Sodium of 1,500 mg or 1,900 mg	3%	$31.4	$2.4	$29.0
	7%	$21.1	$2.4	$18.7

Notes: Assuming the proposed rules are enacted together. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

Table 27. Summary of Net Benefits by Regulatory Option 2013 - 2032 (in billions of 2011$)

Option	Discount Rate	Benefits	Costs	Net Benefits
1 – No New Federal Regulatory Action	3%	$0	$0	$0
	7%	$0	$0	$0
2 – Proposed Rules	3%	$31.4	$2.9	$28.5
	7%	$21.1	$2.9	$18.2
3 – Proposed Rules – 3 Year Compliance Period	3%	$30.6	$1.9	$28.7
	7%	$20.5	$1.9	$18.6
4 – Proposed Rules – 4 Year Compliance Period	3%	$30.2	$0.7	$29.5
	7%	$20.1	$0.7	$19.4
5 – Proposed Rules - DV for Sodium of 1,500 mg or 1,900 mg	3%	$31.4	$2.9	$28.5
	7%	$21.1	$2.9	$18.2

Notes: Assuming the proposed rules are enacted separately. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

II. Initial Regulatory Flexibility Analysis

A. Introduction

We have examined the economic implications of these proposed nutrition labeling rules as required by the Regulatory Flexibility Act (5 U.S.C. §§ 601-612). If a rule has a significant

economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. We conclude that the proposed rules, if finalized, will have a significant economic impact on a substantial number of small entities.

B. Economic Effects on Small Entities

1. Number of small entities affected

Generally, we use SBA's definition of small business as it applies to the relevant economic sector, in this case, NAICS 311, 312 and 325. As noted in section I.D., SBA defines a small food manufacturer as one who has less than 500 employees. The total number of firms under 500 employees is 38,917, or 65 percent of 59,872 total firms.

2. Costs to small entities

The proposed rules would result in costs to small business. We cannot estimate the exact cost per small entity, because we do not know how many UPCs on average are owned by small entities. However, we estimate that the rule would cost roughly $3,163 per UPC (= [$1,876 million + $440 million + $28 million] / 741,134). Therefore, a small firm owning one to three UPC's would incur a one-time cost of $3,163 to $9,489. The cost of the rule per entity (including large firms) is roughly $39,150. This latter number definitely overstates the cost per small entity, because the average cost overall is most likely driven by large firms owning a large number of UPCs.

C. Regulatory Options

1. Exemptions for Small Entities

One possible approach to reduce impact on small entities would be to exempt all small entities from the rule. This would significantly reduce costs, as well as benefits.

We do note that the targeted exemption from labeling that currently exists for some small business will continue to be available. Currently, we allow certain small businesses whose products do not sell more than 100,000 units to apply for a labeling exemption for that particular product. Such an exemption is granted for 12 months (on a per product basis) and the business has the option to re-apply for a continuation of this exemption. Currently, there are about 3,000 small businesses registered with FDA for a small business nutrition labeling exemption. On average we grant labeling exemptions to approximately 10,000 products per year.

2. Longer Compliance Times

We recognize that it may be more difficult for some small entities to learn about and implement these label changes than it would be for large entities. One commonly cited way to add flexibility for small businesses is to lengthen the time to comply with the rule. We note that there is already substantial flexibility built into the proposed rules. The 2 year compliance time would allow manufacturers to coordinate approximately 65 percent of their label changes so that they do not have to discard too much of their inventories. We invite comment on this.

Increasing the compliance time would reduce the cost per UPC, and therefore the cost to small entities, substantially. With three years to comply, the average estimated one-time cost of the rule per UPC is reduced from $3,163 to roughly $2,072 (= [$1,236 million + $272 million + $28 million] / 741,134). With four years to comply, the average estimated one-time cost of the rule per UPC would be reduced to roughly $874 (= [$387 million + $233 million + $28 million] / 741,134). The full costs and benefits associated with longer compliance times are estimated under Options 3 (3 years) and 4 (4 years) of the Regulatory Impact Analysis.

It is also important to note that there is some flexibility how entities comply with the regulation. The wide range in cost estimates is a function of the variety of approaches (printing

methods, package materials, etc.) that businesses may choose to take to comply with the proposed requirements. Therefore, businesses may choose from among a wide variety of less or more expensive avenues of label printing for compliance, depending on their situation.

D. Summary

Under the Regulatory Flexibility Act (5 U.S.C. 606(b)), we tentatively conclude that the proposed rules will have a significant economic impact on a substantial number of small entities.

III. Unfunded Mandates

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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed nutrition rules have met the threshold under the Unfunded Mandates Reform Act. We have carried out the cost-benefit analysis in preceding sections of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the proposed rule's effects on:

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and

- Exports.

The relevant issues listed above are covered in detail in the cost benefit analysis of the preceding sections. Note that since the requirements in the proposed rules do not mandate any changes in products, current export products would not be required to change in any way. Food manufacturers, however, do not necessarily distinguish between production for export and production for the domestic market. Furthermore, because the costs of the proposed rules per firm are low relative to the revenue generated by even the smallest food establishment, the proposed rules would not significantly affect employment, economic growth or national productivity.

IV. Paperwork Reduction Act of 1995

We are publishing two proposed rules on nutrition labeling in the *Federal Register*. The two proposed rules, if finalized, are expected to have the same effective date and compliance date. Assuming that this happens, a manufacturer or packer is likely to be able to coordinate the required label changes. However, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA), we estimate the hour burden of the proposed rules as if the rules have proceeded as a unique change to the labeling regulations. In contrast, we have published a Regulatory Impact Analysis for the two proposed rules which estimates the cost to manufacturers and packers of implementing the changes to the labeling regulations in a coordinated manner. If the two proposed rules are finalized with the same effective date and compliance date, we plan to estimate the information collection burden on manufacturers and packers of implementing the changes to the labeling regulations in a coordinated manner when finalizing the proposed rules to avoid double-counting the burden of the rules under the PRA.

A. Nutrition Facts Label Rule (Proposed Rule 1)

The Nutrition Facts Label proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA. A description of these provisions is given in this section with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title***:** Record Retention, Reporting, and Third-Party Disclosure Requirements for the Declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E and Folate/Folic Acid

Proposed Recordkeeping Requirements

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States whose products contain (1) a mixture of naturally occurring and added sugars or (2) a mixture of non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber. The likely respondents to this

information collection also include manufacturers of retail food products marketed in the United States whose products contain (1) mixtures of different forms of vitamin E or (2) both folate and folic acid.

Description: The proposed rule, if finalized, would require that under certain circumstances manufacturers make and keep certain records to verify the amount of added sugars, when a food product contains both naturally-occurring sugars and added sugars, and for specific foods containing added sugars, alone or in combination with naturally-occurring sugars, where the added sugars are subject to fermentation, isolated or synthetic non-digestible carbohydrates that do not meet the proposed definition of dietary fiber, different forms of vitamin E, and folate/folic acid declared on the label, which is the amount in the finished food product. Manufacturers would be required to provide such records to an appropriate regulatory official upon request during inspection. Manufacturers would also be required to maintain the records to verify the label declaration of the aforementioned nutrients for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. Manufacturers of food products that contain an isolated and synthetic non-digestible carbohydrate that does not meet the definition of dietary fiber will have the option of submitting a citizen petition or a health claim petition to FDA demonstrating the physiological benefits of said non-digestible carbohydrate. If the citizen petition is granted or the health claim is authorized, then said non-digestible carbohydrate is considered to meet the definition of dietary fiber, implying that amounts of said non-digestible carbohydrate may be declared as dietary fiber on the Nutrition or Supplement Facts label by food manufacturers who manufacture food products that contain said non-digestible carbohydrate. The proposed requirement is necessary because analytical methods are not available that would allow us to differentiate between naturally occurring and added

sugars, non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber, the various forms of vitamin E, and folate or folic acid in order to quantify the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E or folate/folic acid in the final food product. Analytical methods may also not be able to quantify the amount of added sugars in certain foods that undergo fermentation. For the nutrients described above for which there are no analytical methods available to verify the label declaration, we must rely on information known only to the manufacturer, *e.g.*, analyses of nutrient databases, the food's formulation or recipe, batch records, or other records, to determine whether their product contains the declared amount of the nutrient and in compliance with the requirements of § 101.9(g).

If the rule is finalized as proposed, we would require that firms make and keep certain records necessary to verify the amount of the nutrients in the finished food product. The proposed rule does not specify what records must be used to verify the amounts of these nutrients, but does specify the information that the records must contain. The proposed rule would require manufacturers to provide FDA with the records that contain the required information for each of these nutrients to verify the amount of the nutrient declared on the label. These records may include analyses of nutrient databases, recipes or formulations, batch records, or any other records that contain the required information to verify the nutrient content in the final product. For yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and non-malt beverage beers, all of which undergo fermentation during food processing, sugars added before and during fermentation may be reduced in quantity during the process. Thus, the amount of added sugars in the finished food product may be uncertain. While some manufacturers of these products may be able to determine the amount of added sugars in their

finished food products by either conducting laboratory analyses or relying on a scientific document, manufacturers of such foods will be permitted to declare the amount of added sugars present in the food product *prior* to fermentation. We assume that most manufacturers of these products will choose to declare the amount of added sugars present in the food product *prior* to fermentation, with that number not exceeding the amount of total sugars declared.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

Type of Declaration/ Proposed CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Added Sugars/ § 101.9(c)(6)(iii)[2]	59,872	1	59,872	1	59,872
Dietary Fiber/ § 101.9(c)(6)(i)[2]	59,872	1	59,872	1	59,872
Soluble Fiber/ § 101.9(c)(6)(i)(A)[2]	59,872	1	59,872	1	59,872
Insoluble Fiber/ § 101.9(c)(6)(i)(B)[2]	59,872	1	59,872	1	59,872
Dietary Fiber/ § 101.9(c)(6)(i)	20	1	20	1	20
Vitamin E/ § 101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Folate/Folic Acid/ § 101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Total					359,252
Total Initial Hours					359,252

New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					359,468

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars, added sugars that undergo fermentation in certain fermented foods, and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.
[3]These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, we believe that the new records that would be required to be retained by the proposed rules are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, e.g., analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the recordkeeping burden of the proposed rules consists of the time required to identify and assemble the records for copying and retention. Based on our previous experience with similar recordkeeping requirements (Ref. 13), we estimate the recordkeeping burden of the proposed rule to be 1 hour per product as estimated in Table 1.

If the rule is finalized as proposed, the declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber would be mandatory, and we estimate that all roughly 60,000 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. We estimate that there are less than 20 isolated and synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen or health claim petition filed by a manufacturer related to a particular isolated and synthetic non-digestible carbohydrate is granted or denied, it applies to all food products that contain said non-digestible carbohydrate. Thus, it is estimated that at most 20 manufacturers would incur a

recordkeeping burden associated with filing a citizen or health claim petition related to an isolated and synthetic non-digestible carbohydrate that does not meet the definition of dietary fiber and that the required recordkeeping would be 1 hour per manufacturer. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes. However, we estimate that all roughly 60,000 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer.

It is hard to predict with certainty the exact number of newly introduced products that would be covered under the proposed rule each year, but based on the industry growth rate estimated using U.S. Census Bureau Business and Industry data we estimate that number to be about 216. Thus, we estimate that about 216 new products would be affected by the proposed rule, and that the required recordkeeping would be 1 hour per product, for an annual recurring recordkeeping burden of 216 hours (216 × 1). Adding the burden from new products to the burden for existing products results in a total of 359,468 recordkeeping burden hours (359,252 + 216) for the covered establishments under the proposed rule, as reported in Table 1.

Proposed Reporting Requirements

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States whose products contain (1) either a combination of both naturally occurring and added sugars or added sugars that undergo fermentation in certain fermented foods or (2) a mixture of non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber, soluble fiber, and insoluble fiber. The likely respondents to this information collection also include manufacturers of retail food products marketed in the United States whose products contain (1) mixtures of different forms of

vitamin E or (2) both folate and folic acid if a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Description: If the rule is finalized as proposed, we would require that firms provide records upon request during an inspection that they use to verify the declared amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid on the Nutrition Facts or Supplement Facts label.

The proposed reporting requirement is necessary because, at the present time, analytical methods are not available that would allow us to differentiate between naturally occurring and added sugars, added sugars undergoing fermentation in certain fermented foods, non-digestible carbohydrates that both do and do not meet the proposed definition of dietary fiber, soluble fiber, and insoluble fiber, the various forms of vitamin E, and folate or folic acid in order to quantify the amount of added sugars, dietary fiber, vitamin E or folate/folic acid in the final food product. For these foods, we must rely on information known only to the manufacturer to assess compliance with the qualifying amount of nutrient. The food manufacturer would assemble and provide the records to FDA regulatory officials upon request during an inspection. We would review the records to verify the label declaration and assess compliance.

Table 2.--Estimated Annual Reporting Burden[1]

Type of Declaration/ Proposed CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Added Sugars/ § 101.9(c)(6)(iii)[2]	59,872	1	59,872	1	59,872
Dietary Fiber/	59,872	1	59,872	1	59,872

RE and

§ 101.9(c)(6)(i)[2]					
Soluble Fiber/ § 101.9(c)(6)(i)(A)[2]	59,872	1	59,872	1	59,872
Insoluble Fiber/ § 101.9(c)(6)(i)(B)[2]	59,872	1	59,872	1	59,872
Vitamin E/ § 101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Folate/Folic Acid/ § 101.9(c)(8)[3]	59,872	1	59,872	1	59,872
Total					359,232
Total Initial Hours					359,232
New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					359,448

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars, added sugars that undergo fermentation in certain fermented foods, and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.
[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, we believe that the records that would be required to be provided to FDA, upon request, are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, e.g., analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the reporting burden to the food manufacturer consists of the time required to assemble and provide the records to appropriate regulatory officials. Based on our previous experience with similar

reporting requirements, we estimate the reporting burden of the proposed rule to be 1 hour per response, as estimated in Table 2.

We do not expect to request records from all covered manufacturers to assess compliance, but for the purpose of this analysis the number of respondents is estimated to be all covered establishments. We estimate the number of responses per record keeper to be 1 and the hourly burden per response to be 1 hour. As shown in Table 2, the initial reporting burden for covered establishments is 359,232 hours. Also, in accordance with our previous estimate of the number of newly introduced products that would be covered by the proposed requirement to be 216, we estimate the recurring reporting burden hours to be 216. Adding the burden from new products to the initial hours results in a total of 359,448 reporting burden hours (359,232 + 216) for the covered establishments under the proposed rule, as estimated in Table 2.

Proposed Third-Party Disclosure Requirements

Description of Respondents:

Respondents to this collection of information include manufacturers of food products. We estimate the burden of this collection of information as follows:

Table 3: Estimated Annual Third Party Disclosure Burden[1]

Proposed CFR Section	Number of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs (in billions)
101.9 and 101.36	59,872	12	741,134	2	1,482,268	$1.44

1. There are no operating and maintenance costs associated with this collection of information

We have estimated that the burden associated with the proposed changes would be a one-time burden created by the need for food manufactures to revise the nutrition labels. We estimate

that the third party disclosure burden would be approximately 2 hours per disclosure, for a total burden of 1,482,268 hours.

Third party disclosure burden for manufacturers:

The incremental time burden for reviewing labels to assess how to bring them into compliance with the proposed requirements has been estimated to be 1 hour per label. These requirements do not generate any recurring burden per label because establishments must already print packaging for food products as part of normal business practices, and must disclose required nutrition information under NLEA.

Each label redesign would require an estimated 1 additional hour, making the total burden hours to be 2 hours in burden per UPC. We invite comments on this assumption.

We estimate that about 60,000 manufacturers representing about 741,134 UPCs, with an average disclosure of 12 (741,134/60,000), would be covered under the proposed rule (Ref. 13). The total number of responses is equal to the total number of UPCs being changed. Multiplying the total number of responses by the hours per response gives the total burden hours (Table 3, Column 6). Based on the Regulatory Impact Analysis, we have estimated the capital cost to be $1,948 per UPC, which gives the total estimated capital cost of $1.44 billion ($1,948 × 741,134).

B. Serving Size Rule (Proposed Rule 2)

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA. A description of these provisions is given in this section with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Third-Party Disclosure Requirements for Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments

Proposed Reporting Requirements

None.

Proposed Recordkeeping Requirements

None.

Proposed Third-Party Disclosure Requirements

Description of Respondents: The respondents to this information collection are manufacturers and packagers of retail food products marketed in the United States.

Description:

The proposed rule, if finalized, would revise §101.9 and §101.12 to: (1) require changes to the definition of a single-serving container, (2) require a second column of nutrition information per package for products that contain at least 200 and up to and including 400

percent of the applicable RACCs, as well as per unit for discrete units in multi-serving packages that contain at least 200 percent and up to and including 400 percent of the applicable RACCs (3) change the RACCs, from which label serving sizes are derived, for certain food products, (4) make several technical amendments to the regulations for serving sizes, and (5) change the label serving size for breath mints to "1 unit." These revisions, in most instances, would require changes to the nutrition information that is presented in the Nutrition Facts label of retail food products. The present version of §101.12 is approved by OMB in accordance with the PRA under OMB control number 0910-0381. This proposed rule, if finalized, would modify the information collection associated with the present version of §101.9 and § 101.12 by adding a one-time burden of 536,366 hours to the burden associated with the collection because a manufacturer or packager of retail food products not using a label serving size in conformity with the new single-serving size requirements and new RACCs, and not using nutrition information based on the new single-serving size requirements and new RACCs would be required to make a one-time change to the label of its products. A manufacturer or packager of retail food products that would be required to use DCL would also be required to make a one-time change to the labels of its products. The nutrient information disclosed on labels of retail food products is necessary to inform purchasers of the nutritional value of the food.

We estimate the burden of this collection of information as follows:

Table 1: Estimated Annual Third Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs (in millions)
101.9 and 101.12	27,890	12	345,241	2	690,482	$992

[1] There are no operating and maintenance costs associated with this collection of information.

Under proposed §101.9 and §101.12, some manufacturers or packagers of retail food products would need to make a one-time labeling change to modify the serving sizes and the nutrition information based on the new single-serving size requirements or new RACCs, and some would need to make a one-time change to add a second column of nutrition information per package or per discrete unit in the Nutrition Facts label. The one-time third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. The one-time third-party disclosure burden for the proposed rule is estimated in Table 1.

Based upon our knowledge of food labeling, we estimate that the affected manufacturers or packers would require 2 hours per product to modify the label's Nutrition Facts panel. We estimate that it would take an affected manufacturer 1 hour to review a label to assess how to bring it into compliance with the proposed requirements. Each label redesign would require an estimated 1 additional hour per UPC, for a total of 2 hours per UPC. We invite comments on this estimate. The proposed rule does not generate any recurring burden per label because establishments must already print packaging for food products as part of normal business practices, and must disclose required nutrition and serving size information under NLEA.

We estimate that about 27,890 manufacturers or packagers would be affected by the proposed rule and that about 345,241 products would require relabeling, for an average of 12 (345,241/27,890) products per respondent (Ref. 13). The total one-time third-party disclosure burden of 690,482 hours is reported in Table 1.

The final column of Table 1 gives the estimated capital cost associated with the relabeling required by the proposed rule, if finalized as proposed. Based on the Regulatory

Impact Analysis, we estimated the capital cost to be $2,873 per UPC, which gives the total estimated capital cost of $992 million ($2,873 × 345,241).

These costs are based on the assumption that the proposed rule is finalized with a compliance date 2 years after publication and the expectation that, over a longer period of time, any labeling change is more likely to be able to be coordinated with a change in a label that may already be scheduled by the manufacturer or packager.

In compliance with the PRA, FDA has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by [insert date 30 days after date of publication in the *FEDERAL REGISTER*] to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the title "Third-Party Disclosure Requirements for Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual Column Labeling; Updating, Modifying and Establishing Reference Amounts Customarily Consumed; and Technical Amendments."

References

1 Ruhm CJ. Understanding overeating and obesity. *J Health Econ* 2012; **31/6**: 781-796.

2 O'Donoghue T, Rabin M. Optimal sin taxes. *Journal of Public Economics* 2006; **90/10**: 1825-1849.

3 Loewenstein G. Out of Control: Visceral Influences on Behavior. *Organizational Behavior and Human Decision Processes* 1996; **65/3**: 272-292.

4 O'Donoghue T, Rabin M. Doing It Now or Later. *American Economic Review* 1999; **89/1**: 103-124.

5 Akerlof GA. Procrastination and obedience. *American Economic Review* 1991; **81/2**: 1.

6 Epstein LH, Saelens BE. Behavioral Economics of Obesity: Food Intake and Energy Expenditure. In: Bickel WK, Vuchinich RE (eds). *Reframing Health Behavior Change With Behavioral Economics.* Lawrence Erlbaum Asociates, Inc.: Mahwah, NJ, 2000, pp. 295-314.

7 Conlisk J. Why Bounded Rationality? *Journal of Economic Literature* 1996; **34/2**: 669-700.

8 Lin J, Lee JY, Yen ST. Do dietary intakes affect search for nutrient information on food labels? *Social Science & Medicine* 2004; **59/9**: 1955-1967.

9 Wansink B, Kim J. Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste. *Journal of Nutrition Education and Behavior* 2005; **37/5**: 242-245.

10 Wansink B, Painter JE, North J. Bottomless Bowls: Why Visual Cues of Portion Size May Influence Intake. *Obesity Research* 2005; **13/1**: 93-100.

11 Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA: The Journal of the American Medical Association* 2003; **289/4**: 450-453.

12 Wansink B. Environmental factors that increase the food intake and consumption volume of unknowing consumers. *Annual Review of Nutrition* 2004; **24/1**: 455-479.

13 RTI International. "Model to Estimate Costs of Using Labeling as a Risk-Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Methodology Report." Prepared for Andrew Stivers DHHS/FDA/CFSAN/ORPSS. Prepared by Mary K. Muth, Melanie J. Ball, Michaela C. Coglaiti and Shawn A. Karns. Contract No. GS-10F-0097L, Task Order Number 5, March 2011.

14 Hubbard RG and O'Brien AP. Microeconomics. 3rd Edition. 2010. Boston, MA, Pearson.

15 White, W., Gledhill, E., Karns, S., and Muth, M. (2002). "Cost of Reformulating Foods and Cosmetics, Final Report." RTI International. Prepared for Ed Puro, DHHS/FDA/CFSAN. RTI Project Number 08184.003.

16 Abaluck J. What Would We Eat if we Knew More: The Implications of a Large-Scale Change in Nutrition Labeling. 10-17-2011.

17 Post, R., Budak, C., Canavan, J., Duncan-Harrington, T., Jones, B., Jones, S., Murphy-Jenkins, R., Myrick, T., Wheeler, M., White, P., Yoder, L., Kegley, M. "A Guide to Federal Food Labeling Requirements for Meat and Poultry Products". The Labeling and Consumer Protection Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, U.S. Department of Agriculture, 2007.

18 U.S. Department of Health and Human Services. (2009). *Guidance for Industry: A Food Labeling Guide*, 3rd Edition, Washington, DC.

19 Pieters, R., and M. Wedel. Attention Capture and Transfer in Advertising: Brand, Pictorial, and Texas-Size Effect, Journal of Marketing, 2004; 68:36-50.

20 Lando, A. and S. Lo. Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Choices. Journal of the Academy of Nutrition and Dietetics. 2013;113:241-250.

21 National Institutes of Health Office of Dietary Supplements. Dietary Supplement Fact Sheet: Vitamin B12. Accessed on November 18, 2013 at http://ods.od.nih.gov/factsheets/VitaminB12-HealthProfessional/.

22 O'Neil CE, Keast DR, Fulgoni VL, Nicklas TA. Food sources of energy and nutrients among adults in the US: NHANES 2003–2006. Nutrients. 2012 Dec 19;4(12):2097-120.

23 Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline," Washington, DC: National Academy Press; 1998.

24 Danaei G, Ding EL, Mozaffarian D, Taylor B, Rehm J, Murray CJL et al. The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors. *PLoS Med* 2009; **6/4**: e1000058.

25 Ford ES, Bergmann MM, Boeing H, Li C, Capewell S. Healthy lifestyle behaviors and all-cause mortality among adults in the United States. *Preventive Medicine* 2012; **55/1**: 23-27.

26 Mokdad AH, Marks J, Stroup DF, Gerberding JL. Actual causes of death in the united states, 2000. *JAMA: The Journal of the American Medical Association* 2004; **291/10**: 1238-1245.

27 Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity in the United States, 2009-2010. *NCHS Data Brief* 2012;/**82**: 1-8.

28 Bibbins-Domingo K, Chertow GM, Coxson PG, Moran A, Lightwood JM, Pletcher MJ et al. Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease. *N Engl J Med* 2010; **362/7**: 590-599.

29 National Center for Health Statistics. Health, United States, 2011: With Special Feature on Socioeconomic Status and Health.

30 Antonuk B, Block LG. The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food. *Journal of Nutrition Education and Behavior* 2006; **38/6**: 365-370.

31 O'Brien, T. "Status of Nutrition Labeling of Processed Foods: 1995." Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration.

32 Brecher, SJ, Bender, MM, Wilkening, VL, McCabe, NM, and EM Anderson. Status of Nutrition Labeling, Health Claims, and Nutrient Content Claims for Processed Foods: 1997 Food Label and Package Survey. *Journal of the American Dietetic Association* 2000; 100: 1057-1062.

33 Ferguson, MS. Statistical Support Memo for Justifying Using Historical FLAPS Data. *FDA Internal Memorandum* 2013.

34 U.S.Food and Drug Administration. (November 10, 2011) "Calories Count: Report of the Working Group on Obesity", March 12, 2004. Retrieved from http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm.

35 Gomez-Palacio B., Vit A. Graphic Design Referenced: A Visual Guide to the Language, Applications, and History of Graphic Design. First ed. Beverly, MA: Rockport Publishers, 2012.50-54.

36 Campos, S.e.al. Nutrition Labels on Pre-Packaged Foods: A Systematic Review. Public Health Nutrition. 2011;14:1496-1506.

37 Cowburn, G., Stockley L. Consumer Understanding and Use of Nutrition Labeling: A Systematic Review. Public Health Nutrition. 2005;8:21-28.

38 Gidding, S.S., Dennison, B.A., Birch, L.L., et al. Dietary recommendations for children and adolescents: a guide for practitioners: consensus statement from the American Heart Association. Circulation. 2005;112:2061-2075.

39 Johnson, R.K., Appel, L.J., Brands, M., et al. Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. Circulation. 2009;120:1011-1020.

40 World Health Organization. "Diet, nutrition, and the prevention of chronic diseases. Report of a WHO Study Group," Geneva: World Health Organization; 1990. pp.1-204.

41 Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification," Washington, DC: National Academies Press; 2003.

42 Lidwell, W., Holden, K., Butler, J., editors. Universal Principles of Design. First ed. Beverly, MA: Rockport Publishers, 2003.40-41.

43 Palisade Corporation. @Risk. 5.7. 2011.

44 Walmart. Walmart Launches Major Initiative to Make Food Healthier and Healthier Food More Affordable, 2011. http://news.walmart.com/news-archive/2011/01/20/walmart-launches-major-initiative-to-make-food-healthier-healthier-food-more-affordable, Accessed December 10, 2012.

45 Thomas, RG, Pehrsson, PR, Ahuja, JKC, Smieja, E, and KB Miller. Recent Trends in Ready-to-eat Breakfast Cereals in the U.S. 36th National Nutrient Databank Conference. *Procedia Food Science* 2013; **2**:20–26.

46 Dhingra, Ravi, Sullivan, Lisa, Jacques, Paul F., Wang, Thomas J., Fox, Caroline S., Meigs, James B., D'Agostino, Ralph B., Gaziano, J. Michael, and Vasan, Ramachandran S. Soft Drink Consumption and Risk of Developing Cardiometabolic Risk Factors and the Metabolic Syndrome in Middle-Aged Adults in the Community. Circulation 116(5), 480-488. 7-31-2007.

47 Kosova, EC, Auinger, P, and AA Bremer. The Relationships between Sugar-Sweetened Beverage Intake and Cardiometabolic Markers in Young Children. *Journal of the Academy of Nutrition and Dietetics* 2013; 113(2): 219-227.

48 Malik, VS, Pan, A, Willett, WC, and FB Hu. Sugar-Sweetened Beverages and Weight Gain in Children and Adults: A Systematic Review and Meta-Analysis. *The American Journal of Clinical Nutrition* 2013; 98: 1084-1102.

49 Hu, FB and VS Malik. Sugar-Sweetened Beverages and Risk of Obesity and Type 2 Diabetes: Epidemiologic Evidence. *Physiology and Behavior* 2010; 100: 47-54.

50 Koning, L, Malik, VS, Rimm, EB, Willett, WC, and FB Hu. Sugar-Sweetened and Artificially Sweetened Beverage Consumption and Risk of Type 2 Diabetes in Men. *The American Journal of Clinical Nutrition* 2011; 93: 1321-1327.

51 Fung, TT, Malik, V, Rexrode, KM, Manson, JE, Willett, WC, and FB Hu. Sweetened Beverage Consumption and Risk of Coronary Heart Disease in Women. *The American Journal of Clinical Nutrition* 2009; 89: 1037-1042.

52 Bernstein, AM, Koning, L, Flint, AJ, Rexrode, KM, and WC Willett. Soda Consumption and the Risk of Stroke in Men and Women. *The American Journal of Clinical Nutrition* 2012; 95: 1190-1199.

53 Evatt, ML, Mersereau, PW, Bobo, JK, Kimmons, J, and J Williams. Why Vitamin B_{12} Deficiency Should Be on Your Radar Screen. Course WB1349 Prepared for the National Center on Birth Defects and Developmental Disabilities. Centers for Disease Control and Prevention. February 11, 2010.

54 Stabler, S. Vitamin B_{12} Deficiency. *The New England Journal of Medicine* 2013; 368(2): 149-160.

55 U.S.Department of Agriculture and U.S.Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 2010. Washington, DC.

56 Brill, A. The Long-Term Returns of Obesity Prevention Policies. Robert Wood Johnson Foundation. April, 2013. Available at: http://www.rwjf.org/en/research-publications/find-rwjf-research/2013/04/the-long-term-returns-of-obesity-prevention-programs.html.

57 Knopman D, Boland LL, Mosley T, Howard G, Liao D, Szklo M et al. Cardiovascular risk factors and cognitive decline in middle-aged adults. *Neurology* 2001; **56/1**: 42-48.

58 Rogers PJ. A healthy body, a healthy mind: long-term impact of diet on mood and cognitive function. *The Proceedings of the Nutrition Society* 2001; **60/1**: 135-143.

59 Jia, H, Zack MM, Moriarty, DG, and DG Fryback. Predicting the EuroQol Group's EQ-5D Index from CDC's "Healthy Days" in a US Sample. *Medical Decision Making* 2011; 31: 174-185.

60 DeVol R, Bedroussian A. An Unhealthy America: The Economic Burden of Chronic Disease. 2007. Milken Institute.

61 Cawley J, Meyerhoefer C. The medical care costs of obesity: An instrumental variables approach. *J Health Econ* 2012; **31/1**: 219-230.

62 American Diabetes Association. The Economic Costs of Diabetes in the U.S. in 2007. *Diabetes Care* 2008; **31/3**: 596-615.

63 Wild S, Roglic G, Green A, Sicree R, King H. Global Prevalence of Diabetes: Estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004; **27/5**: 1047-1053.

64 Mensah GA, Brown DW. An Overview Of Cardiovascular Disease Burden In The United States. *Health Affairs* 2007; **26/1**: 38-48.

65 Boyle JP, Theodore J Thompson, Edward W Gregg, Lawrence E Barker, David F Williamson. Projection of the Year 2050 Burden of Diabetes in the US Adult Population:

Dynamic Modeling of Incidence, Mortality, and Prediabetes Prevalence. *Population Health Metrics* 2010; **8/29**.

66 Institute of Medicine. Sodium Intake in Populations: Assessment of Evidence. *Report Brief* May 2013: 1 – 3.

67 Institute of Medicine. Strategies to reduce sodium intake in the United States. 2010. Washington, DC, The National Academies Press.

68 Coxson, P. G. et al., "Mortality Benefits From US Population-Wide Reduction in Sodium Consumption: Projections From 3 Modeling Approaches," *Hypertension* 61, no. 3 (2013): 564-570.

69 Smith-Spangler, C. M. et al., "Population Strategies to Decrease Sodium Intake and the Burden of Cardiovascular Disease: a Cost-Effectiveness Analysis," *Annals of Internal Medicine* 152, no. 8 (2010): 481-483.

70 Palar, K. and R. Sturm, "Potential Societal Savings From Reduced Sodium Consumption in the U.S. Adult Population," *American Journal of Health Promotion* 24, no. 1 (2009): 49-57.

71 Dall, T. M. et al., "Potential Health Benefits and Medical Cost Savings From Calorie, Sodium, and Saturated Fat Reductions in the American Diet," *American Journal of Health Promotion* 23, no. 6 (2009): 412-422.

72 Viscusi WK and Aldy JE. The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World. *Journal of Risk and Uncertainty* 2003; **27/1**: 5–76.

Appendix A

Assuming that eating the optimally healthy diet would result in a gain of 0.04 life years per year, and a VSL of $6.4 million, Abaluck (2011) estimated (at a 4 percent discount rate) that the average individual would gain about $3,000 worth of life-years each year if they ate the healthiest diet possible and if the elasticity of nutrient demand with respect to information were perfectly inelastic. While the actual value would vary across consumers by age, the weighted average gain would be comparable to the annual gain for an individual with a life expectancy of 37 remaining years. Using these benchmark parameters, Abaluck (2011) re-calculated the welfare gains from the 1993 rules that implemented the NLEA and additional labeling resulting in the "re-evaluated" welfare gain estimates that could be realized if the consumer's perceived marginal cost of consumption matched benchmark preferences.

Because the benchmark parameters depend on the choice of VSL and discount rate, a lower VSL and a higher discount rate would result in a lower "re-evaluated" welfare gain. Abaluck (2011) indicates, however, that the change in the estimated welfare gain would be approximately proportional to the change in the discounted value of a statistical life year (VSLY). Therefore, the ratio of an alternate discounted VSLY to the average discounted VSLY used by Abaluck can be applied as a scaling factor to obtain estimates of the "re-evaluated" welfare gains under alternate normative benchmark values.

Given that the average welfare gain estimated by Abaluck (2011) is similar to the gain for an individual with 37 remaining years and assuming a present discounted value of life of $6.4 million (in 2000$), FDA finds that the VSLY is equal to $334,333 at a 4 percent discount rate (in 2000$). Since individuals gain additional life-years at the end of their life, FDA discounts this

value over 37 years at 4 percent and converts it to 1990 dollars (with a GDP deflator of 0.814) to yield an average discounted VSLY of $63,800 (= 334,333×[1/1.04^{37}]×0.814).

In previous regulatory impact analyses, FDA used a primary VSLY of $219,626 (in 2011$) and discount rates of 3 percent and 7 percent. Additionally, FDA adjusts for future income growth using an average annual growth rate from 2001 to 2011 in real GDP per capita of 0.7 percent and an income elasticity of 0.5 (Ref. 72). Using this preferred methodology for valuing life-years, FDA estimates a discounted VSLY of $53,320 (in 1990$ using a GDP deflator of 0.637) at a 3 percent discount rate (= {[219,626 × (1.007^{37})$^{0.5}$]/1.03^{37}} × 0.637) and $13,022 (in 1990$) at a 7 percent discount rate (= {[219,626 × (1.007^{37})$^{0.5}$]/1.07^{37}} × 0.637).

Dividing the FDA preferred discounted VSLY by the discounted VSLY used by Abaluck (2011) yields the ratio which FDA uses to calibrate the "re-evaluated" gains according to our preferred benchmark parameters. The relative "re-evaluated" annual gains per person would equal 0.836 (= 53,320/63,800) at a 3 percent discount rate and 0.204 (= 13,022/63,800) at a 7 percent discount rate times those reported by Abaluck.

Similarly, FDA adjusts the welfare estimates from Abaluck (2011) and estimates the welfare gains for children and adolescents (0 to 14 years of age). Using the average predicted life expectancy at birth for individuals born between 1998 and 2010 (i.e., 2 to 12 year olds) from the U.S. Census Bureau Statistical Abstract of the United States, FDA assumes that children have 70.3 (= 77.3 – 7) remaining life years. Since individuals gain additional life-years at the end of their life, FDA discounts the VSLY used in Abaluck (2011) over 70.3 years at 4 percent and converts it to 1990 dollars to yield an average discounted VSLY of $17,283 (= 334,333×[1/1.04$^{70.3}$]×0.814). FDA estimates a discounted VSLY of $22,380 (in 1990$) at a 3 percent discount rate (= {[219,626 × (1.007$^{70.3}$)$^{0.5}$]/1.03$^{70.3}$} × 0.637) and $1,537 (in 1990$) at a 7

percent discount rate (= {[219,626 × $(1.007^{70.3})^{0.5}$]/$1.07^{70.3}$} × 0.637). Then the relative "re-evaluated" annual gains per person would equal 1.295 (= 22,380/17,283) at a 3 percent discount rate and 0.089 (= 1,537/17,283) at a 7 percent discount rate times those reported by Abaluck (2011).