REGULATORY IMPACT ANALYSIS FOR FINAL RULES ON:

"FOOD LABELING: REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS"

DOCKET NO. FDA-2012-N-1210

AND

"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 (formerly Docket No. 2004N-0456)

REGULATORY FLEXIBILITY ANALYSIS

PAPERWORK REDUCTION ACT OF 1995

Executive Summary

The Nutrition Facts Label Final Rule amends our labeling regulations for foods to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The Serving Size Final Rule amends our regulations on serving sizes based on newer consumption data and other recent scientific evidence to provide updated serving size information on the label to assist consumers in maintaining healthy dietary practices. These final rules' impacts are characterized by substantial uncertainty, with annualized benefits shown in our sensitivity analysis to potentially range between $0.2 and $2 or $5 billion, and annualized costs ranging between $0.2, $0.5 and $0.8 billion, over the next twenty years (2014 dollars) at seven percent interest. This analysis will be made available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.

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I. Analysis of Impacts

A. Introduction

FDA (FDA or we) has examined the impacts of the final 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 (Pub. L. 104-4). The final rules (collectively, the nutrition labeling final rules or the final rules) include the following:

1. Title: Food Labeling: Revision of the Nutrition and Supplement Facts Labels. (Docket No. FDA-2012-N-1210)

2. Title: Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling (DCL); Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed (RACCs); Serving Size for Breath Mints; and Technical Amendments. (Docket No. FDA-2004-N-0258 (formerly Docket No. 2004N-0456)).

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 final rules on nutrition labeling in the Federal Register. We have developed one final Regulatory Impact Analysis (RIA) that assesses the impacts of the two final rules taken together. We believe that the final rules, taken as a whole, are an economically 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

final rules are small, but not negligible, and as a result we find that the final rules, taken as a whole, will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. These final rules, taken as a whole, would result in an expenditure that meets or exceeds this amount.

B. Summary of the Final Rules

Food Labeling: Revision of the Nutrition and Supplement Facts Labels (the Nutrition Facts Label rule)

The purpose of this final rule is to amend our labeling regulations for foods to provide updated nutrition information on the label to assist consumers in making informed purchasing decisions. As such, we are:

- Updating the list of nutrients that are required or permitted to be declared.
- Updating the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs) based on current dietary recommendations from consensus reports.
- Establishing a DRV for added sugars and requiring the declaration of the percent Daily Value (DV) for added sugars.
- Providing a definition of dietary fiber.

- Establishing DRVs and RDIs for nutrients in foods[1] purported for infants up to 12 months, young children (1 through 3 years), and pregnant and lactating women.
- Modifying the categorization of the subpopulation of children ages 2 through 4 years to children 1 through 3 years of age.
- Requiring 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.
- Increasing the prominence of calories and the serving size information; right-justifying the quantitative amounts of the serving size information if adequate space is available; removing the declaration of "Calories from fat"; declaring added sugars as an indented listing, "Includes 'X' g Added Sugars," directly beneath the listing for "Total Sugars"; declaring the quantitative amounts - in addition to percent DVs - of mandatory vitamins and minerals, and for voluntarily declared vitamins and minerals, when declared, permitting the voluntary declaration of quantitative amounts and percent DVs; modifying the footnote; and adding a horizontal line directly beneath the "Nutrition Facts" or "Supplement Facts" heading.

Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; DCL; Updating, Modifying, and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments (the Serving Size rule)

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

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

- A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount be considered a single-serving container, and the entire content of the product be labeled as one serving, including products that have RACCs of 100 g (or 100 mL) or larger.
- The serving size of a product in a multi-serving package containing discrete units in which each discrete unit contains at least 200 percent of the applicable reference amount be the amount that approximates the reference amount.
- Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 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 300 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 column 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 (NHANES), 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. Summary of Costs and Benefits

Summary of Costs

Costs of complying with the final rules may include undertaking a minor label change or an extensive or major label redesign; reformulating products to continue to make certain health claims and nutrient content claims or as a result of the requirement to display new information on the product label; recordkeeping costs associated with making and keeping records sufficient to verify the label declaration for the amounts of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid; research and additional labeling costs related to the new dietary fiber definition; and labeling costs associated with future Universal Product Code (UPC) growth. Each is discussed in turn.

Labeling costs have been summed across an estimate of the total number of products for which label changes may result from the final rules using FDA's Labeling Cost Model (Ref. 1), developed by Research Triangle Institute (RTI). We estimate that there would be over 30,000 manufacturers and close to 800,000 UPCs for which label changes may result after implementation of the final rules. The estimated present value (PV) of the labeling costs of the final rules, over the next 20 years[2] and assuming the same compliance dates for both rules, ranges from $1,405 million to $4,578 million, with an estimated mean[3] cost of $2,720 million

[2] We believe that 20 years is an appropriate time horizon to show the likely implications of the final rules. A ten-year time horizon might underrepresent the full effects of the rules due to limited or no benefits accruing prior to the compliance dates. 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.

[3] Throughout this document, "mean" refers to the mean of a distribution of values, not to the mean of the low and high values.

(2014$)[4], using a 3 percent discount rate, and ranges from $1,331 million to $4,369 million, with an estimated mean cost of $2,570 million (2014$), using a 7 percent discount rate. The uncertainty in the estimates is due largely to the highly variable costs of printing methods utilized by manufacturers (Ref. 1).

Reformulation costs have been summed across an estimate of the total number of formulas for which reformulation is projected as a result of the final rules using FDA's Reformulation Cost Model (Ref. 2), developed by RTI. We estimate the PV of the reformulation costs of the final rules over the next 20 years to be between $651 million and $2,682 million, with an estimated mean cost of $1,446 million (2014$). The uncertainty in the estimates is due to the highly variable costs of the various steps in the reformulation process undertaken by manufacturers (Ref. 2).

The PV of recordkeeping costs over the next 20 years is estimated to be $21.4 million at a 3 percent discount rate and $21.3 million at a 7 percent discount rate (2014$). Related to the new definition of dietary fiber, the PV of study costs over the next 20 years is estimated to be roughly $4 million (2014$), and the PV of additional labeling costs over the next 20 years is estimated to range from $176 million to $1,101 million, with a mean estimate of $430 million (2014$).[5] Finally, the PV of labeling costs associated with future UPC growth over the next 20 years is estimated to range from $66 million to $198 million, with a mean estimate of $135 million, using a 3 percent discount rate, and from $35 million to $107 million, with a mean estimate of $72 million, using a 7 percent discount rate.

[4] By 2014$ we mean that the amounts are in 2014 dollars.
[5] The PVs of reformulation, fiber study, and additional labeling costs are equivalent at 3 or 7 percent because we estimate that these one-time costs are incurred upon publication of the rules instead of at the end of the compliance period.

To summarize, the PV of total costs over the next 20 years ranges from $2,323 million to $8,584 million, with a mean estimate of $4,756 million (2014$), using a 3 percent discount rate. Using a 7 percent discount rate, the PV of total costs over the next 20 years ranges from $2,218 million to $8,284 million, with a mean estimate of $4,543 million (2014$).

Summary of Benefits

The Nutrition and Supplement Facts labels contain nutrient content information that can help people maintain healthy dietary practices. The growth in the prevalence of obesity and diabetes and 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. The final rules will help consumers maintain healthy dietary practices by (i) better aligning the information provided on the Nutrition and Supplement Facts labels with new data on consumption, scientific evidence on the relationship between nutrition and chronic disease, and dietary recommendations and (ii) improving the design and content of the Nutrition and Supplement Facts labels to make relevant label information more salient and easy to understand so that consumers can make more informed consumption decisions. The final rules may also potentially prompt industry to reformulate products to maintain health and nutrient content claims, and reformulate products based on new label information required by the final rules.

To illustrate the quantification of the benefits of the final rules, we extrapolated from the welfare effects estimated in a retrospective study on the impact of the Nutrition Labeling and Education Act of 1990 (NLEA) by Abaluck (2011) (Ref. 3). Abaluck (2011) measured consumer welfare gains as the willingness-to-pay (WTP) for nutrient content based on revealed preference data, i.e., data on food consumption and prices. We lack direct evidence with which

to scale Abaluck's estimates of the effect of NLEA in a manner that precisely reflects the impacts of other changes in nutrition labels; therefore, throughout this analysis we incorporate uncertainty ranges so as to assess the sensitivity of benefits estimates to key analytic inputs. The extent of the uncertainty is highlighted by the wide range of numerical benefits results; the PV over the next 20 years ranges from $2.8 billion to $77.7 billion, with a mean estimate of $33.1 billion (2014$), at a discount rate of 3 percent, and ranges from $1.9 billion to $52.5 billion, with a mean estimate of $22.3 billion (2014$), at a discount rate of 7 percent.[6]

Table 1 - Summary of the Primary Sensitivity Analysis of the Costs and Benefits of the Final Rules (in billions of 2014$)

PV	**Benefits** (Low)	**Benefits** (Mean)	**Benefits** (High)	**Costs** (Low)	**Costs** (Mean)	**Costs** (High)
3%	$2.8	$33.1	$77.7	$2.3	$4.8	$8.6
7%	$1.9	$22.3	$52.5	$2.2	$4.5	$8.3
Annualized Amount						
3%	$0.2	$2.2	$5.2	$0.2	$0.3	$0.6
7%	$0.2	$2.1	$5.0	$0.2	$0.4	$0.8

Notes: Costs estimates reflect an assumption that the rules have the same compliance date. Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

D. Need for Regulation

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.

[6] There is substantial uncertainty regarding the impacts of the two nutrition labeling rules. For a full discussion of the uncertainty, please see the Welfare Estimates – Primary Sensitivity Analysis section of this Regulatory Impact Analysis.

Before NLEA, consumers lacked access to nutrition information for specific product categories. After promulgating a series of regulations implementing NLEA, 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, FDA, through our requirements to provide Nutrition and Supplement Facts labels, requires that manufacturers convey relevant nutrition information to consumers. This information, which consumers value (Ref. 3), can be used by consumers to better inform choices at the point of purchase.

To the extent that there is information failure with respect to nutrition information, the revisions to the Nutrition and Supplement Facts labels may provide relief. If the revised labels provide fewer barriers to obtaining nutrition information, they may further assist consumers in making healthier dietary choices by facilitating access to, and understanding of, the information about the underlying nutrient amounts in prepackaged foods. This is because, as discussed in the preambles of the Nutrition Facts Label and Serving Size rules, the revised labels will reflect more recent science. Thus, the final rules may reduce information failure arising from lack of consumer access to sufficient information, and understanding of that information, and therefore may assist consumers in making healthy dietary choices.

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. 4 - 7).[7] 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. 4). The author suggests that we can characterize decisions related to eating and body weight as an interaction between a "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. 4).[8] 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. 8).[9]

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

[7] 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 he or she chooses 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.

[8] 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).

[9] Several other behavioral economics models exist. These models can account for the seemingly irrational behaviors of overeating 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. 4, 6 - 9).

their underlying or true preferences, leading them to regret their decisions at a later date.[10] 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 DCL format cues the consumer into the caloric consequences of consuming the entire package or discrete unit, as applicable. Similarly, the DCL format and the added sugars declaration may encourage individuals to consume less energy dense and nutrient poor foods by 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. Some research has found evidence that increased portion sizes of food products may have contributed to the obesity epidemic (Ref. 11). 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. One study suggests that package and portion size influence consumers' intake of food products (Ref. 12). 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. 12 - 14). The DCL provision of the final 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, may provide a contextual cue to consumers

[10] Bounded rationality refers to the idea that there are limits (e.g., limited time, limited computing power, limited information) to the ability of people to engage in rational decision making. Because of such limits, individuals typically 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. 10).

that the package or discrete unit contains more than one serving and may aid consumers in calculating the amount of calories and nutrients in a particular package. 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 may increase the usefulness of nutrition information on packaged foods. Additionally, given that the Nutrition Facts Label final rule will require the declaration of added sugars and that the 2015 Dietary Guidelines Advisory Committee ("DGAC") and 2015-2020 Dietary Guidelines for Americans ("DGA") recommend limiting calories from 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 final rules include:

- Increased knowledge of the nutrient content of packaged foods, which may help consumers make healthier food choices; and
- Increased ease of nutrition label use from the availability of more easy-to-understand information for products that bear DCLs.

These effects may help reduce the information failure and increase the salience of the information on food packages, thereby assisting consumers in maintaining healthy dietary practices.

Other major predicted elements of the consumer and industry response to the nutrition labeling final rules include:

- 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.

E. Single Analysis for the Two Final Rules

We prepared this RIA for the two final rules together, since the two final rules involve some form of a label change. Promulgating the requirements for the final label changes together would allow manufacturers to undertake all of the revisions to the Nutrition or Supplement Facts label under one label change. For example, for manufacturers that would be required to make label changes under the Serving Size and Nutrition Facts Label rules, it would be more efficient to make changes to their product's serving size and to the other information on the Nutrition or Supplement Facts label at the same time. If promulgated and made effective at different points in time, these final rules could require manufacturers to make two label changes: one for the changes required under the final Serving Size rule and one for the changes required under the Nutrition Facts Label final rule. Two distinct label changes could result in greater cost.

F. Coverage of the Rule and Industry Overview

The nutrition labeling final rules, together, cover all manufacturers of foods that are required by FDA to provide nutrition labeling. This represents over 30,000 manufacturers that manufacture close to 800,000 UPCs. We estimate that approximately 99 percent of the covered firms are small businesses as defined by the Small Business Administration (SBA). SBA's definition of a small business, as it is applied to food manufacturers, includes those entities that have less than 500 employees.

Table 2 - Industry Coverage Breakdown By Final Rules

Final Rule	**Type of Label Change**	**Covered UPCs**
Nutrition Facts Label		
Conventional Food	Minor	375,532
Conventional Food	Major	5,297
Dietary Supplements	Minor	64,194

Dietary Supplements	Major	191
Total Nutrition Facts Label UPCs		445,214
Serving Size		
Conventional Food	Minor	255,852
Conventional Food	Major	76,363
Conventional Food	Extensive	2,817
Total Serving Size UPCs		335,032
Total UPCs		780,246

Table 2 presents the industry coverage breakdown by the two final rules and the type of label changes or re-designs each entails. A minor label change is defined as a one-color/printing plate change that does not require a label redesign (Ref. 1). Examples include one or more of the following: 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 (affecting one color/plate) (Ref. 1). A major label change is defined as a multiple color/printing plate change that requires a label redesign (Ref. 1). Examples include changes to the name of the product; changes to the standard of identity or fanciful (trade) name for a food product; the requirement for a product to provide a Nutrition or Supplement Facts panel when none was previously required; 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. 1). An extensive label change is defined as a major format change that requires a change to the product packaging to accommodate labeling information (Ref. 1). Examples include the addition of a peel-back label and increases in the package surface area for labeling information.

The Nutrition Facts Label rule will require significantly more label changes and will cover more UPCs and manufacturers than will the Serving Size rule. A substantial majority of the required labeling changes under the Nutrition Facts Label rule would be minor. However, certain changes in nutrient DVs and the new definition of dietary fiber may 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. While, as discussed in the Nutrition Facts Label rule and Serving Size rule, we may reevaluate claim requirements in light of the changes we are making to be less stringent than what is set forth in these rules, for the purposes of this analysis, we assume that no changes to claim requirements are made. To the extent that requirements for certain nutrient content claims and health claims may change in response to the changes made in the Nutrition Facts Label and Serving Size rules before the compliance dates for these rules, this analysis could overestimate the costs to manufacturers in complying with the Nutrition Facts Label and Serving Size rules.

Under the Serving Size rule, certain products would have to undertake minor label changes related to the updating, modifying, and establishing of RACCs for certain products, and also related to the change in the definition of a single-serving container and the change in serving size for a product in a multi-serving package in discrete units in which each discrete unit contains at least 200 percent of the RACC. Additionally, for certain products (i.e., those that are packaged and sold individually that contain at least 200 percent and up to and including 300 percent of the applicable RACC and those containing discrete units that contain at least 200 percent and up to and including 300 percent of the applicable RACC) the DCL provisions of the Serving Size rule would require manufacturers to undertake a major label change. Also, certain

changes in RACCs will require manufacturers to either reformulate some products 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. Finally, the change in the definition of a single-serving container to require products that have RACCs of 100 g or 100 mL or larger and that are packaged such that they contain more than 150 percent but less than 200 percent of the RACC to be defined as a single-serving container (versus offering such products the option of being labeled as one or two servings) will require some manufacturers to increase the package size of their products if they want to continue to make a health or nutrient content claim, which entails an extensive labeling change.[11,12]

Under the combined effects of both rules, some products will be required to bear a Nutrition Facts panel when such information was not previously required.[13] The addition of a Nutrition Facts panel when none was required previously entails a major labeling change.

[11] Consider, as an example, UPC X. UPC X has a RACC of 100 g, contains 0.4 g of fat per RACC, and as packaged contains 160 g of product (proportionally, UPC X contains 0.64 g of fat per 160 g of product). UPC X is currently labeled as containing 2 servings. Under preexisting 21 CFR 101.62(b), UPC X would be permitted to make a fat-free claim on its label, as UPC X contain less than 0.5 g of fat per RACC and per labeled serving (UPC X contains 0.4 g of fat per RACC and 0.32 g of fat per labeled serving). Under the final rules, UPC X would be required to be labeled as a single serving and so would contain 0.4 g of fat per RACC but 0.64 g of fat per labeled serving. Thus, under the final rules, UPC X would no longer satisfy the requirements to make a fat-free claim. If UPC X changed its package size to, for example, contain 450 g of product, then UPC X would be able to keep its fat free claim.

[12] Even though the cost of reformulation is less than half the cost of increasing the package size, it is unlikely that in the situation where the change to the serving size requirements affects the ability of a manufacturer to make a claim, that manufacturers of affected products would choose reformulation in lieu of increasing the package size, as reformulation would result in some package sizes having a different formulation, and therefore a potentially different taste, than other package sizes of the same general product. It is also unlikely that in this instance manufacturers would choose the relatively cheaper option of claim removal in lieu of increasing the package size, as this would result in some package sizes carrying the claim and others not carrying the claim despite the fact that all package sizes would contain the same formulation of the product.

[13] Such products may include, for example, unsweetened instant coffee and tea, which may no longer contain "insignificant" amounts of potassium due to the combined effects of the Nutrition Facts label and Serving Size final rules, and bottled water, which may no longer contain "insignificant" amounts of sodium under the Nutrition Facts final rule, the Serving Size final rule, or both (see 21 CFR 101.9(j)(4)). While, as noted in the Serving Size final rule, we are declining to amend the definition of "insignificant" in 21 CFR 101.9(j)(4) at this time, we intend to consider the applicability of an exemption from nutrition labeling requirements in a future rulemaking with respect to certain products and, until such time as we have had the opportunity to consider such matters further, intend to consider the exercise of enforcement discretion with respect to mandatory nutrition labeling on products that would have been exempt from nutrition labeling requirements under § 101.9(j)(4) prior to the effective date of the two

It is important to note that there is significant overlap in terms of which food manufacturers will be required to make labeling changes or reformulate their products as a result of both final rules. For example, many food manufacturers that will have to update some of the nutrition information for their products will also have to update the serving size information for their products. Additionally, all food manufacturers that will be affected by changes that result from implementation of the Serving Size final rule will also be required to change their labeling as a result of the Nutrition Facts label final rule. This overlap, as previously mentioned in Section D of this document, allows firms to avoid a significant portion of the costs that would otherwise be incurred, by undertaking all of the required label changes via one label change.

G. Comments on the Preliminary Regulatory Impact Analysis (PRIA) and the Supplemental PRIA and Our Responses

FDA's proposed rules "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (Docket No. FDA-2012-N-1210) and "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) were published on March 3, 2014, and their comment period ended on August 1, 2014. In addition, we published a supplemental notice to the proposed rule "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" titled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions" on July 27, 2015 (Docket No. FDA-2012-N-1210) and its comment period ended on

rules. However, to avoid underestimating the potential costs to industry that may result from the combined effects of the two rules, our analysis in this document considers the costs to industry assuming manufacturers of products that were previously exempt from nutrition labeling requirement were to make labeling changes to include nutrition labeling.

October 23, 2015. We prepared PRIAs in connection with the proposed rules and supplemental notice. In this section, we summarize and respond to the comments we received on those PRIAs. We have numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) Some comments stated that manufacturers will need to analyze products related to the mandatory declarations of potassium, vitamin D, and added sugar.

(Response 1) In this final RIA, analytical testing costs are included in our labeling cost estimates. Currently, there are no analytical methods that can distinguish between added and naturally occurring sugars. In such cases, manufacturers must make and keep certain written records to verify their declaration of added sugars on the Nutrition or Supplement Facts label. We accounted for these kinds of recordkeeping costs in the PRIA and continue to account for them in this final RIA.

(Comment 2) Some comments expressed concern that under the proposed rules manufacturers will no longer be allowed to use the word "folate" on the Supplement Facts label, but instead will be required to use the term "folic acid." The comments stated that as a result companies currently using dietary folate in their products would need to reformulate to remove the folate and replace it with folic acid.

(Response 2) Under the final rules, both "folate" and "folic acid" will be required to appear on the Supplement Facts label.

(Comment 3) Some comments stated that certain changes to RACCs and DVs called for by the proposed rules will require manufacturers to reformulate to maintain health and nutrient content claims tied to these RACCs and DVs.

(Response 3) We accounted for these types of reformulation costs in the PRIA (see p. 29) and continue to account for them in this final RIA.

(Comment 4) With regards to the dietary fiber citizen petition process, some comments stated that if the proposed process is kept, it is unlikely that FDA will have reviewed all fibers and notified manufacturers in time for compliance with the 2 year time limit, thus requiring manufacturers of products with extrinsic fibers to change the label twice, once to comply with the proposed rules and a second time once the fiber is approved.

(Response 4) In this final RIA, we estimate the cost of an additional label change for the approximately 20 percent of UPCs which we estimate might have to change their label twice related to the citizen petition review process.

(Comment 5) Some comments stated that the FDA's proposed changes to labeling single-serving containers will make some foods ineligible to make health or nutrient content claims. Comments noted that there will be instances in which products in large packages (i.e., those greater than 200 percent of the RACC) will be able to make a health or nutrient content claim while the smaller package size version (between 150 and 200 percent of the RACC) of the same product will not be able to make such a claim because the latter is considered a single serving, thus requiring manufacturers to either reformulate or repackage their product to continue to make the claim, relabel to remove the claim, or remove the product from the market.

(Response 5) In this final RIA, we account for this possibility very conservatively[14] by estimating the cost of an extensive label change (repackaging) for all UPCs which both (i) contain a health or nutrient content claim and (ii) are packaged such that they contain

[14] "Conservative" cost estimates are cost estimates which, because of data and other limitations, are likely overestimated.

more than 150 percent and less than 200 of the RACC. However, we do not believe that the changes to the single-serving container requirements will affect a lot of UPCs that make nutrient content claims or health claims, because some UPCs containing more than 150 percent and less than 200 percent of the RACC are already labeled as one serving, and further, eligibility to make a nutrient content claim or health claim is generally dependent on the RACC for a product (not the serving size).

(Comment 6) Some comments questioned our choice of a 2-year compliance period given that the PRIA showed that net benefits are maximized under a 4-year compliance period.

(Response 6) Under the final rules, the compliance period is 36 months for small businesses and 24 months for large businesses. (As noted previously, for purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more.) We believe that this provides industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner.

(Comment 7) Some comments expressed concern that the proposed rules might increase the amount of space presently occupied by the Nutrition Facts Panel.

(Response 7) The Nutrition Facts label will occupy more space on a product's package in the case of DCL and in cases when a Nutrition Facts label was not previously required (see footnote 8). The costs associated with DCL were captured in the PRIA, and we continue to capture them in the final RIA. The costs associated with providing a Nutrition Facts label when one was not previously required are captured in this final RIA.

(Comment 8) Some comments expressed concern that the footnote will not be finalized until after the publication of the final rule, which could require an additional labeling change.

(Response 8) The footnote language is included in the final rule. Therefore, manufacturers would be able to include the footnote language in the same label change as any other of the required changes under the two rules.

(Comment 9) Some comments expressed concern that with respect to the use of nutrient content claims and health claims on products with DCL, the FDA is proposing to require a statement accompanying the claim clarifying that the level of the nutrient that is the subject of the claim is based on the RACC. The commenters expressed concern that this could result in additional labeling costs.

(Response 9) The labeling costs associated with this (major label change) are subsumed under the labeling costs associated with adding a DCL (major label change), which were captured in the PRIA and continue to be captured in the final RIA. Other concerns relating to the requirement to add a statement accompanying such claims are addressed in the Serving Size final rule.

(Comment 10) Some comments have requested that FDA articulate in the final rules how FDA intends to monitor and measure any public health impacts of the final rules for the purpose of eventually conducting a retrospective analysis.

(Response 10) Although no new data collection required by this rulemaking would necessarily help to facilitate a retrospective review, FDA does expect to monitor and review the effects of these final rules, as emphasized in Executive Order 13563. This will most likely occur through analysis of public data sources, such as NHANES.

(Comment 11) One comment stated that in the "Need for Regulation" section of the PRIA, we described a market failure that might exist but did not demonstrate that the market failure actually does exist.

(Response 11) We have identified the problems that the rule is intended to address and assessed the significance of those problems consistent with Section 1(b)(1) of Executive Order 12866, which requires us to identify the problem that the rule intends to address as well as assess the significance of that problem (Executive Orders 13258 and 13422, which previously amended Executive Order 12866, were revoked by Executive Order 13497 on January 30, 2009). In the "Need for Regulation" section of the PRIA, we identified the problems of information failure and intrapersonal market failure that the proposed rules would intend to address, if finalized, and we continue with this approach in the final RIA. The PRIA further explained that the information failure results from a lack of consumer access to certain nutrition information, stating that "[g]iven 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." We assessed the significance of intrapersonal market failure utilizing citations from the behavioral economics literature and citations of consumer research that support the importance of salience and cues in consumption decisions. We continue to assess the significance of information failure and intrapersonal market failure in these ways in the final RIA.

(Comment 12) Some comments stated that the increase in the Vitamin D DV combined with current Vitamin D fortification limits could jeopardize the ability of some manufacturers

to make related nutrient content and health claims, forcing them to remove such claims from their labels.

(Response 12) We estimated in the PRIA, and continue to estimate in the final RIA, the number of UPCs which will either relabel to remove a health or nutrient content claim or reformulate to maintain a health or nutrient content claim as a result of the various DV changes described in the proposed rules. We estimated in the PRIA, and continue to utilize this estimate in the final RIA, a 50 percent/50 percent relabel/reformulate split before assigning costs to these UPCs. We asked for comment on these estimates. The comments we received are discussed later in this document.

(Comment 13) Some comments expressed concern that the increase in the coffee RACC size could bring Potassium levels above the two percent threshold, positing the first and only criterion on which the industry would need to change packaging to add a Nutrition Facts Panel.

(Response 13) In the final RIA, we estimate the cost of adding a Nutrition Facts label from scratch for products, including certain coffee, tea, and bottled water products, that would be required to add a Nutrition Facts label based on the final rules.[15] As noted in the Serving Size final rule, however, we intend to consider the applicability of an exemption from nutrition labeling requirements in a future rulemaking with respect to certain products, and until such time as we have had the opportunity to consider such matters further, we intend to consider the exercise of enforcement discretion with respect to mandatory nutrition labeling products that would have been exempt from certain nutrition labeling under § 101.9(j)(4) prior to the effective date of the final rules. This final RIA,

[15] See footnote 13.

however, nonetheless considers the costs to industry that would result from adding a Nutrition Facts label to certain coffee, tea, and bottled water products that previously were not required to provide a Nutrition Facts label.

(Comment 14) A comment questioned our estimate regarding the percentage of affected UPCs which will reformulate to maintain health and nutrient content claims related to various changes described in the proposed rules (50 percent), as well as our estimate regarding the percentage of affected UPCs which will reformulate to reduce added sugar content in response to the added sugar declaration described in the proposed rules (5 to 6 percent), stating that we provide no basis for these estimates.

(Response 14) While some affected products will be relabeled and some will undergo reformulation, we have identified no data with which we are able to project the percent of products that will be relabeled and the percent that will undergo reformulation. In the absence of data, the PRIA estimated that half of the affected products will be relabeled and the other half will be reformulated, and we asked for comment on these estimates in lieu of reliable data about how manufacturers might respond to the proposed rules. Neither this comment nor any other information we received in response to the PRIA provided further basis upon which to adjust these assumptions, and so we retain our initial assumptions in this final RIA.

(Comment 15) A comment stated that each of the changes to the Nutrition Facts label on its own represents a minor label change, but taken together such changes represent a major label change.

(Response 15) When the changes to the Nutrition and Supplement Facts labels described in the proposed rules are such that only one new printing plate must be cut for the black printing

of the label, such a change is defined by the FDA Labeling Cost Model as a minor label change. Thus, multiple revisions required by the two rules that require only one new printing plate to be cut for the black printing of the label are considered a minor label change.

(Comment 16) A comment stated that under the Serving Size rule, we incorrectly only included conventional foods in our cost analysis.

(Response 16) None of the provisions of the Serving Size rule affect dietary supplements. The changes to DCL requirements appear in 21 CFR 101.9, and under 21 CFR 101.9(j)(6), dietary supplements are exempt from the requirements of 21 CFR 101.9 and must be labeled in compliance with 21 CFR 101.36. Additionally, the final amendments to 21 CFR 101.12 did not alter the requirements for dietary supplements.

(Comment 17) A comment stated that the new breath mint serving size requirement was omitted from our cost analysis.

(Response 17) For purposes of this analysis, the labeling costs associated with the new breath mint serving size requirement were captured in Table 4 of the PRIA under "Conventional Food," "Changes Due to RACC Proposals" and are captured similarly in the final RIA.

(Comment 18) A comment stated that in the PRIA the estimate of UPC counts is dated and insensitive to changes in future UPC counts. The comment further stated that this is inconsistent with how population is treated in the benefits section of the PRIA, saying that while it may be true that the Labeling Cost Model is based on 2008 data, it should be possible to scale costs based on actual and projected growth of UPC labels since 2008.

(Response 18) We estimated labeling costs using 2008 data in the proposed rules and 2012 data in the final rules (the Labeling Cost Model has been updated so that the conventional

food and dietary supplement UPC counts are now based on 2012 data and labeling costs are estimated in the final RIA using this updated version of the Labeling Cost Model).

We acknowledge that the labeling costs of the final rules do depend in part on the number of new UPCs in the future which will need to change their labels because of the final rules. According to the FDA Labeling Cost Model, the addition of a Nutrition or Supplement Facts panel to a previously unlabeled UPC, such as to a new UPC, represents a major label change. New UPCs under the final rules would have had to add a label under NLEA, which is to say that new UPCs under the final rules would have had to make a major label change under NLEA. Thus, the labeling costs for future UPCs subject to minor and major label changes under the final rules would not generally be considered a cost of the final rules. However, future UPC growth is relevant for UPCs that would need to bear a Nutrition Facts Panel for which none was previously required and UPCs which would require an extensive label change. We estimate that a fixed fraction of future UPCs fall into these categories, and we estimate associated labeling costs for UPCs affected by these requirements over the next 20 years.

(Comment 19) A comment stated that it is likely that the single-serving and DCL provisions of the proposed rules will create an incentive for food firms with UPCs in these categories to create new package sizes. The comment stated that, for example, if a package of cookies has 350 percent of the RACC, the firm may want to increase the package size to over 400 percent to avoid the DCL requirement. The comment concluded by stating that we ignored such costs.

(Response 19) According to the FDA Labeling Cost Model, the costs of increasing package size are roughly forty times the cost of adding a DCL. Thus, we estimate that most

manufacturers would choose to add a DCL to their existing package in lieu of increasing the size of their existing package. We captured DCL costs in the PRIA and continue to capture them in the final RIA. We also note that the example of the package size provided in the comment would no longer be required to provide a DCL on a per-package basis, as the Serving Size final rule will require a second column of nutrition information on packages containing at least 200 percent and up to and including 300 percent of the RACC (see § 101.9(b)(12)), subject to certain exceptions.

(Comment 20) A comment stated that an important cost of each regulation is the cost to government from enforcing that regulation. The comment concluded by saying that we did not account for such costs in the PRIA.

(Response 20) According to the most recent version (9/17/2003) of the Office of Management and Budget's (OMB's) Circular A-4, these costs, like all categories of impacts, should be included in the analysis only when they are significant. Based on internal data, we estimate the current cost of labeling enforcement efforts to be roughly $1.3 million per year (2014$), and we do not expect a significant increase in such efforts as a result of the final rules. Thus, in the case of the proposed rules, as well as the final rules, we do not consider these costs to be significant. Therefore, they are not captured in the PRIA or in this final RIA.

(Comment 21) A comment stated that throughout the cost section of the PRIA, we do not explain the criteria used to determine the categorization of UPC data, saying that this lack of transparency makes it difficult to assess the validity of the cost estimates. The comment requested more detail.

(Response 21) This comment refers in part to our description of the Labeling Cost Model in the PRIA. Greater detail regarding the Labeling Cost Model is provided in the Labeling Cost Model report, which we cited in the PRIA and made available on regulations.gov, and continue to cite in the final RIA and make available on regulations.gov. We provide additional detail in this final RIA related to how we obtained our estimates of the number of UPCs affected by the various provisions of the final rules (e.g., source of data, richer descriptions of steps in the estimation process).

(Comment 22) Some comments expressed concern about the fact that the Abaluck paper cited in the benefits section of the PRIA is unpublished and, therefore, has not undergone a formal peer review process.

(Response 22) The comment period serves as a form of review of the Abaluck paper by providing the public with time to provide comments on it. In this instance, the comment period provided the public with several months to comment on the Abaluck paper that forms the basis of our analysis of the benefits of the proposed rules. We provide responses to the comments we received on the Abaluck paper later in this section.

(Comment 23) One commenter stated that by relying on Abaluck to estimate the benefits of the proposed rules, we are assuming that the proposed rules and NLEA have similar impacts.

(Response 23) We disagree. Our starting point for estimating the benefits of the proposed rules was the benefits associated with the original Nutrition and Supplement Facts label that was mandated by NLEA that were estimated by Abaluck. We then acknowledged that the proposed rules and NLEA do *not* have similar impacts, stating on p. 48 of the PRIA that ". . . 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" before proceeding to adjust Abaluck's benefits estimates downward to reflect the effect of the proposed rules by the factors outlined on pp. 48 – 56 of the PRIA. We retain this approach in the illustrative calculations that appear in the final RIA.

(Comment 24) Some comments expressed concern that we did not individually estimate the costs and benefits of each of the changes described in the proposed rules.

(Response 24) The way in which we estimated the benefits of the proposed rules is such that we were unable to disentangle the marginal benefit of each of the changes described in the proposed rules. This continues to be true for our illustration of the benefits of the final rules. We were unable to measure the marginal cost of each individual change described in the proposed rules because the various costs associated with the proposed rules are too interdependent to allow us to do so, and this continues to be true for our estimate of the costs of the final rules. For example, a UPC subject to DCL would need to undergo a major label change assuming the product had not previously provided a DCL on a voluntary basis, the cost of which would also cover the various changes to the Nutrition and Supplement Facts Panels described in the proposed rules. As a second example, a UPC would need to undergo a minor label change whether the UPC makes one or all of the various changes to the Nutrition and Supplement Facts Panels described in the proposed rules.

(Comment 25) Some comments expressed disagreement with the s_1 parameter of our benefits model, saying that s_1 appears to be based entirely on quantity of change, not quality.

(Response 25) We agree that our s_1 measure is based entirely on quantity, and not quality, of change, the implication of which is that each label change receives equal weight. We

took such an approach in the PRIA because, due to data and other limitations, we were unable to estimate quality weights associated with each label change. In light of such limitations, we believed that this approach represented a reasonable approximation. We retain this approach in the illustrative calculations that appear in the final RIA but note that uncertainty regarding s_1 is primarily why we maintain significant uncertainty ranges around all calculations.

(Comment 26) One comment expressed concern that Abaluck's sample is limited to women aged 19 to 50 who are the primary meal preparers in their households, stating that we address this issue in the PRIA by calculating separate benefits estimates for women only but that these estimates are not then used in the discussion of net benefits.

(Response 26) To estimate benefits, and thus net benefits, we extrapolated to the entire U.S. population because the proposed rules are expected to affect the entire U.S. population, not just women aged 19 to 50 who are the main meal planners in each household. We continue with this approach in the final RIA. However, we acknowledged in the PRIA, and continue to acknowledge in the final RIA, that Abaluck generates his WTP estimates from a sample of women 19 to 50 years of age who are the main meal planners in each household. Because we do not know for certain whether such a sample generalizes to the population as a whole, as a sensitivity analysis we estimated in the PRIA, and continue to illustrate in the final RIA, the benefits of the proposed rules based just on a female subpopulation.

(Comment 27) One comment stated that regarding the annual welfare gain per person values taken from the Abaluck paper for the ΔW parameter of the benefits model, we wisely use the structural equation estimates that Abaluck notes are a better fit but, without comment,

only uses two of the structural models in its analysis, omitting two other models with lower values ($32.10 and $28.30).

(Response 27) We relied just on Abaluck's Model 1 and Model 2 estimates in the PRIA, and continue to do so in the final RIA, due to the uncertainty surrounding the proper specification of Model 3 and Model 4. Model 3 and Model 4 disaggregate total fats into unsaturated and saturated fats, but according to Abaluck, because only total fats were listed on nutrition labels prior to NLEA, it is not clear what information, if any, we should assume label users possessed about the content of saturated or unsaturated fats in labeled foods prior to NLEA, and such prior information is a component of Abaluck's WTP estimates.

(Comment 28) One comment stated that regarding the PRIA benefit model's USE parameter, we adjust for changes in use over time by taking the ratio of post-rule label usage (77 percent in the 2009-2010 NHANES plus expected increase due to the rule) to usage soon after NLEA (65 percent, unreferenced in the PRIA). The comment stated that these two data sources may not be compatible, given that NHANES changed the mode of asking this question after 2006, saying that in NHANES 2005-2006 the question was asked in person and the respondent was shown a Nutrition Facts Panel, but starting with the 2007-2008 collection, the question was asked over the phone without a visual. The result, the comment said, was an increase from 53 percent to 72 percent usage in 2 years, which the comment believes is likely due to question format rather than to actual usage change. The comment concluded by stating that if this is being incorporated into the analysis, then we are likely overestimating changes in usage.

(Response 28) Label use soon after NLEA is not relevant to our benefits estimates. More specifically, we estimated the benefits of the proposed rules, and illustrate the benefits of the final rules, using the formula $B_t^{Label} = \Delta W^{Label} \times s_1 \times USE \times (1 - USDA) \times POP_t$. Note that $s_1 = USE_{Right\ After\ NLEA\ Publication} * (\%UPCs_{Single\ Column\ Label} * \%Single\ Column\ Label\ Content\ Changed + \%UPCs_{Dual\ Column\ Label} * \%Dual\ Column\ Label\ Content\ Changed)$ and $USE = USE_{Current} / USE_{Right\ After\ NLEA\ Publication}$. $USE_{Right\ After\ NLEA\ Publication}$ mathematically cancels. Thus, only current use is relevant to our estimate of the benefits of the proposed and final rules. In this final RIA, we continue to estimate current label use using 2009-2010 NHANES data, as these continue to be the most recent data from which this information is available. Furthermore, in this final RIA, we have updated our discussion of benefits so as to remove any mention of $USE_{Right\ After\ NLEA\ Publication}$ since it is not relevant to our benefits illustrations.

(Comment 29) One comment stated that our statement in the PRIA that "Antonuk and Block (2006) found a 13.9 percent increase in attention to the label when switching from single-column labeling (SCL) to DCL format" is not true, saying that this appears to be the case for non-dieters only and that the effect is much smaller for dieters, but that the difference in both cases is not likely to be significant (though it is not tested in the paper).

(Response 29) In the PRIA, we adjusted recent label use using this amount (13.9 percent) to estimate label use once the proposed rules take effect. However, in light of our confirmation that the differences in attention to the label when switching from the SCL to the DCL format are statistically significant neither for non-dieters nor for dieters, we do not make this adjustment in the final RIA.

(Comment 30) A comment stated that Abaluck's re-evaluated approach completely ignores the hedonic elements of food consumption and assumes that consumers only purchase food for its healthfulness. The comment said that it is possible that the entire discrepancy between Abaluck's WTP and re-evaluated estimates is due to a rational tradeoff between taste, cost, and healthfulness, not to uninternalized nutrition benefits. The comment states that it is also possible that some of the discrepancy is due to uninternalized nutrition benefits but that we give no direct evidence to support this claim. The comment concluded by saying that given that the scope of unintentional nutrition benefits is entirely speculative, use of the Abaluck quantitative estimate, which the comment says assumes that 100 percent of the discrepancy is due to unintentional nutrition benefits, is not justifiable.

(Response 30) In this final RIA, we no longer rely on Abaluck's re-evaluated estimates, which were used to estimate other sources of benefits in the PRIA, because such estimates reflect what consumers *should* be willing to pay for NLEA (based on medical evidence on the effect of diet on health) versus what they actually *are* willing to pay for NLEA, the latter which we used as the basis of our primary benefits estimates in the PRIA and which we continue to use as the basis of our benefits illustrations in the final RIA.

(Comment 31) A comment stated that the results of the Abaluck study are highly dependent on assumptions about price responsiveness. The comment stated that changes in consumption figures are converted to dollar values using price estimates from the Continuing Survey of Food Intakes by Individuals (CSFII) and price elasticity (responsiveness) estimates from other studies, but that it is impossible to assess whether

the responsiveness values used are credible or sufficiently tailored to product categories, however, because they are not cited.

(Response 31) The results of the Abaluck study are dependent on price responsiveness estimates. The comment incorrectly asserted that it is impossible to assess whether the responsiveness values used are credible or sufficiently tailored to product categories because they are not cited. The Abaluck study cites on p. 19 a 2010 *American Journal of Public Health* paper titled "The Impact of Food Prices on Consumption: A Systematic Review of Research on the Price Elasticity of Demand for Food" by Tatiana Andreyeva, Michael Long, and Kelly Brownell as his source for price elasticities for each product group.

(Comment 32) A comment stated that one stage in the calculation of welfare gains from NLEA involves scaling to account for prior knowledge and that Abaluck estimates that, pre-labeling, consumers already had knowledge of 20 percent of the information included on NLEA labels. The comment says that this estimate is cited to a study on Starbucks customers, but that no such estimates are given in the cited paper and that Abaluck gives no explanation for how the information from the cited paper is used.

(Response 32) The comment misunderstands the study on Starbucks customers. In this study, the authors conducted a survey in which Starbucks customers were asked prior to the adoption of menu calorie labeling how many calories they believed were in various Starbucks food items. Regressing these estimates of calorie content per gram on actual calorie content per gram produced a coefficient of 0.2, or 20 percent, suggesting that consumers estimate the calorie content of food items to be about 20 percent of the actual calorie content. Abaluck describes how he uses this estimate on p. 21 of his paper.

(Comment 33) A comment stated that Abaluck artificially constrains the mathematical modeling used in the study by assuming that only benefits, not adverse outcomes, can result from providing additional nutritional information. The comment says that Abaluck's model does not allow for an increase in the consumption of other food by more than the decrease in the unhealthy foods avoided, even though this behavior has been observed in many studies. The comment cites Qing Yang, "Gain Weight By Going Diet? Artificial Sweeteners and the Neurobiology of Sugar Cravings," Yale J. Biol. Med., June 2010, 83(2), 101-108 and also states that the phenomenon that decreases in one area are eclipsed by more consumption in another is well known in behavioral economics as "the Jevons effect."

(Response 33) Abaluck's satiation constraint states that individuals, on average, consume a constant *weight* of food in each day. That is to say, any decline in the *grams* consumed in some product groups must be offset by an increase in the *grams* consumed in other product groups, healthy or otherwise. Therefore, we disagree that Abaluck's model does not allow for an increase in consumption of calories from other food by more than the decrease in unhealthy foods avoided. Based on the satiation constraint, Abaluck could have found that labeling led individuals to substitute towards foods with more calories within product groups, which would have been consistent with the phenomenon described in the Yang paper cited by the comment, and would have made them worse off. Instead, Abaluck found the opposite.

(Comment 34) A comment stated that the Abaluck paper assumes that consumers will automatically improve their dietary choices in response to additional information, even though the only two empirical studies cited in his paper (Elbel, Kersh, Brescoll, and

Dixon (2009) and Bollinger, Leslie, and Sorensen (2010)) show just the opposite, that nutritional labeling in restaurants was not effective in altering dietary choices.

(Response 34) We disagree with the comment's characterization of the findings of the study conducted by Bollinger, Leslie, and Sorensen (2010), which finds a modest but statistically significant impact of calorie labeling on food consumption (6 percent reduction in calorie consumption). Abaluck also cites Mathios (2000), who finds that post NLEA there was a significant decline in sales for the highest fat salad dressings, as well as Variyam and Cawley (2006) and Variyam (2008), who examine the impact of NLEA and label use on nutrient consumption and BMI and find decreases in obesity rates among non-Hispanic white women. Only Elbel et al. (2009), who look at menu labeling in fast food restaurants in New York, do not find an impact.

(Comment 35) A comment stated that there is no empirical evidence in Abaluck that any improvement in dietary choices actually occurred but rather that it is only a computation of what the benefits in monetary terms would be if people had actually behaved as Abaluck's mathematical model assumes that they might in response to certain information. The comment stated that Abaluck explicitly concedes that his is a theoretical computation of what the monetary benefits would be if people made healthier dietary choices, not an empirical demonstration that any particular labeling regime will in fact result in healthier dietary choices, via the statement made in the conclusion of his paper that "[t]he value reported here for the potential welfare gains from consuming healthier foods is by no means definitive . . .."

(Response 35) This comment references Abaluck's re-evaluated estimates. To illustrate the benefits of the final rules in the final RIA, we rely on Abaluck's WTP estimates, not his re-evaluated estimates.

(Comment 36) A comment stated that to the extent that any dietary benefits from prior labeling requirements actually occurred, Abaluck attributes most of them to the "calories from fat" labeling which, according to the comment, FDA is now proposing to ban. The comment asserted that the flaw in Abaluck's methods are demonstrated by the fact that Abaluck attributes most of the alleged benefits that he calculates to a requirement that the comment says that many, including FDA, believe to have backfired.

(Response 36) To estimate the benefits of the proposed rules in the PRIA, we relied on the welfare estimates presented in Table 7 of the Abaluck paper, and continue to do so to illustrate the benefits of the final rules in this final RIA. We note that the labeling benefits attributable to the labeling declarations related to fat are limited to the "total fat" declaration and not the "calories from fat" declaration. While we acknowledge that the total fat declaration contributes to the dietary benefits from prior labeling requirements, it is not the only contributor. Underlying these welfare estimates are the estimates presented in Table 5 of the Abaluck paper of peoples' WTP for NLEA nutrient information not just for total fat but for many other nutrients as well. We disagree that Abaluck's methods are flawed in this regard.

(Comment 37) Some comments expressed concern that the projected public health benefits are overestimated due to consumers' misunderstanding of the proposed label revisions. Specifically, many comments asserted that many consumers will be confused regarding

the focus on "added sugars" and that, therefore, the desired public health outcomes will not be attained.

(Response 37) Clarifying language regarding added sugars has been added to the Nutrition Facts label in the final rule. FDA believes that this clarifying language will reduce the confusion found among some consumers in consumer research. In addition, educational initiatives with partners such as other federal government agencies within the Department of Health and Human Services and United States Department of Agriculture (USDA), state health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations, could increase consumers' knowledge and effective use of the new food label.

(Comment 38) Some comments raised concerns that projected reformulations would either not materialize or not lead to desired improvements in nutritional quality because (1) consumers will avoid more nutritious products with relatively more added sugars or (2) products may be reformulated to include less added sugars but be less nutritious overall.

(Response 38) It is possible that as a result of the final rules some consumers may avoid more nutritious products with relatively more added sugars in favor of one of the following: less nutritious products with more added sugars, less nutritious products with less added sugars, or more nutritious products with less added sugars. However, due to data limitations, we are unable to quantify the cumulative change in benefits associated with these effects.

As noted in both the Nutrition Facts Label rule and Serving Size rule, the purpose of the amended requirements in these rules is to promote the public health and provide consumers access to factual information that will help them understand the

nutrient content of food products; while any product reformulation that might result in improvements in the nutritional profile of foods would be a beneficial result, it is not the purpose of the regulations, as these comments suggest. We have nonetheless considered potential improvements to the public health as a potential benefit of the rules. To the extent this comment suggests that we overestimated benefits that would result from the potential reformulation of products, however, we disagree. In the PRIA, we estimated reformulation costs, but due to data limitations did not estimate benefits associated with product reformulation. We continue with this approach in this final RIA. The issues raised in this comment are therefore irrelevant to our calculations.

(Comment 39) Some comments noted that specific consumer products that include significant amounts of added sugars for palatability would be unduly affected by the focus on added sugars.

(Response 39) We did not consider the potential economic impact to such manufacturers differently from our evaluation of other manufacturers. The declaration of added sugars and the percent DV on the label allow consumers to understand the sources of added sugars in their diet and make healthy dietary choices, which can include some amounts of added sugars. Education about the consumption of limited amounts of added sugars in the diet, including to improve the palatability of certain foods, are also planned. Industry may also reformulate products to include less added sugars (for example, by using other sweeteners or using alternate blends). Also, any specific losses, should they occur, would be offset in the aggregate by any gains incurred in turn by producers of substitute products.

(Comment 40) A comment suggests that the 2015 Supplemental PRIA does not include reliable data on costs that small businesses will face in implementing the proposed regulations, especially those related to reformulation.

(Response 40) We disagree. The Regulatory Flexibility Analysis associated with the 2015 supplemental PRIA used the same factors evaluated in the Regulatory Flexibility Analysis contained in the PRIA, which includes an estimate of the cost to all businesses, including small businesses, that would result from the need to relabel, reformulate, and maintain records as a result of these final rules. The comment provided no basis upon which to adjust these cost estimates. Furthermore, we have no reason to believe that the data we used to produce these estimates are not reliable. The Regulatory Flexibility Analysis contained in this final RIA likewise includes an estimate of the cost of the rules to all businesses, including small businesses, that is comprised of updated relabeling, reformulation, and recordkeeping costs, as well as study costs related to the new definition of dietary fiber.

(Comment 41) A comment notes that the 2015 Supplement does not include an analysis of the costs involved with the professional skills necessary for record-keeping and reports related to the added sugars disclosure.

(Response 41) The costs associated with making and keeping records to verify the amount of added sugars declared on the Nutrition Facts label were captured in the PRIA (beginning on p. 27) and, thus, were also captured in the 2015 supplemental PRIA. We continue to capture such costs in this final RIA.

(Comment 42) A comment references the Regulatory Flexibility Act in expressing concern that the initial regulatory flexibility analysis does not assess other federal rules that may overlap or conflict with the new label requirements.

(Response 42) We are not aware of any other federal rules that overlap or conflict with the requirements in this regulation. Therefore, we did not identify any such rules in the RFA section of the PRIA or this final RIA.

(Comment 43) A comment suggested that no estimates are provided on the number of small businesses subject to alternate compliance dates, or exempt from the rule altogether, if such guidance will be provided.

(Response 43) This comment correctly asserts that we did not conduct a full economic analysis for alternative regulatory options (e.g., certain exemptions and different compliance dates) that we suggested were possible regulatory approaches in the PRIA. The final rules and this Final RIA, however, clarify that no small businesses are exempted from the rule and analyze costs pertaining to the compliance dates selected for both small businesses and large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Under the final rules, the compliance period is 36 months for small businesses and 24 months for large businesses. We estimate that about 95 percent of food manufacturers (i.e., close to 30,000 manufacturers) have annual food sales of less than $10 million.

H. Costs and Benefits of Regulatory Options – Detailed Analysis

We have identified five regulatory options for the final rules:

1.) No new federal regulatory action;

2.) The final rules that would give small manufacturers a 3-year compliance period and large manufacturers a 2-year compliance period;

3.) The final rules, but with a 2-year compliance period for all manufacturers;

4.) The final rules, but with a 3-year compliance period for all manufacturers;

5.) The final rules, but with a 4-year compliance period for all manufacturers; and,

Requiring different compliance dates for the Nutrition Facts label rule and the Serving Size rule is a policy choice that could be made. Therefore, in our discussions of regulatory alternatives (2) through (6), we present impact estimates with both sub-options: the same and differing compliance dates.

1. Option 1: No new federal regulatory action

This option serves as our baseline. We define costs and benefits relative to this baseline. By definition, the baseline has no costs and no benefits.

2. Option 2: The final rules that would give small manufacturers a 3-year compliance period and large manufacturers a 2-year compliance period

Under this option, some manufacturers would be required to undertake an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims, while other manufacturers would need to undertake a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required, to satisfy the requirements of DCL for packages of certain sizes, or to remove a health or nutrient content claim in response to certain changes in the DVs, RACCs, or the new definition of dietary fiber. All manufacturers would need to undertake a minor label change due to certain changes in the nutrition information that must be declared on Nutrition and Supplement Facts labels (e.g., mandatory declaration of "Added Sugars," increasing the

prominence of calories), and some manufacturers would need to undertake a minor label change due to the update, modification, and establishment of certain RACCs or to the change in the definition of a single-serving container. Some manufacturers may choose to reformulate their product as a result of new mandatory label declarations or for the purpose of continuing to make certain health or nutrient content claims which their preexisting formulation would no longer be eligible to make as a result of changes to the regulations. Also, some manufacturers will incur study costs and additional labeling costs (minor label change) related to the new dietary fiber definition, and some will incur recordkeeping costs associated with the requirement that under certain circumstances manufacturers make and keep records sufficient to verify the label declaration for the amounts of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid. Finally, we estimate future labeling costs for UPCs based on the assumptions that some manufacturers will undertake (1) an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims and (2) a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required. The requirements of the final rules are described in greater detail in the individual final rules published in the Federal Register.

Costs and benefits under this regulatory option are estimated using a weighted average of costs and benefits using a 2-year compliance period for large businesses and costs and benefits using a 3-year compliance period for small businesses. The respective weights used are the percentage of sales earned by large businesses (which for purposes of this analysis we consider to be businesses earning $10 million or more in annual food sales) and the percentage of sales earned by small businesses (which for purposes of this analysis we consider to be businesses earning less than $10 million in annual food sales). Using Nielsen data, as well as the

classifications of large and small businesses above, we estimate that 95 percent of sales are earned by large businesses and 5 percent of sales are earned by small businesses.

a. Costs

i.) Relabeling Costs

In order to comply with the final rules, some manufacturers would have to change some of their labels for the Serving Size final rule, whereas all manufacturers would have to make changes to all of their labels to comply with changes resulting from the Nutrition Facts Label final rule (e.g., increasing the prominence of calories). Relabeling costs were estimated using FDA's Labeling Cost Model (Ref. 1). The 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. Because of the number of steps involved in changing the information on food packaging and labeling, the entire labeling change process generally takes several months (Ref. 1).

Labeling costs, which include labor, materials, inventory (discarded inventory and disposal costs), recordkeeping, and in certain cases recurring costs associated with package size increases, are first calculated on a per-UPC basis and then aggregated across each product category, and are calculated separately as low, mean, and high cost estimates (Ref. 1). To determine the UPC counts in each product category, the model utilizes 2012 Nielsen ScanTrack data (Ref. 1). The model allows the user to select the types of products that would be covered under the regulation, the type of label change (extensive, major, or minor, as described in detail in Section E) that would be required under the regulation, and the compliance period (3 months to 60 months, in three month increments) (Ref. 1).

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. 15). 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 final 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.[16]

Available data show that most products that are voluntarily relabeled are relabeled in a two- to five-year cycle, with private-label[17] products less likely to be relabeled in any given year than branded products (Ref. 1). Manufacturers who can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) will incur lower costs associated with the required labeling change than they would otherwise (Ref. 1). Longer compliance periods increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling changes (Ref. 1). However, even if manufacturers can coordinate a required labeling change, the FDA Labeling Cost Model includes costs of administrative and recordkeeping activities associated with labeling changes because manufacturers still incur costs associated with understanding the regulation, determining their response, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels (Ref. 1). Other types of costs, though, such as prepress, graphic design, and engraving plates or cylinders, are not attributable to the

[16] 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.
[17] 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).

regulation if the required labeling change is coordinated with a planned voluntary label change (Ref. 1).

With a 2-year compliance period, the Labeling Cost Model estimates that manufacturers of 74 percent of private-label conventional food products would have to undertake a labeling change that is uncoordinated with their regulatory scheduled changes. For branded conventional food products we estimate no uncoordinated labeling changes. For dietary supplements, 78 percent of branded products and 84 percent of private-label products would have to undertake an uncoordinated labeling change.

With a 3-year compliance period, the Labeling Cost Model estimates that 43 percent of private-label conventional food products would have to undertake an uncoordinated labeling change. For branded conventional food products, we estimate no uncoordinated labeling changes. For dietary supplements, 55 percent of branded products and 69 percent of private-label products would have to undertake an uncoordinated labeling change.

The number of UPCs that would have to undertake coordinated versus uncoordinated labeling changes for each of the final rules is illustrated in Table 3. Table 3 also shows the number of UPCs that can undertake one label change to satisfy the requirements of all of the final rules.

The final Nutrition Facts Label rule covers all packaged food subject to FDA regulation, as reflected in the total UPC count of 780,246. As described earlier, all food UPCs will have to undergo various changes to the Nutrition and Supplement Facts labels, as applicable. In addition, based on analyses conducted using a combination of Gladson and Mintel data, we estimate that under the final Nutrition Facts Label rule, some products will need to relabel to

remove a health or nutrient content claim in response to certain DV changes.[18] Additionally, based on analysis of the combined Gladson/Mintel data, we estimate that under the final Nutrition Facts Label rule, some products will need to relabel to remove a health or nutrient content claim in response to the new definition of dietary fiber. Further detail regarding these analyses is provided in Subsection ii (Reformulation Costs).

The final Serving Size rule is updating, modifying, and establishing RACCs for some foods. Using Nielsen data, we identified UPCs affected by amendments to the RACC requirements and estimate that these UPCs will need to undergo a label change. In addition, the final Serving Size rule is changing the definition of a single-serving container such that *all* food UPCs containing less than 200 percent of the RACC must be labeled as a single-serving container. As a result, those food UPCs with RACCs of 100 g or 100 mL or larger and that are packaged such that they contain more than 150 percent but less than 200 percent of the RACC will no longer have the option of being labeled as either one or two servings (as they did under the preexisting requirements). Some of these food UPCs will need to change their label so that the label lists just one serving. Using Nielsen data, we identified UPCs packaged such that the UPC contains between 150 percent and 200 percent of the RACC, and conservatively estimate that these UPCs will need to undertake such a label change. Further, under the final Serving Size rule, some food products will be required to include a DCL (i.e., certain food products in packages that contain at least 200 percent and up to and including 300 percent of the RACC, certain food products in discrete units in which each discrete unit weighs at least 200 percent and up to and including 300 percent of the RACC). We identified, using Nielsen data, those UPCs

[18] 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.

packaged such that the UPC contains at least two times the RACC but no more than three times the RACC, and estimate that these UPCs will require a DCL. Using Gladson and Mintel data, we estimate that some UPCs will need to be relabeled to remove a health or nutrient content claim in response to certain RACC changes. Further detail regarding this analysis is provided in Subsection ii (Reformulation Costs). Changes in the RACCs of certain products under the final Serving Size rule and/or modified nutrient labeling requirements under the Nutrition Facts final rule (e.g., mandatory labeling of potassium, a change in the daily value of sodium) would require that certain products bear a Nutrition Facts panel for which none was previously required. Based on comments we have received, it appears that most products for which a Nutrition Facts panel will be required when such labeling was not required previously are certain coffee, tea, and bottled water products. Using Nielsen data, we identified the total number of coffee, tea, and water UPCs in the marketplace and conservatively estimate that none required a Nutrition Facts panel previously and that all will require a Nutrition Facts panel under the combined effects of the two regulations.[19] For purposes of this analysis, because we have no way of reliably allocating affected UPCs across the Nutrition Facts Label and Serving Size rules, we assign all of these UPCs to the Serving Size rule. This has no effect on total labeling costs under the same compliance date scenario, which is the scenario that is consistent with the final rules, and conservatively overestimates total labeling costs under the different compliance dates scenario. Finally, the change in the definition of a single-serving container mandated by the final Serving Size rule to now require products that both (i) have RACCs of 100 g or 100 mL or larger and (ii) are packaged such that they contain more than 150 percent but less than 200 percent of the

[19] As noted previously in this document, the Serving Size final rule announces that we intend to consider the exercise of enforcement discretion with respect to with respect to mandatory nutrition labeling on products that would have been exempt from nutrition labeling under § 101.9(j)(4) prior to the effective date of the two rules.

RACC to be defined as a single-serving container, versus offering such products the option of being labeled as one or two servings, will require some of these products to increase their package size to continue to make a health or nutrient content claim. Using Nielsen and Mintel data, we identified UPCs for products that both (1) are packaged such that the UPC contains between 150 percent and 200 percent of the RACC and (2) make a health or nutrient content claim. Based on these data, we conservatively estimate that certain UPCs will need to increase their package size to continue to make certain health or nutrient content claims.

Table 3 - Industry Coverage by Final Rule - Coordinated vs. Uncoordinated

Final Rule	**Source of Label Change**	**Type of Label Change**	**Affected UPCs**		**Affected UPCs**	
			Different Compliance Dates		*Same Compliance Date*	
			Uncoordinated	Coordinated	Uncoordinated	Coordinated
Nutrition Facts Label (NFL)						
Conventional Food	Various Changes to the NFL	Minor	200,756	509,808	106,099	269,433
Conventional Food	Claim Removal Related to DV Change	Major	494	985	494	985
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	1,236	2,582	1,236	2,582
Dietary Supplements	Various Changes to the NFL	Minor	51,231	12,963	51,231	12,963
Dietary Supplements	Claim Removal Related to DV Change	Major	57	15	57	15
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	95	24	95	24
Total NFL UPCs			780,246		445,214	
Serving Size (SS)						
Conventional Food	Changes Due to RACC Amendments	Minor	31,048	111,578	31,048	111,578
Conventional Food	Change in Definition of	Minor	29,536	83,690	29,536	83,690

	Single-Serving Size Container					
Conventional Food	DCL	Major	11,268	33,204	11,268	33,204
Conventional Food	Claim Removal Related to RACC Change	Major	224	514	224	514
Conventional Food	First Time Nutrition Facts Panel Due To RACC Proposals	Major	8,967	22,186	8,967	22,186
Conventional Food	Package Size Change to Retain Claims as an Effect of Change of Definition of Single-Serving Container	Extensive	2,817	-	2,817	-
Total SS UPCs			335,032		335,032	
Total			1,115,278		780,246	

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more.

From Table 3 it can be seen that if the rules have different compliance dates, then the covered products under the final Serving Size rule (335,032 UPCs) would have to undergo two label changes—one for the final Nutrition Facts label rule and one for the final Serving Size rule—or incur the cost of accelerating the second label change so as to coordinate the two revisions. However, a UPC subject to multiple label changes under one rule only has to apply a one-time change under that rule. For example, under the final Nutrition Facts label rule, a UPC subject both to changes to the Nutrition and Supplement Facts labels that affect all UPCs (e.g., changes to the listing of required nutrients) 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 both of the final rules have the same compliance date, the covered products under the final Serving Size rule can satisfy the requirements of both the final Nutrition Facts Label rule and the final Serving

Size rule under one label change. For example, a UPC subject both to changes to the Nutrition and Supplement Facts labels that affect all UPCs (e.g., changes to the listing of required nutrients) under the final Nutrition Facts Label rule and DCL under the final Serving Size rule was counted only under the final Serving Size rule because, as noted previously, we considered major label changes to subsume minor label changes for the purpose of this economic analysis.

Label cost estimates in 2014 dollars are presented in Table 4. We first compare the cost of the final rules if they have different compliance dates with the cost under the same compliance date.[20] Such a comparison illustrates the reduction in label costs that firms would experience if they undertook all of the label changes mandated by the final rules under one label redesign. The labeling cost of the final rules, if they had different compliance dates, would be between $3.2 billion and $3.4 billion at the mean estimate. This translates into per UPC costs (at the mean) of between $4,101 and $4,358 per UPC.

If the final rules have the same compliance date, the cost savings are significant. As described in the "Same Compliance Date" columns in Table 4, the labeling cost of the final rules would be reduced by about 20 percent, to between $2.6 billion and $2.7 billion, at the mean estimate. This translates into per-UPC costs (at the mean) of between $3,332 and $3,460. Again, these cost savings arise because firms that are affected by both of the final rules are now able to undertake just one label change to comply with the requirements of the two final rules.

Table 4 - Summary of Relabeling Costs of the Final Rules (in millions of 2014$)

Final Rule	Source of Label Change	Type of Label Change	Different Compliance Dates	Same Compliance Date

[20] The Nutrition Facts Label rule and the Serving Size rule have the same compliance date. Thus, the "Different Compliance Dates" labeling cost estimates are mainly for illustration purposes. That said, these estimates are likely conservative; had the final rules had different compliance dates, the dates would likely have been close enough together so that manufacturers would have still been able to undertake just one label change to comply with the requirements of the two final rules.

			Low	Mean	High	Low	Mean	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$607	$1,340	$2,535	$321	$708	$1,339
Conventional Food	Claim Removal Related to DV Change	Major	$3	$7	$12	$3	$7	$12
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$8	$17	$31	$8	$17	$31
Dietary Supplements	Various Changes to the NFL	Minor	$116	$253	$467	$116	$253	$467
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.3	$1	$1	$0.3	$1	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$1	$1	$2	$1	$1	$2
Analytical Testing Costs			$322	$421	$530	$322	$421	$530
Total NFL			$1,057	$2,040	$3,578	$771	$1,408	$2,382
Serving Size (SS)								
Conventional Food	Changes Due to RACC Amendments	Minor	$102	$231	$442	$102	$231	$442
Conventional Food	Change in Definition of Single-Serving Container	Minor	$96	$209	$393	$96	$209	$393
Conventional Food	DCL	Major	$76	$162	$303	$76	$162	$303
Conventional Food	Claim Removal Related to RACC Change	Major	$2	$3	$6	$2	$3	$6
Conventional Food	First Time Nutrition Facts Panel Due To RACC Proposals	Major	$78	$147	$256	$78	$147	$256
Conventional Food	Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive (3%)	$280	$560	$796	$280	$560	$796
Conventional Food	Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive (7%)	$206	$410	$587	$206	$410	$587
Total SS (3%)			$634	$1,312	$2,196	$634	$1,312	$2,196
Total SS (7%)			$560	$1,162	$1,987	$560	$1,162	$1,987
TOTAL NFL + SS (3%)			$1,691	$3,352	$5,774	$1,405	$2,720	$4,578

TOTAL NFL + SS (7%)			$1,617	$3,202	$5,565	$1,331	$2,570	$4,369
Annualized (3%)			$114	$225	$388	$94	$183	$308
Annualized (7%)			$153	$302	$525	$126	$243	$413

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Analytical testing costs associated with the mandatory declarations of potassium and vitamin D are conservatively estimated across *all* conventional food and dietary supplement UPCs using the FDA Labeling Cost Model. The cost of an extensive label change includes recurring annual costs associated with increased package sizes. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

With the same compliance date, it can be seen that the labeling cost estimates of the final rules range from $1.4 billion to $4.6 billion using a 3 percent discount rate, and from $1.3 billion to $4.4 billion using a 7 percent discount rate. Table 4 also presents annualized labeling costs, using both a 3 percent and a 7 percent discount rate.

The final Nutrition Facts Label rule 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 must 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 other appropriate verification documentation that a manufacturer has that verifies the nutrient content in the final product. We estimate that manufacturers currently maintain the above-mentioned records in the normal course of doing business. Thus, the time burden to the covered food manufacturer would be to review these records to verify the amount of such nutrients in a food and to make such records available to appropriate regulatory officials upon request. Referring to the Paperwork

Reduction Act (PRA) analysis in Section III of this final RIA, we estimate that manufacturers will incur 187,726 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 $55.59 in 2014 dollars. We increase this cost by 100 percent to account for benefits and overhead, making the total cost of time $111.18. Thus, total recordkeeping costs, discounted over 20 years and in 2014 dollars, are estimated to be approximately $21.4 million using a 3 percent discount rate and roughly $21.3 million using a 7 percent discount rate.

Under the final Nutrition Facts Label rule, manufacturers of food products that contain an isolated or synthetic non-digestible carbohydrate that does not meet the new definition of dietary fiber will not be able to declare the isolated or synthetic non-digestible carbohydrate as dietary fiber on the Nutrition or Supplement Facts label. However, manufacturers can submit a citizen petition to request the agency amend the definition of "dietary fiber" to include the isolated or synthetic non-digestible carbohydrate as a "dietary fiber" for purposes of nutrition labeling. In addition, if the isolated or synthetic non-digestible carbohydrate is the subject of an authorized health claim, FDA would consider the carbohydrate to be a dietary fiber with a beneficial physiological effect to human health and would amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber. If a citizen petition is submitted and the request to amend the definition is granted, or if the isolated or synthetic non-digestible carbohydrate is subject to an authorized health claim, the isolated or synthetic non-digestible carbohydrate is considered to meet the definition of dietary fiber and the definition would be amended to include

the dietary fiber in the listing of dietary fibers that must be included in the total amount of dietary fiber declared on the Nutrition or Supplement Facts label when present in a food.

FDA estimates that there are currently about 35 isolated or synthetic non-digestible carbohydrates that are added to food. Based on a review of the relevant literature, FDA found that certain isolated or synthetic fibers have a demonstrated beneficial physiological effect to health in the final rule, and includes such fibers in the definition for dietary fiber. Based on FDA's review, the scientific evidence for approximately 28 isolated or synthetic carbohydrates is generally mixed, or appears to be insufficient to demonstrate a beneficial physiological effect to human health. However, it is not clear whether there may be additional data or information concerning the beneficial health effects of these non-digestible carbohydrates that interested persons have and are not yet publically available. Therefore, FDA is not making a determination on whether these other non-digestible carbohydrates meet the definition of "dietary fiber" in the final rule and plans to provide an opportunity for comment on the available scientific evidence for these non-digestible carbohydrates. Thus, FDA intends to publish a separate notice to seek comment on the available scientific data on these non-digestible carbohydrates to determine if it should consider additional non-digestible carbohydrates to be added to the list of dietary fibers. Although FDA intends to publish a separate notice to seek comment on the available scientific data on these non-digestible carbohydrates to determine if it should consider additional non-digestible carbohydrates to be added to the list of dietary fibers, for purposes of the economic analysis we estimate additional studies will be needed for the approximately 28 remaining isolated or synthetic non-digestible carbohydrates. Thus, we estimate the cost associated with conducting 84 studies, three for each of the 28 remaining isolated or synthetic non-digestible

carbohydrates.[21] FDA estimates that to conduct such a study would require approximately 480 labor hours (= 2 scientists x 20 hours/week x 12 weeks) and about $10,000 in material costs. According to the Bureau of Labor Statistics National Industry-Specific Occupational Employment and Wage Estimates, the mean hourly wage of a biological scientist is $38.08 in 2014 dollars. We increase this cost by 100 percent to account for benefits and overhead, making the total cost of time $76.16 per hour. Thus, we estimate that the total cost of conducting 84 studies is approximately $3.9 million in 2014 dollars (= (480 x $76.16 + $10,000) x 84).[22]

It is possible that a request to amend the definition of "dietary fiber" to add a new fiber, or the submission of a health claim for an isolated or synthetic non-digestible carbohydrate may be submitted to FDA prior to the end of the final Nutrition Facts Label rule's compliance period, but not granted or authorized until after the end of the final Nutrition Facts Label rule's compliance period. In such instances, food products which contain such an isolated or synthetic non-digestible carbohydrate would have to undertake two labeling changes – one to comply with the final rules and an additional labeling change, after a citizen petition is granted or a health claim is authorized, to declare the isolated or synthetic non-digestible carbohydrate as dietary fiber on the Nutrition or Supplement Facts label. We estimate that at most approximately 20 percent of UPCs that contain an isolated or synthetic non-digestible carbohydrate might have to undertake such an additional labeling change. Using Gladson and Mintel data, we estimate that close to 60,000 UPCs contain an isolated or synthetic non-digestible carbohydrate. Thus, we estimate that at most close to 12,000 (= 0.2 x 60,000) UPCs might have to undertake this type of

[21] We have no way of estimating the number of isolated or synthetic non-digestible carbohydrates that will be discovered in the future.

[22] Estimated fiber study costs are small relative to the estimated total cost of the final rules. Thus, to the extent that we underestimated the number of studies per fiber, it will have a negligible impact on the estimated total cost of the final rules.

additional labeling change at a cost, estimated using the FDA Labeling Cost Model and in 2014 dollars, of between $176 million and $1,101 million, with a mean estimate of $430 million.[23]

The above costs are summarized in Table 5 below. Table 5 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 5 – Summary of Recordkeeping Costs and Study and Additional Labeling Costs Related to the New Definition of Dietary Fiber (in millions of 2014$)

	Low	Mean	High
Recordkeeping Costs	$21	$21	$21
Study Costs Related to New Definition of Dietary Fiber	$4	$4	$4
Additional Labeling Costs Related to New Definition of Dietary Fiber	$176	$430	$1,101
Total	$201	$455	$1,126
Annualized (3%)	$14	$31	$76
Annualized (7%)	$19	$43	$106

Notes: These costs do not depend on compliance period. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

According to the FDA Labeling Cost Model, the addition of a Nutrition or Supplement Facts panel to a previously unlabeled UPC, such as to a new UPC, represents a major label change. New UPCs under the final rules would have had to add a label under NLEA, which is to say that new UPCs under the final rules would have had to make a major label change under NLEA. Thus, the labeling costs for future UPCs subject to minor and major label changes under the final rules would not generally be considered a cost of the final rules. However, future UPC growth is relevant for UPCs that would need to bear a Nutrition Facts Panel for which none was previously required and UPCs which would require an extensive label change. We estimate that

[23] The additional labeling change represents a minor labeling change (Ref. 1). In light of the physiological benefits associated with consuming dietary fiber, we estimate that manufacturers, upon receiving post-compliance period approval of their dietary fiber citizen petition or health claim petition, would relabel as quickly as possible. Thus, labeling costs are estimated using the "3 Months or Less" compliance period option in the FDA Labeling Cost Model. However, it should be noted that each amendment that adds a new fiber to the definition will also have a compliance period, which will provide manufacturers with additional time, and may allow them to coordinate their fiber-related label change with other future planned label changes.

a fixed fraction of future UPCs fall into these categories, and we estimate associated labeling costs for UPCs affected by these requirements over the next 20 years. Looking at Nielsen data, we estimate that food UPCs have historically grown by about 1.3 percent per year. Lacking data or other information that indicates that historical and future UPC growth rates will diverge, we use 1.3 percent as our estimate of future annual growth in food UPCs. Using this annual growth rate in food UPCs, as well as the FDA Labeling Cost Model, we estimate labeling costs for UPCs affected by the above requirements over the next 20 years of between $66 million and $198 million, with a mean estimate of $135 million, using a 3 percent discount rate, and between $35 million and $107 million, with a mean estimate of $72 million, using a 7 percent discount rate (2014$). These costs are summarized in Table 6 below. Table 6 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 6 – Summary of Labeling Costs Associated With Future UPC Growth (in millions of 2014$)

	Type of Label Change	Low	Mean	High
Present Value (3%)				
First Time Nutrition Facts Panel Due to RACC	Major	$6	$14	$26
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$60	$121	$172
Total		$66	$135	$198
Present Value (7%)				
First Time Nutrition Facts Panel Due to RACC	Major	$4	$10	$18
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$31	$62	$89
Total		$35	$72	$107
Annualized (3%)		$4	$9	$13
Annualized (7%)		$3	$7	$10

Notes: Annualized amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

ii.) Reformulation Costs

The final rules could motivate food manufacturers to reformulate their products in response to the requirements in these final rules. Incentives to reformulate can be categorized into three groups: (i) reformulations to maintain health and nutrient content claims motivated by DV, RACC changes and changes in the definition of dietary fiber, (ii) reformulations motivated by the mandatory labeling of the quantity of added sugars, and (iii) reformulations motivated by the reduction in the Vitamin B_{12} DV. We estimate reformulation costs associated with each group in turn.[24]

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

The final rules could affect manufacturers 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 additional nutritional information that may improve consumer perception of a product compared to that of a competitor's product. Under the FD&C Act and FDA regulations, RACCs (and sometimes serving sizes as well) are to be used to determine whether a product meets the criteria for a nutrient content claim or health claim. The changes the final 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 or synthetic fibers from the definition) could cause a product currently making a health or nutrient content claim to become ineligible to make the claim. In the absence of regulations changing the requirements for nutrient content claims and health claims, as

[24] It should be noted that labeling costs associated with product reformulation (e.g., changing nutrient amounts, changing ingredient lists) are subsumed under the labeling costs estimated in Subsection i (Labeling Costs) of this RIA.

discussed above, this would require manufacturers of these products to either remove the claim from their product's label, reformulate, or repackage in order to continue to make the claim.[25] It is difficult to predict how the requirements of the final rules would influence manufacturers' decisions to reformulate, repackage, or remove the claim from the product label. We therefore estimate that, given the requirements of the final rules, some manufacturers would reformulate while others would remove the claim from their product's label.

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 final rules through a change in RACC. For each product, the current nutrition and serving size data were used to calculate new hypothetical nutrition data

[25] To illustrate, consider these examples:

1) Brand X Low Fat Ice Cream – Brand X currently packages its product in pint-sized cartons, with 3 grams of fat per ½ cup. The Serving Size final rule increases the RACC of ice cream from ½ cup to 2/3 cup. Pursuant to 21 CFR 101.62(b)(2), under preexisting RACCs, this product is eligible to make a "low fat" claim on its label since it contains 3 grams or less of total fat per RACC, assuming it satisfies the other requirements of paragraph (b)(2). By increasing the RACC, Brand X would contain more than 3 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 the DV of calcium and, pursuant to 21 CFR 101.54(b), currently qualifies for the nutrient content claim "excellent source of calcium" since it contains 20 percent or more of the calcium DV per RACC. The Serving Size final rule decreases the RACC of yogurt to 6 oz., which brings the percent DV of calcium down to less than 20 percent. Brand Y is no longer permitted to claim the product is an "excellent source of calcium," and must either reformulate to keep the claim, or change the claim to "good source" of calcium, the latter which, pursuant to 21 CFR 101.54(c), requires that the product contains 10 to 19 percent of the calcium DV per RACC.

3) Brand Z Breakfast Bar – Pursuant to 21 CFR 101.54(b), in order to make an "Excellent Source of Fiber" claim, Brand Z breakfast bars must contain 20 percent or more of the fiber DV (DV = 28 grams) per RACC (RACC = 40 grams). Brand Z breakfast bars currently contain 6 grams of dietary fiber per 40 gram bar (21 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 Nutrition Facts final rule. Thus, under the Nutrition Facts final 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.

under the final RACCs. 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. 16) (e.g., "good source," "low sodium," "Vitamin C added," etc.). Products currently making label claims but rendered ineligible after the introduction of the RACC changes were flagged as needing either relabeling to remove the claim or reformulation to continue to make the claim. An equivalent refinement methodology was used to estimate the number of UPCs for which, related to DV changes, either reformulation would be required to continue to make a health or nutrient content claim about the product or relabeling would be required to remove the claim from the label.

To estimate the number of UPCs which, related to the new definition of dietary fiber, would need to be reformulated for the product to continue to bear a health or nutrient content claim, or would need to be relabeled to remove the claim 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 estimate 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 either 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 estimates of formula counts[26]. To estimate formula counts, we relied on UPC and formula count data from the FDA Labeling Cost Model (Ref. 1). The FDA Labeling Cost Model estimates both total UPCs as well as total formulas for various food product categories. For each product category, we multiply the ratio

[26] To understand the distinction between UPCs and formulas, Soda X has one "taste" (formula), but comes in a variety of sizes (e.g., 12 ounce can, 2-liter bottle), each of which represents a unique UPC.

of Formulas to UPCs estimated using the FDA Labeling Cost Model by the UPC counts estimated using the Gladson and Mintel databases. The UPC and resulting formula counts are illustrated below in Tables 7 and 8.

Table 7. Estimates by Product Category of the Number of UPCs and Formulas with a Health or Nutrient Content Claim Affected by the RACC and DV Changes Mandated by the Final Rules

Product Category	UPCs	Formulas
Baked Goods	570	468
Baking Ingredients	80	64
Beverages	894	602
Breakfast Foods	950	648
Candy and Gum	96	68
Dairy Foods	808	620
Dressings and Sauces	48	42
Entrees	90	80
Fruits and Vegetables	260	200
Pizza	20	16
Seafood	144	108
Side Dishes and Starches	170	146
Snack Foods	238	176
Soups	72	62
Dietary Supplements	144	122
Total	**4,584**	**3,422**

Table 8. Estimates by Product Category of the Number of UPCs and Formulas with a Health or Nutrient Content Claim Affected by the New Definition of Dietary Fiber

Product Category	UPCs	Formulas
Baked Goods	1,514	1,242
Baking Ingredients	122	98
Beverages	992	668
Breakfast Foods	1,976	1,348
Candy and Gum	126	92
Condiments/Dips/Spreads	70	58
Dairy Foods	804	616
Desserts	28	22
Dressings and Sauces	72	62
Entrees	592	530
Fruits and Vegetables	104	80

Infant Foods	188	152
Pizza	58	52
Seafood	50	38
Side Dishes and Starches	204	174
Snack Foods	530	392
Soups	200	176
Sweeteners	4	4
Dietary Supplements	238	200
Total	**7,872**	**6,004**

Reformulation costs are estimated using the FDA Reformulation Cost Model (Ref. 2). The FDA Reformulation Cost Model, the development of which was based on an expert panel of individuals who previously oversaw product reformulation at major food manufacturing companies or who currently provide formulation consulting services to small and large food manufacturers, estimates the costs to food manufacturers of reformulating foods based on variations in (i) food product complexity (some products are more easily reformulated than others), (ii) company size (larger companies put substantially more effort into reformulation than smaller companies), (iii) reformulation types (reformulation of a non-critical minor ingredient, of a critical minor ingredient, and of a major ingredient) and activities (determination of response to regulation; project management; product reformulation/process modification; packaging assessment and development; product and package performance testing; sensory evaluation; analytical testing; production scale-up; discarding of unused inventory of raw materials, packaging, and labels; and updating product records), and (iv) compliance period (costs are higher for shorter compliance periods because if the compliance period is short, manufacturers will incur increased costs for overtime labor, additional staffing, and rush charges with vendors

and suppliers).[27] A summary of per-formula costs by food product complexity, company size, reformulation type, and reformulation activity is provided on pp. 3-47 to 3-52 of the FDA Reformulation Cost Model. We estimate that the ingredients in question generally play a non-critical, minor role in product formulation.[28]

If we rely on the formula counts in Tables 7 and 8, 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 decides to remove a claim instead of reformulating, we estimate that any loss in sales directly attributable to the removal of the claim would be transferred to a substitute product, with negligible value lost to society. 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 we already capture in the labeling cost estimation section of this Final RIA). In lieu of reliable data regarding manufacturers' response to the final rules that would cause us to weight the split one way or the other, we estimate that 50 percent of the Table 7 and 8 UPCs would choose to reformulate and 50 percent would choose to relabel (we previously asked for comment on this estimate, but received none that provided a basis upon which to adjust the estimate). This brings the total formula count to 4,713 ($0.5 \times 3{,}422 + 0.5 \times 6{,}004$). Using this formula count and the

[27] 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. 17). However, due to data limitations, we are unable to quantify either the total costs or how the costs are distributed across manufacturers and consumers.

[28] We previously asked for comment on our estimate that the ingredients in question generally play a non-critical, minor role in product formulation, but received none that provided a basis upon which to adjust it.

FDA Reformulation Cost Model, we estimate total reformulation costs associated with maintaining health and nutrient content claims related to RACC and DV changes and the new definition of dietary fiber of between $156 million and $642 million, with a mean estimate of $346 million (2014$).

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

The final rules, particularly the label disclosures of added sugars and the percent DV for added sugars, may increase the visibility of nutrients that, based on current scientific evidence, consumers should limit. These label changes may motivate some food manufacturers to reformulate existing products. To estimate the number of formulas that would be reformulated as a result of these label changes, we use a similar methodology to that which was used in the previous section.

To identify products that significantly contribute added sugars to diets, we considered the evidence supporting the 2015 DGA, as well as the Gladson and Mintel databases. The identified products span 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 products. These formula counts, by product category, are reported in Table 9. A total of 113,968 formulas were identified as significantly contributing added sugars to diets.

Table 9. Estimates of the Number of Formulas, by Product Category, That Significantly Contribute Added Sugars to Diets

Product Category	Total Formulas	7.5% Reformulated	9% Reformulated
Baked Goods	20,897	1,567	1,881
Beverages	25,584	1,919	2,303
Breakfast Foods	5,578	418	502
Condiments/Dips/Spreads	9,853	739	887
Dairy Foods	24,270	1,820	2,184
Dressings and Sauces	11,956	897	1,076

Entrees	10,502	788	945
Infant Foods	1,901	143	171
Pizza	3,427	257	308
Total	**113,968**	**8,548**	**10,257**
	Average:	**9,403**	

The labeling changes for added sugars would likely have a variety of effects[29] on manufacturers regarding their decision to reformulate voluntarily. The required disclosures of added sugars and the percent DV for added sugars on Nutrition and Supplement Facts labels under the final rules is new, and so would require an entirely new line item, providing a set of information that was not previously available.

We estimate that 7.5 to 9 percent of formulas that significantly contribute added sugars to diets will be reformulated. 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 (we previously asked for comment on this estimate, but received none that provided a basis upon which to adjust the estimate). Referring back to Table 9, an estimated range of 7.5 to 9 percent reformulation yields total formula counts of between 8,548 and 10,257 formulas, with an average formula count of 9,403 formulas. Using this average formula count and the FDA Reformulation Cost Model, we estimate total reformulation costs associated with foods that significantly contribute added sugars to diets of between $296 million and $1,221 million, with a mean estimate of $658 million (2014$).

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

[29] We acknowledge that the requirement to enlarge and bold the calorie content on package labels may have an impact. There are studies that suggest that increasing or bolding the font could lead to increases in attention of readers (Ref. 18). However, a study by Lando and Lo (2013) (Ref. 19) 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 bolding alone.

Under the final 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 final 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 final 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. 20) and, thus, reformulate their products to reduce B_{12} amounts.[30] We estimate reformulation costs using both the FDA Labeling Cost Model and the FDA Reformulation Cost Model. Using the FDA Labeling Cost Model, we estimate the number of ready-to-eat breakfast cereal formulas to be 5,578. Using this formula count and the FDA Reformulation Cost Model, we estimate total reformulation costs associated with reducing B_{12} amounts in ready-to-eat breakfast cereals of between $199 million and $819 million, with a mean estimate of $442 million (2014$).

Summary of Reformulation Costs

Table 10 presents a summary of estimated reformulation costs. We estimate total reformulation costs (in 2014 dollars) of between $651 million and $2,682 million, with a mean estimate of $1,446 million. Table 10 also presents annualized reformulation costs, at 3 percent and 7 percent.

[30] 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 contains levels of vitamin B_{12} well in excess of 100 percent of the DV, though, and thus are unlikely to be reformulated.

Table 10 - Summary of Reformulation Costs of the Final Rules (in millions of 2014$)

Category	Low	Mean	High
Claims	$156	$346	$642
Added Sugars	$296	$658	$1,221
B_{12}	$199	$442	$819
Total	$651	$1,446	$2,682
Annualized (3%)	$44	$97	$180
Annualized (7%)	$61	$137	$253

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Summary of Total Cost of the Final Rules

Table 11 summarizes the PV and annualized total cost of the final rules, using both a 3 percent and 7 percent discount rate.

Table 11 - Summary of Total Costs of the Final Rules (in millions of 2014$)

	Low	Mean	High
PV (3%)			
Relabeling	$1,405	$2,720	$4,578
Recordkeeping	$21	$21	$21
Fiber Studies	$4	$4	$4
Additional Labeling	$176	$430	$1,101
Future UPC Growth Labeling	$66	$135	$198
Reformulation	$651	$1,446	$2,682
Total	$2,323	$4,756	$8,584
PV (7%)			
Relabeling	$1,331	$2,570	$4,369
Recordkeeping	$21	$21	$21
Fiber Studies	$4	$4	$4
Additional Labeling	$176	$430	$1,101
Future UPC Growth Labeling	$35	$72	$107
Reformulation	$651	$1,446	$2,682
Total	$2,218	$4,543	$8,284
Annualized (3%)	$156	$320	$577
Annualized (7%)	$209	$429	$782

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Analysis assumes that the Nutrition Facts Label and Serving Size rules will have the same compliance date. Annualized Amount = Amount / Annualizing

Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20). PVs of fiber study, additional labeling, and reformulation costs are equivalent at 3 or 7 percent because we conservatively estimate that these one-time costs are incurred upon publication of the rules instead of at the end of the compliance period.

b. Benefits

Background

A large body of scientific research has consistently confirmed the significant effect of diet on health, quality of life, and longevity (Refs. 21 – 23). 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 cardiovascular disease (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. 21 – 23). 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. 21). In 2005, 133 million Americans, almost one out of every two adults, had at least one chronic illness (Ref. 21). An estimated 37 percent of Americans suffer from CVD (Ref. 22), 11 percent of individuals 20 years and older have diabetes, 35 percent of adults have pre-diabetes (Ref. 24), and an estimated 41 percent of the population will receive a diagnosis of cancer during their lifetime (Ref. 25). While the causes of these chronic diseases are multifactorial, having a poor diet contributes to excess morbidity and mortality (Ref. 26), 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 consumers in maintaining healthy dietary practices. The final

rules (1) better align the information provided on Nutrition and Supplement Facts labels with new data on consumption, scientific evidence on the relationship between nutrition and chronic diseases, and dietary recommendations, (2) improve the design and content of the Nutrition and Supplement Facts labels such that relevant information is more salient and easy to understand for the purpose of informing consumption decisions, and (3) could have the effect of prompting industry to reformulate products to maintain health claims and nutrient content claims and reformulate products based on new label information required by the final rules.

In addition to alerting consumers to calorie and nutrient content, major predicted elements of the consumer and industry response to the nutrition labeling final 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 availability of more easy-to-understand information for products that bear DCLs;
- Greater transparency 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 sodium and added sugars or increase other vitamins and minerals.

These responses could potentially result in reduced consumption of less nutritious food products. Note that consumers may offset any reduction in their consumption of less nutritious food products with consumption of unlabeled and less nutritious meals or snacks. Consumers substitute between nutrient sources when attempting to modify their food choices (Ref. 27). Because we lack any data or information on how consumers would substitute between foods in

response to the labeling changes, the benefits estimates in this analysis may over- or understate the realized effects of the final rules.

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. We expect that the final rules will lead to changes in the prevalence and/or intensity of label use, as well as some product reformulation, which may result in changes in nutrient intake. The benefits of the final rules would come from consumer welfare gains primarily due to increases in health and longevity generated by improvements in overall diet.

Welfare Estimates—Primary Sensitivity Analysis

We illustrate the welfare gains (benefits) of the final rules, B_t^{Label}, using the formula:

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

where ΔW^{Label} represents the change in consumer welfare from NLEA, s_1 is the weighted average change in label content associated with the final rules relative to the 1993 rules that implemented NLEA, USE represents estimated current use of the Nutrition Facts label, USDA represents the percentage of labeled food regulated by the USDA Food Safety Inspection Service (FSIS), and POP_t is the population of the United States in period t. Equation 1 encapsulates our illustration of the welfare gains from consumers using the information on the updated Nutrition and Supplement Facts labels.

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

To illustrate the effect of the final 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 19 to 50 years of age who are the main meal planner in their household 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 CSFII, Abaluck (2011) estimates the change in nutrient intake attributable to changes brought about by NLEA in nutritional information content across foods.[31] Abaluck (2011) bases 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.

Abaluck (2011) measures the consumer welfare gains as the WTP 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

[31] 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. 28), 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. 29) and Ferguson (2013) (Ref. 30).

value the measured change in nutrient intake. We refer to these estimates as the WTP estimates. In Table 12, we summarize these estimates and convert them to 2014 dollars. Abaluck (2011) finds that NLEA led to an average increase in consumer welfare of $61 (2014$) per year per label user.

Table 12 - Annual Welfare Gains Per Person Based on Abaluck (2011)

		Annual Welfare Gain Per Person					
		1990$			2014$		
NLEA		Model 1	Model 2		Model 1	Model 2	Mean
WTP		$41	$33		$67	$55	$61

Notes: These estimates can be found in Table 7 of Abaluck (2011). Models 1 and 2 are different specifications of Abaluck's model of WTP for nutrient content. Model 1 estimates the WTP for calories, sodium, and cholesterol and Model 2 disaggregates calories into protein, non-fiber carbohydrates (e.g., sugars), dietary fiber, and total fat. The annual welfare gains per person presented here are the same for children and adults.

The estimates generated by Abaluck (2011) (that is, the mean WTP estimates of welfare gains from NLEA, $61) represent welfare gains and, thus, are of the appropriate form for estimating the benefits of the final rules. However, we must calibrate these estimates to the expected effects of the final rules. For example, the changes to the Nutrition and Supplement Facts labels mandated by the final rules would increase the available nutrition information on food labels, but by an amount much smaller than the changes brought about by the 1993 rules that implemented NLEA.[32]

We can use the estimated welfare gains from NLEA in Table 12 as the basis of the illustrative calculations of benefits from the final rules. The WTP estimates tie directly to revealed preference data and represent a plausible lower bound for the welfare gains from NLEA.

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

[32] E.g., "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label," 58 FR 2079 (Jan. 6, 1993); "Food Labeling; Reference Daily Intakes and Daily Reference Values," 58 FR 2206 (Jan. 6, 1993); and "Food Labeling: Serving Sizes," 58 FR 2229 (Jan. 6, 1993).

We cannot use the estimated welfare gains associated with the 1993 rules that implemented NLEA in Abaluck (2011) for the estimation of the benefits of the final rules directly because the NLEA estimate would overstate the incremental effects of the nutrition labeling final rules. This is because the 1993 rules that implemented NLEA added nutrition labels to previously unlabeled products and revised nutrition labels on previously labeled products, whereas the nutrition labeling final rules involve only modifications to the existing label. That is, the estimated welfare gain from Abaluck (2011) represents the estimated welfare gain that resulted from generally no requirement to provide a Nutrition Facts panel on packaged foods to the requirement to provide a Nutrition Facts panel, and the estimated welfare gain resulting from the final rules would represent impacts that would result from changes to existing requirements.

The final rules represent a significant modification of existing Nutrition and Supplement Facts labels. Changes to Nutrition and Supplement Facts labels mandated by the final rules are summarized in the preambles to the final Nutrition Facts Label and final Serving Size rules published in the Federal Register.

The Nutrition Facts Label and Serving Size final rules would change approximately 92 percent of UPCs.[33] Of these UPCs, all would be required to change the first or only (as applicable) column of nutrition information. Under the combined final rules, approximately 6 percent of UPCs will be required to include a second column of nutrition information.

We lack direct evidence with which to scale Abaluck's estimates of the effect of NLEA in a manner that precisely reflects the impacts of other changes in nutrition labels; therefore, throughout this analysis we incorporate uncertainty ranges so as to assess the sensitivity of

[33] We exclude dietary supplements from this percentage estimate, as we believe that the benefits from the final rules are overwhelmingly attributable to changes in the consumption of conventional food.

benefits estimates to key analytic inputs (especially the factor used to scale the NLEA results for the present final rules). We estimate that the change in label content associated with the inclusion of the first or only (as applicable) column of nutrition information is uniformly distributed between 16 percent and 60 percent, with a mean of 38 percent (= [16 + 60] / 2) and that the change in label content associated with the addition of a second column of nutrition information is uniformly distributed between 0 percent and 50 percent, with a mean of 25 percent (= [0 + 50] / 2). Weighting these amounts by the share of total UPCs that SCL and DCL products represent (92 percent) and the share of total UPCs that DCL products represent (6 percent), respectively, produces a mean effect of the final rules of 36.5 percent (= [0.38 × 0.92] + [0.25 × 0.06]) of the estimated welfare gains associated with the 1993 rules that implemented NLEA in Abaluck (2011).

Given the assumptions presented above, we will scale the estimated welfare gain associated with the 1993 rules that implemented NLEA in Abaluck (2011) by a range of values (denoted s_1) to capture the fact that the final rules will result in a welfare gain somewhat lower than that which resulted after implementation of the 1993 nutrition labeling rules. We use a uniform distribution with a minimum of 0, a maximum of 0.365, and a mean of 0.183 (= [0 + 0.365] / 2) for s_1, which implies that the effect of the final rules lies between 0 and 36.5 percent of the estimated welfare gains associated with the 1993 rules that implemented NLEA in Abaluck (2011).[34, 35] Our choice of zero as a lower bound is intended to reflect the uncertainty

[34] We acknowledge that s_1 is based entirely on quantity, and not quality, of change, the implication of which is that each label change receives equal weight. We take such an approach because, due to data and other limitations, we are unable to estimate quality weights associated with each label change. We previously asked for comment on our s_1 estimate, but received none that provided a basis upon which to adjust it.

[35] At the means of the benefits model parameters, the breakeven estimate of s_1, defined as the value of s_1 that produces an estimate of benefits that equals the costs of the final rules, is 0.0262 using a 3 percent discount rate and 0.0371 using a 7 percent discount rate. Thus, an s_1 of at least 3.72 percent would produce an estimate of benefits that would exceed the estimated costs of the final rules.

surrounding the impact of the final rules relative to the 1993 rules that implemented NLEA. However, we do not expect that these rules 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, to allow for the possibility of even a very small effect.

Food Label Use ("USE")

The estimated welfare gains associated with the 1993 rules that implemented NLEA in Abaluck (2011) do not take into account label use.[36] Data from the 2009-2010 NHANES show that 79 percent of respondents used the Nutrition Facts label at least "Sometimes." A change in labeling regulations (and the educational messages that accompany the change) via the final rules will likely increase label use beyond 79 percent, but we have no way of quantifying this likely increase. Thus, following the implementation of the final rules we estimate that the prevalence of label use would remain at its current level of 79 percent. Therefore, in the model, USE = 0.79.

USDA Regulated Food Labels ("USDA")

The estimated welfare effects of the 1993 rules that implemented 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, poultry, and egg products. The USDA labeling regulations for packaged foods mirror the FDA regulations almost exactly. We estimate that approximately 16.4 percent of the calories an average American consumes daily come from foods regulated by the USDA (Ref. 31). Therefore, to accommodate for the possibility that the welfare effects capture the benefits of labeling on some USDA-regulated products, we scaled the

[36] Because Abaluck (2011) generates a per capita WTP from revealed preference estimation there is no need to explicitly address label usage. The estimates generated will only show changes in consumer purchase behavior if the newly required label motivated some change. Because we are unable to observe pre and post data on purchases, we must make some inferences about those consumers who currently do, and will continue to, use the label.

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 final rules. That is, USDA ~ U(0, 0.328), with a mean of 0.164 (= [0 + 0.328] / 2), or, equivalently, (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 final rules are summarized in a value (WTP) that is simultaneous with the timing when manufacturers comply with the final rules. We adjust the annual stream of benefits from the final rules for the projected growth in the total population in the United States over the next 20 years[37] from the U.S. Census Bureau's National Population Projections.

Compliance Period ("c_t")

The welfare gains from the final rules illustrated according to the steps described 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 rules, depending on the compliance date, for consumers to realize the full annual welfare gains. We estimate 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. 1) if time t falls before the compliance date. Table 13 illustrates the relationship between the compliance period and the percentage of UPCs which are able to coordinate a scheduled

[37] We use 2015 – 2034 population data. Thus, benefits might be slightly underestimated due to population growth, which is a conservative approach.

label change with a required label change. For example, for a 2-year compliance period, $c_t = 0$ in the first year of the final rules, $c_t = 0.08$ in the second year of the final rules, and $c_t = 1$ in the third year of the final rules through the twentieth year.

Table 13 – 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	67%
36 Months	80%
48 Months	98%

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.[38]

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

Benefits Illustrated

Using the @Risk software (Ref. 32), we carried out a simulation with 10,000 iterations to illustratively calculate the PV of the benefits from the final rules over the next 20 years. Each iteration of the simulation randomly draws a value for s_1[39] and (1 – USDA), which each have a uniform distribution with their respective minima and maxima, and calculates the PV of the stream of benefits over the next 20 years using Equations (1) and (2). Table 14 displays the results of this simulation.

Table 14 - Summary of Benefits Simulation Results for the Entire U.S. Population (in billions of 2014$)

	Low	Mean	High

[38] We take t = 1 to be the first year of the rule, t = 2 to be the second year of the rule, and so on.
[39] 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 estimated to have a uniform distribution with their respective minima and maxima.

PV (3%)	$2.8	$33.1	$77.7
PV (7%)	$1.9	$22.3	$52.5
Annualized (3%)	$0.2	$2.2	$5.2
Annualized (7%)	$0.2	$2.1	$5.0

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Estimates reflect total U.S. population (children and adults). Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

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 PV of the stream of illustratively calculated benefits for the total U.S. population over the next 20 years ranges from $2.8 billion to $77.7 billion with a mean estimate of $33.1 billion, using a 3 percent discount rate, and from $1.9 billion to $52.5 billion with a mean estimate of $22.3 billion, using a 7 percent discount rate (2014$). Table 14 also presents annualized benefits, using both a 3 percent and 7 percent discount rate.

Other Sources of Benefits

Reformulation

Manufacturers may reformulate to reduce the amounts of added sugars because the Nutrition Facts Label rule will require manufacturers to list added sugars and the percent DV for added sugars on the Nutrition or Supplement Facts label (increased visibility). 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 Nutrition Facts Label 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. 33). Because vitamin B_{12} deficiency may contribute to certain health problems (Refs. 33 – 34), 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 two reasons. First, only approximately 3.2 percent of persons aged 51 years or older currently have a vitamin B_{12} deficiency (Ref. 33), which translates into an even lower percentage of the United States population as a whole. Second, 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.

Finally, manufacturers may also reformulate in response to certain amendments to the RACC regulations, 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 Serving Size final rule increases the RACC for ice cream from ½ cup to ⅔ cup. Ice cream products that currently make a low-fat claim must, among other requirements, contain 3 g or less of total fat per RACC. Thus, products which currently make a low-fat claim and contain, for example, 3 g of fat per ½ cup contain, proportionally, 4 g of fat per ⅔ cup. Therefore, under the Serving Size final rule, manufacturers of such products would need to lower the amount of total fat in their ice cream to

3 g or less per ⅔ cup in order to continue to make a low-fat claim as a result of the Serving Size final rule. Reductions in fat, especially saturated fat, are associated with a reduced risk of cardiovascular disease (Ref. 35). In addition, under the final rules, only an isolated or synthetic non-digestible carbohydrate which has a physiological effect that is beneficial to human health, and listed as a dietary fiber in the definition of "dietary fiber," may be declared on the Nutrition or Supplement Facts label. Thus, under the Nutrition Facts final rule, manufacturers of products which both contain a carbohydrate that has not been shown to have beneficial physiological effect to human health, 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 to human health (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 could reduce the risk of morbidity and prolong life to the extent consumers use such changed label information to maintain healthy dietary practices. 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, osteoporosis, and dental disease (Ref. 23; Refs. 36 - 38). Each of these conditions 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. However, due to data limitations, we are unable to

directly quantify the effect of the final rules on reduced morbidity. However, such effects are implicitly captured in our WTP estimates.

Medical Costs

We have not fully quantified the effect the final rules may have on medical spending in this analysis because, due to data limitations, we are unable to directly estimate the effect of the final rules on the incidence of diet-related disease. If, however, the requirements in the final rules help improve diet quality and reduce the prevalence of chronic diet-related diseases, then consumers and other payers would spend less on medical treatment for these diseases (the portion consumers spend on themselves is implicitly included in our WTP estimates; any portion borne by the rest of society has not been quantified). For example, 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 report estimates that preventing obesity would save $684 (2014$) per Medicaid recipient per year and $2,025 (2014$) per Medicare recipient per year (Ref. 39).

The medical costs associated with diet-related diseases and conditions increase medical spending for persons afflicted with these diseases and conditions. These diseases and conditions, 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.

Offsetting Utility Loss

As with morbidity effects and medical savings borne by consumers themselves, there is a potential impact of the final rules that is theoretically implicitly captured in the WTP estimates:

offsetting loss of utility (which is an economics term sometimes described as enjoyment, usefulness or satisfaction). Consumers may prefer the taste of relatively less nutritious 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 final rules.

Additional 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 the 1993 rules that implemented NLEA in Abaluck (2011) into the illustrated welfare gains from the final rules, to include the change in label content associated with 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 perform simulations that reflect an assumption 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 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 who are the main meal planner in their household from the DHKS and CSFII. Using an identical methodology to that which is used to produce the illustrative benefits results in Table 14, we illustrate the benefits from the final rules for women only.[40] Table 15 contains

[40] Given the fairly broad age range of women in Abaluck's sample, we feel that it is reasonable to include all women in our sensitivity analysis here. However, using the same female subsample used by Abaluck (women aged 19 to

our illustrations of the benefits from the final rules if only women received benefits. We illustratively calculate that the PV of the stream of benefits for women ranges from $1.5 billion to $39.6 billion with a mean of $16.8 billion, using a 3 percent discount rate, and from $1.0 billion to $26.6 billion with a mean of $11.4 billion, using a 7 percent discount rate (2014$). Table 15 also presents annualized benefits, at both a 3 percent and a 7 percent discount rate.

Table 15 - Summary of Benefits Simulation Results for Women in the U.S. (in billions of 2014$)

	Low	Mean	High
PV (3%)	$1.5	$16.8	$39.4
PV (7%)	$1.0	$11.3	$26.6
Annualized (3%)	$0.1	$1.1	$2.6
Annualized (7%)	$0.1	$1.1	$2.5

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Estimates reflect total female population in the U.S. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

A third source of uncertainty has to do with the Abaluck (2011) annual welfare gains per person, which were previously summarized in Table 12 of this RIA. Underlying these estimates is the full set of Model 1 and Model 2 estimates presented in Table 5 of Abaluck (2011) of peoples' WTP for NLEA nutrient information. All of the WTP coefficients estimated in Model 1 are statistically significant at conventional levels (10 percent or better), and some of the WTP coefficients estimated in Model 2 are statistically significant at conventional levels.[41] Using an identical methodology to that which is used to produce the benefits results in Table 14, we

50) produces mean benefits of $6.8 billion (2014$) using a 3 percent discount rate and $4.6 billion (2014$) using a 7 percent discount rate.

[41] We expect that, all else equal, when individuals learn that a food product has more cholesterol or sodium than they previously thought, they will not increase their consumption of the food product. Thus, a one-tailed test of the type H_o: Coefficient = 0, H_a: Coefficient < 0 is used to assess the statistical significance of the cholesterol and sodium coefficients in Models 1 and 2. Two-tailed tests are used to assess the statistical significance of the remaining coefficients in Models 1 and 2.

illustrate the benefits using the Model 1 annual welfare gain per person of $67 illustrated in Table 12 and, being extremely conservative, a Model 2 annual welfare gain per person of $0, which produces an average annual welfare gain per person of $34 (2014$). Table 16 contains our illustration of the benefits using an average annual welfare gain per person of $34 instead of the $61 that was used in the primary illustration (2014$). We illustratively calculate that the PV of the stream of benefits in this case ranges from $1.6 billion to $43.3 billion with a mean of $18.4 billion, using a 3 percent discount rate, and from $1.1 billion to $29.0 billion with a mean of $12.4 billion, using a 7 percent discount rate (2014$). Table 16 also presents annualized benefits, at both a 3 percent and a 7 percent discount rate.

Table 16 - Summary Benefits Simulation Results for the Entire U.S. Population (in billions of 2014$)

	Low	Mean	High
PV (3%)	$1.6	$18.4	$43.3
PV (7%)	$1.1	$12.4	$29.0
Annualized (3%)	$0.1	$1.2	$2.9
Annualized (7%)	$0.1	$1.2	$2.7

Notes: Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Estimates reflect total U.S. population (children and adults) and rely on an average annual welfare gain per person of $34 (2014$). Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

3. Option 3: The final rules, but with a 2-year compliance period for all manufacturers

a. Costs

i.) Relabeling Costs

A 2-year compliance period for all manufacturers would give small manufacturers less time to comply with the final rules and would thus, as compared with the 3-year compliance period, increase the labeling costs associated with the final rules. This increase in costs would

result from small firms having to undertake a greater amount of labeling changes uncoordinated with regularly scheduled changes.

Label costs under this scenario are summarized in Table 17. With the same compliance date, the labeling cost estimates of the final rules under a 2-year compliance period range from $1,421 million to $4,621 million with a mean estimate of $2,748 million, using a 3 percent discount rate, and from $1,347 million to $4,412 million with a mean estimate of $2,599 million, using a 7 percent discount rate (2014$). Table 17 also presents annualized labeling costs, using both a 3 percent and a 7 percent discount rate.

Table 17 - Summary of Relabeling Costs – 24 Month Compliance Period (in millions of 2014$)

Final Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Mean	High	Low	Mean	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$620	$1,362	$2,569	$327	$720	$1,358
Conventional Food	Claim Removal Related to DV Change	Major	$3	$7	$12	$3	$7	$12
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$8	$17	$31	$8	$17	$31
Dietary Supplements	Various Changes to the NFL	Minor	$117	$255	$472	$117	$255	$472
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.3	$1	$1	$0.3	$1	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$1	$1	$2	$1	$1	$2
Analytical Testing Costs			$322	$421	$530	$322	$421	$530
Total NFL			$1,071	$2,064	$3,617	$778	$1,422	$2,406
Serving Size (SS)								
Conventional Food	Changes Due to RACC Amendments	Minor	$105	$235	$448	$105	$235	$448
Conventional Food	Change in Definition of Single-Serving Container	Minor	$98	$213	$399	$98	$213	$399
Conventional Food	DCL	Major	$78	$165	$306	$78	$165	$306

Conventional Food	Claim Removal Related to RACC Change	Major	$2	$3	$6	$2	$3	$6
Conventional Food	First Time Nutrition Facts Panel Due To RACC Proposals	Major	$80	$150	$260	$80	$150	$260
Conventional Food	Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive (3%)	$280	$560	$796	$280	$560	$796
Conventional Food	Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive (7%)	$206	$411	$587	$206	$411	$587
Total SS (3%)			$643	$1,326	$2,215	$643	$1,326	$2,215
Total SS (7%)			$569	$1,177	$2,006	$569	$1,177	$2,006
TOTAL NFL + SS (3%)			$1,714	$3,390	$5,832	$1,421	$2,748	$4,621
TOTAL NFL + SS (7%)			$1,640	$3,241	$5,623	$1,347	$2,599	$4,412
Annualized (3%)			$115	$228	$392	$95	$185	$311
Annualized (7%)			$155	$306	$531	$127	$245	$417

Notes: Analytical testing costs associated with the mandatory declarations of potassium and vitamin D are conservatively estimated across *all* conventional food and dietary supplement UPCs using the FDA Labeling Cost Model. The cost of an extensive label change includes recurring annual costs associated with increased package sizes. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Related recordkeeping costs are estimated to be $21.4 million at a 3 percent discount rate and $21.3 million at a 7 percent discount rate (2014$). Related to the new definition of dietary fiber, study costs are estimated to be roughly $4 million (2014$), and additional labeling costs[42] are estimated to range from $176 million to $1,101 million with a mean estimate of $430 million

[42] The additional labeling change represents a minor labeling change (Ref. 1). Labeling costs are estimated using the "3 Months or Less" compliance period option in the FDA Labeling Cost Model (we conservatively estimate that manufacturers, upon receiving post-compliance period approval of their dietary fiber citizen petition or health claim petition, would relabel as quickly as possible).

(2014$). These costs are summarized below in Table 18. Table 18 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 18 – Summary of Recordkeeping Costs and Study and Additional Labeling Costs Related to the New Definition of Dietary Fiber (in millions of 2014$)

	Low	Mean	High
Recordkeeping Costs	$21	$21	$21
Study Costs Related to New Definition of Dietary Fiber	$4	$4	$4
Additional Labeling Costs Related to New Definition of Dietary Fiber	$176	$430	$1,101
Total	$201	$455	$1,126
Annualized (3%)	$14	$31	$76
Annualized (7%)	$19	$43	$106

Notes: These costs do not depend on compliance period. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Labeling costs associated with future UPC growth are estimated to range from $66 million to $198 million, with a mean estimate of $135 million, using a 3 percent discount rate, and from $35 million to $107 million, with a mean estimate of $72 million, using a 7 percent discount rate (2014$). These costs are summarized below in Table 19. Table 19 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 19 – Summary of Labeling Costs Associated With Future UPC Growth (in millions of 2014$)

	Type of Label Change	Low	Mean	High
Present Value (3%)				
First Time Nutrition Facts Panel Due to RACC	Major	$6	$14	$26
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$60	$121	$172
Total		$66	$135	$198
Present Value (7%)				
First Time Nutrition Facts Panel Due to RACC	Major	$4	$10	$18
Package Size and Claim Effects of Change of Definition of Single-	Extensive	$31	$62	$89

Serving Container				
Total		$35	$72	$107
Annualized (3%)		$4	$9	$13
Annualized (7%)		$3	$7	$10

Notes: Annualized amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

ii.) Reformulation Costs

Reformulation costs under a 2-year compliance period are summarized in Table 20. A 2-year compliance period gives small manufacturers less time to reformulate their products and would thus, as compared with the 3-year compliance period, increase reformulation costs associated with the final rules (as discussed earlier in the RIA in describing the FDA Reformulation Cost Model, reformulation costs are higher for shorter compliance periods because if the compliance period is short, manufacturers will incur increased costs for overtime labor, additional staffing, and rush charges with vendors and suppliers). Total costs of reformulation due to requirements affecting eligibility to make health claims and nutrient content claims and voluntary reformulation due to increased visibility of added sugars and B_{12} range from $655 million to $2,698 million with a mean estimate of $1,454 million (2014$). Table 20 also presents annualized reformulation costs, using both a 3 percent and a 7 percent discount rate.

Table 20 - Summary of Reformulation Costs – 24 Month Compliance Period (in millions of 2014$)

Category	**Low**	**Mean**	**High**
Claims	$157	$348	$646
Added Sugars	$298	$662	$1,228
B_{12}	$200	$444	$824
Total	$655	$1,454	$2,698
Annualized (3%)	$44	$98	$181
Annualized (7%)	$62	$137	$255

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

b. Benefits

We illustratively calculate that under a 2-year compliance period the PV of the stream of benefits for the total U.S. population over the next 20 years ranges from $2.8 billion to $77.8 billion with a mean of $33.2 billion, using a 3 percent discount rate, and from $1.9 billion to $52.6 billion with a mean of $22.4 billion, using a 7 percent discount rate, as illustrated in Table 21 (2014$). Table 21 also presents annualized benefits, using both a 3 percent and a 7 percent discount rate.

Table 21 - Summary of Benefits Simulation Results for Entire U.S. Population - 24 Month Compliance Period (in billions of 2014$)

	Low	Mean	High
PV (3%)	$2.8	$33.2	$77.8
PV (7%)	$1.9	$22.4	$52.6
Annualized (3%)	$0.2	$2.2	$5.2
Annualized (7%)	$0.2	$2.1	$5.0

Notes: Estimates reflect total U.S. population (children and adults). Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

4. Option 4: The final rules, but with a 3-year compliance period for all manufacturers

a. Costs

i.) Relabeling Costs

A 3-year compliance period would give large manufacturers more time to comply with the final rules and would thus decrease the labeling costs associated with the final rules as compared with a 2-year compliance period. This decrease in costs would result from large firms having to undertake fewer labeling changes uncoordinated with their regularly scheduled labeling changes.

Label costs under this scenario are summarized in Table 22. With the same compliance date, the labeling cost estimates of the final rules under a 3-year compliance period range from

$1,100 million to $3,777 million with a mean estimate of $2,210 million, using a 3 percent discount rate, and from $1,026 million to $3,568 million with a mean estimate of $2,060 million, using a 7 percent discount rate (2014$). Table 22 also presents annualized labeling costs, using both a 3 percent and a 7 percent discount rate.

Table 22 - Summary of Relabeling Costs – 36 Month Compliance Period (in millions of 2014$)

Final Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Mean	High	Low	Mean	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$359	$925	$1,881	$190	$489	$994
Conventional Food	Claim Removal Related to DV Change	Major	$2	$5	$9	$2	$5	$9
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$5	$12	$23	$5	$12	$23
Dietary Supplements	Various Changes to the NFL	Minor	$92	$206	$386	$92	$206	$386
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.3	$1	$1	$0.3	$1	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.4	$1	$2	$0.4	$1	$2
Analytical Testing Costs			$322	$421	$530	$322	$421	$530
Total NFL			$781	$1,571	$2,832	$612	$1,135	$1,945
Serving Size (SS)								
Conventional Food	Changes Due to RACC Amendments	Minor	$62	$163	$337	$62	$163	$337
Conventional Food	Change in Definition of Single-Serving Container	Minor	$55	$142	$290	$55	$142	$290
Conventional Food	DCL	Major	$49	$117	$230	$49	$117	$230
Conventional Food	Claim Removal Related to RACC Change	Major	$1	$2	$4	$1	$2	$4
Conventional Food	First Time Nutrition Facts Panel Due To RACC Change	Major	$42	$92	$176	$42	$92	$176
Conventional Food	Package Size and Claim Effects of Definition of Single-Serving	Extensive (3%)	$279	$559	$795	$279	$559	$795

	Container							
Conventional Food	Package Size and Claim Effects of Definition of Single-Serving Container	Extensive (7%)	$205	$409	$586	$205	$409	$586
Total SS (3%)			$488	$1,075	$1,832	$488	$1,075	$1,832
Total SS (7%)			$414	$925	$1,623	$414	$925	$1,623
TOTAL NFL + SS (3%)			$1,269	$2,646	$4,664	$1,100	$2,210	$3,777
TOTAL NFL + SS (7%)			$1,195	$2,496	$4,455	$1,026	$2,060	$3,568
Annualized (3%)			$85	$178	$313	$74	$149	$254
Annualized (7%)			$113	$236	$421	$97	$195	$337

Notes: Analytical testing costs associated with the mandatory declarations of potassium and vitamin D are conservatively estimated across *all* conventional food and dietary supplement UPCs using the FDA Labeling Cost Model. The cost of an extensive label change includes recurring annual costs associated with increased package sizes. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Related recordkeeping costs are estimated to be $21.4 million at a 3 percent discount rate and $21.3 million at a 7 percent discount rate (2014$). Related to the new definition of dietary fiber, study costs are estimated to be roughly $4 million (2014$), and additional labeling costs[43] are estimated to range from $176 million to $1,101 million with a mean estimate of $430 million (2014$). These costs are summarized below in Table 23. Table 23 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 23 – Summary of Recordkeeping Costs and Study and Additional Labeling Costs Related to the New Definition of Dietary Fiber (in millions of 2014$)

	Low	Mean	High
Recordkeeping Costs	$21	$21	$21
Study Costs Related to New Definition of Dietary Fiber	$4	$4	$4
Additional Labeling Costs Related to New Definition of Dietary Fiber	$176	$430	$1,101

[43] The additional labeling change represents a minor labeling change (Ref. 1). Labeling costs are estimated using the "3 Months or Less" compliance period option in the FDA Labeling Cost Model (we conservatively estimate that manufacturers, upon receiving post-compliance period approval of their dietary fiber citizen petition or health claim petition, would relabel as quickly as possible).

Total	$201	$455	$1,126
Annualized (3%)	$14	$31	$76
Annualized (7%)	$19	$43	$106

Notes: These costs do not depend on compliance period. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Labeling costs associated with future UPC growth are estimated to range from $66 million to $198 million, with a mean estimate of $135 million, using a 3 percent discount rate, and from $35 million to $107 million, with a mean estimate of $72 million, using a 7 percent discount rate (2014$). These costs are summarized below in Table 24. Table 24 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

Table 24 – Summary of Labeling Costs Associated With Future UPC Growth (in millions of 2014$)

	Type of Label Change	**Low**	**Mean**	**High**
Present Value (3%)				
First Time Nutrition Facts Panel Due to RACC	Major	$6	$14	$26
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$60	$121	$172
Total		$66	$135	$198
Present Value (7%)				
First Time Nutrition Facts Panel Due to RACC	Major	$4	$10	$18
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$31	$62	$89
Total		$35	$72	$107
Annualized (3%)		$4	$9	$13
Annualized (7%)		$3	$7	$10

Notes: Annualized amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

ii.) Reformulation Costs

Reformulation costs under a 3-year compliance period are summarized in Table 25. Compared with a 2-year compliance period, a 3-year compliance period would decrease

reformulation costs associated with the final rules (as discussed earlier in the RIA in describing the FDA Reformulation Cost Model, reformulation costs are higher for shorter compliance periods because if the compliance period is short, manufacturers will incur increased costs for overtime labor, additional staffing, and rush charges with vendors and suppliers). Total costs of reformulation due to requirements affecting eligibility to make health claims and nutrient content claims and voluntary reformulation due to increased visibility of added sugars and B_{12} range from $575 million to $2,377 million with a mean estimate of $1,280 million (2014$). Table 25 also presents annualized reformulation costs, using both a 3 percent and a 7 percent discount rate.

Table 25 - Summary of Reformulation Costs – 36 Month Compliance Period (in millions of 2014$)

Category	**Low**	**Mean**	**High**
Claims	$137	$305	$566
Added Sugars	$261	$580	$1,078
B_{12}	$177	$395	$733
Total	$575	$1,280	$2,377
Annualized (3%)	$39	$86	$160
Annualized (7%)	$54	$121	$224

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

b. Benefits

We illustratively calculate that under a 3-year compliance period the PV of the stream of benefits for the total U.S. population over the next 20 years ranges from $2.8 billion to $76.1 billion with a mean of $32.4 billion, using a 3 percent discount rate, and from $1.9 billion to $51.1 billion with a mean of $21.7 billion, using a 7 percent discount rate, as illustrated in Table 26 (2014$). Table 26 also presents annualized benefits, using both a 3 percent and a 7 percent discount rate.

Table 26 - Summary of Benefits Simulation Results for Entire U.S. Population - 36 Month

Compliance Period (in billions of 2014$)

	Low	Mean	High
PV (3%)	$2.8	$32.4	$76.1
PV (7%)	$1.9	$21.7	$51.1
Annualized (3%)	$0.2	$2.2	$5.1
Annualized (7%)	$0.2	$2.0	$4.8

Notes: Estimates reflect total U.S. population (children and adults). Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

5. Option 5: The final rules, but with a 4-year compliance period for all manufacturers

a. Costs

i.) Relabeling Costs

A 4-year compliance period for all manufacturers would decrease the labeling costs associated with the final rules, as compared to a 2- or 3-year compliance period. This decrease in costs would result from fewer firms having to undertake labeling changes that are uncoordinated with their regulatory scheduled changes.

Label costs under this scenario are summarized in Table 27. With the same compliance date, it can be seen that the labeling cost estimates of the final rules under a 4-year compliance period range from $800 million to $2,797 million with a mean estimate of $1,636 million, using a 3 percent discount rate, and from $726 million to $2,588 million with a mean estimate of $1,487 million, using a 7 percent discount rate (2014$). Table 27 also presents annualized labeling costs, using both a 3 percent and a 7 percent discount rate.

Table 27 - Summary of Relabeling Costs – 48 Month Compliance Period (in millions of 2014$)

Final Rule	Source of Label Change	Type of Label Change	Different Compliance Dates			Same Compliance Date		
			Low	Mean	High	Low	Mean	High
Nutrition Facts Label (NFL)								
Conventional Food	Various Changes to the NFL	Minor	$139	$494	$1,133	$73	$261	$599

Conventional Food	Claim Removal Related to DV Change	Major	$1	$2	$5	$1	$2	$5
Conventional Food	Claim Removal Related to New Dietary Fiber Definition	Major	$2	$6	$13	$2	$6	$13
Dietary Supplements	Various Changes to the NFL	Minor	$43	$107	$214	$43	$107	$214
Dietary Supplements	Claim Removal Related to DV Change	Major	$0.1	$0.3	$1	$0.1	$0.3	$1
Dietary Supplements	Claim Removal Related to New Dietary Fiber Definition	Major	$0.2	$0.4	$1	$0.2	$0.4	$1
Analytical Testing Costs			$322	$421	$530	$322	$421	$530
Total NFL			$507	$1,031	$1,897	$441	$798	$1,363
Serving Size (SS)								
Conventional Food	Changes Due to RACC Amendments	Minor	$27	$96	$221	$27	$96	$221
Conventional Food	Change in Definition of Single-Serving Container	Minor	$22	$78	$179	$22	$78	$179
Conventional Food	DCL	Major	$18	$61	$138	$18	$61	$138
Conventional Food	Claim Removal Related to RACC Change	Major	$0.3	$1	$2	$0.3	$1	$2
Conventional Food	First Time Nutrition Facts Panel Due To RACC Proposals	Major	$13	$44	$99	$13	$44	$99
Conventional Food	Package Size and Claim Effects of Change to Definition of Single-Serving Container	Extensive (3%)	$279	$558	$795	$279	$558	$795
Conventional Food	Package Size and Claim Effects Change to Definition of Single Serving Container	Extensive (7%)	$205	$409	$586	$205	$409	$586
Total SS (3%)			$359	$838	$1,434	$359	$838	$1,434
Total SS (7%)			$285	$689	$1,225	$285	$689	$1,225
TOTAL NFL + SS (3%)			$866	$1,869	$3,331	$800	$1,636	$2,797
TOTAL NFL + SS (7%)			$792	$1,720	$3,122	$726	$1,487	$2,588
Annualized (3%)			$58	$126	$224	$54	$110	$188
Annualized (7%)			$75	$162	$295	$69	$140	$244

Notes: Analytical testing costs associated with the mandatory declarations of potassium and vitamin D are

conservatively estimated across *all* conventional food and dietary supplement UPCs using the FDA Labeling Cost Model. The cost of an extensive label change includes recurring annual costs associated with increased package sizes. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Related recordkeeping costs are estimated to be $21.4 million at a 3 percent discount rate and $21.3 million at a 7 percent discount rate (2014$). Related to the new definition of dietary fiber, study costs are estimated to be roughly $4 million (2014$) and additional labeling costs[44] are estimated to range from $176 million to $1,101 million with a mean estimate of $430 million (2014$). These costs are summarized below in Table 28. Table 28 also presents annualized costs, using both a 3 percent and a 7 percent discount rate

Table 28 – Summary of Recordkeeping Costs and Study and Additional Labeling Costs Related to the New Definition of Dietary Fiber (in millions of 2014$)

	Low	**Mean**	**High**
Recordkeeping Costs	$21	$21	$21
Study Costs Related to New Definition of Dietary Fiber	$4	$4	$4
Additional Labeling Costs Related to New Definition of Dietary Fiber	$176	$430	$1,101
Total	$201	$455	$1,126
Annualized (3%)	$14	$31	$76
Annualized (7%)	$19	$43	$106

Notes: These costs do not depend on compliance period. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Labeling costs associated with future UPC growth are estimated to range from $66 million to $198 million, with a mean estimate of $135 million, using a 3 percent discount rate, and from $35 million to $107 million, with a mean estimate of $72 million, using a 7 percent discount rate (2014$). These costs are summarized below in Table 29. Table 29 also presents annualized costs, using both a 3 percent and a 7 percent discount rate.

[44] The additional labeling change represents a minor labeling change (Ref. 1). Labeling costs are estimated using the "3 Months or Less" compliance period option in the FDA Labeling Cost Model (we conservatively estimate that manufacturers, upon receiving post-compliance period approval of their dietary fiber citizen petition or health claim petition, would relabel as quickly as possible).

Table 29 – Summary of Labeling Costs Associated With Future UPC Growth (in millions of 2014$)

	Type of Label Change	Low	Mean	High
Present Value (3%)				
First Time Nutrition Facts Panel Due to RACC	Major	$6	$14	$26
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$60	$121	$172
Total		$66	$135	$198
Present Value (7%)				
First Time Nutrition Facts Panel Due to RACC	Major	$4	$10	$18
Package Size and Claim Effects of Change of Definition of Single-Serving Container	Extensive	$31	$62	$89
Total		$35	$72	$107
Annualized (3%)		$4	$9	$13
Annualized (7%)		$3	$7	$10

Notes: Annualized amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

ii.) Reformulation Costs

Reformulation costs under a 4-year compliance period are summarized in Table 30. As compared to a 2- or 3-year compliance period, a 4-year compliance period would decrease reformulation costs associated with the final rules (as discussed earlier in the RIA in describing the FDA Reformulation Cost Model, reformulation costs are higher for shorter compliance periods because if the compliance period is short, manufacturers will incur increased costs for overtime labor, additional staffing, and rush charges with vendors and suppliers). Total costs of reformulation due to requirements affecting eligibility to make health claims and nutrient content claims and voluntary reformulation due to increased visibility of added sugars and B_{12} range from $575 million to $2,377 million with a mean estimate of $1,280 million (2014$). Table 30

also presents annualized reformulation costs, using both a 3 percent and a 7 percent discount rate.

Table 30 - Summary of Reformulation Costs – 48 Month Compliance Period (in millions of 2014$)

Category	Low	Mean	High
Claims	$137	$305	$566
Added Sugars	$261	$580	$1,078
B_{12}	$177	$395	$733
Total	$575	$1,280	$2,377
Annualized (3%)	$39	$86	$160
Annualized (7%)	$54	$121	$224

Notes: Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

b. Benefits

We illustratively calculate that under a 4-year compliance period the PV of the stream of benefits for the total U.S. population over the next 20 years ranges from $2.7 billion to $75.1 billion with a mean estimate of $32.0 billion, using a 3 percent discount rate, and from $1.8 billion to $50.2 billion with a mean estimate of $21.3 billion, using a 7 percent discount rate, as illustrated in Table 31 (2014$). Table 31 also presents annualized benefits, using both a 3 percent and a 7 percent discount rate.

Table 31 - Summary of Benefits Simulation Results for Entire U.S. Population - 48 Month Compliance Period (in billions of 2014$)

	Low	Mean	High
PV (3%)	$2.7	$32.0	$75.1
PV (7%)	$1.8	$21.3	$50.2
Annualized (3%)	$0.2	$2.2	$5.0
Annualized (7%)	$0.2	$2.0	$4.7

Notes: Estimates reflect total U.S. population (children and adults). Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

6. Summary of Estimated Costs and Illustratively Calculated Benefits by Regulatory Option

Estimated costs and illustratively calculated benefits, by regulatory option, are summarized below in Table 32 and Table 33. Table 32 presents results assuming that the final rules are enacted together. Table 33 presents results assuming that the final rules are enacted separately.

Table 32 - Summary of Net Benefits by Regulatory Option If Final Rules Have Same Compliance Date (in billions of 2014$)

		PV				Annualized		
Option	**Discount Rate**	**Benefits**	**Costs**	**Net Benefits**		**Benefits**	**Costs**	**Net Benefits**
1 - No New Federal Regulatory Action	3%	$0.0	$0.0	$0.0		$0.0	$0.0	$0.0
	7%	$0.0	$0.0	$0.0		$0.0	$0.0	$0.0
2 - Final Rules	3%	$33.1	$4.8	$28.3		$2.2	$0.3	$1.9
	7%	$22.3	$4.5	$17.8		$2.1	$0.4	$1.7
3 - Final Rules - 2 Year Compliance Period	3%	$33.2	$4.8	$28.4		$2.2	$0.3	$1.9
	7%	$22.4	$4.6	$17.8		$2.1	$0.4	$1.7
4 - Final Rules - 3 Year Compliance Period	3%	$32.4	$4.1	$28.3		$2.2	$0.3	$1.9
	7%	$21.7	$3.9	$17.8		$2.0	$0.4	$1.6
5 - Final Rules - 4 Year Compliance Period	3%	$32.0	$3.5	$28.5		$2.2	$0.2	$2.0
	7%	$21.3	$3.3	$18.0		$2.0	$0.3	$1.7

Notes: Benefits and costs reflect mean estimates. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

Table 33 - Summary of Net Benefits by Regulatory Option If Final Rules Have Different Compliance Dates (in billions of 2014$)

		PV				Annualized		
Option	**Discount Rate**	**Benefits**	**Costs**	**Net Benefits**		**Benefits**	**Costs**	**Net Benefits**
1 - No New Federal Regulatory Action	3%	$0.0	$0.0	$0.0		$0.0	$0.0	$0.0
	7%	$0.0	$0.0	$0.0		$0.0	$0.0	$0.0
2 - Final Rules	3%	$33.1	$5.4	$27.7		$2.2	$0.4	$1.8
	7%	$22.3	$5.2	$17.1		$2.1	$0.5	$1.6
3 - Final Rules - 2 Year Compliance Period	3%	$33.2	$5.4	$27.8		$2.2	$0.4	$1.8
	7%	$22.4	$5.2	$17.2		$2.1	$0.5	$1.6
4 - Final Rules - 3 Year Compliance Period	3%	$32.4	$4.5	$27.9		$2.2	$0.3	$1.9
	7%	$21.7	$4.3	$17.4		$2.0	$0.4	$1.6

5 - Final Rules - 4 Year Compliance Period	3%	$32.0	$3.7	$28.3		$2.2	$0.2	$2.0
	7%	$21.3	$3.5	$17.8		$2.0	$0.3	$1.7

Notes: Benefits and costs reflect mean estimates. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

II. Regulatory Flexibility Analysis

A. Introduction

We have examined the economic implications of the final 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 final rules 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

For the purposes of the Regulatory Flexibility Act analysis, we use the SBA's definition of a small business as it applies to the relevant economic sectors, in this case, North American Industry Classification System (NAICS) 311, 312 and 325. SBA generally defines a small food manufacturer as one that has 500 or fewer employees. Using Dun and Bradstreet data, we estimate that roughly 99 percent of food manufacturers, or about 30,970 food manufacturers, have 500 or fewer employees and are affected by the final rules.

2. Costs to Small Entities

The final rules will 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 as defined using the SBA definition. However, we estimate that the final rules would

cost roughly $6,096 per UPC (2014$). Therefore, a small firm owning one to three UPC's would incur a cost of between roughly $6,096 to $18,288 (2014$). This is likely a significant overestimate, though, as the share of sales controlled by small firms is typically small, and much smaller than the share of UPCs controlled by small firms (Ref. 2). The cost of the rule per entity (including large firms) is approximately $152,031 (2014$). This number likely significantly overstates the cost per small entity because the share of firms which are small businesses is typically large and the share of sales controlled by small firms typically small (Ref. 2).

C. Regulatory Options

The economic impact of the final rules on small entities is reduced in two ways. First, we note that the targeted exemption from labeling that currently exists for some small businesses will continue to be available. Currently, certain small businesses whose products do not sell more than 100,000 units may apply for a 12-month exemption from certain nutrition labeling requirements for that particular product, and the business has the option to reapply for a continuation of this exemption (21 CFR 101.9(j)(18). 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.

Second, in response to comments we received on the proposed rules,[45] for firms earning less than $10 million in annual food sales, which, based on Nielsen data we estimate to cover approximately 95 percent of all food manufacturers and 48 percent of all food UPCs, we have increased the compliance period from 2 years to 3 years. We estimate that this extended compliance period reduces the cost per UPC for covered firms from roughly $640 per UPC to about $545 per UPC, and the cost per covered firm from approximately $8,062 per firm to

[45] A summary of and our responses to these comments are provided in the final rules published in the Federal Register.

around $6,864 per firm (2014$) because with a longer compliance period there will be fewer uncoordinated labeling changes and manufacturers will have less of a need for overtime labor and additional staffing and to pay rush charges to vendors and suppliers related to reformulation.

D. Summary

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

III. PRA of 1995

We are publishing two final rules on nutrition labeling in the Federal Register. The two final rules will have the same effective date and compliance date. Thus, a manufacturer is likely to be able to coordinate the required label changes in the two separate rules. However, we estimate the hour burden of the final rules as if the rules have proceeded as a unique change to the labeling regulations.

A. Nutrition Facts Label Rule

The Nutrition Facts Label final 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 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.

*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

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 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 Nutrition Facts Label rule requires 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, isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber, different forms of vitamin E, and folate/folic acid declared on the Nutrition Facts or Supplement Facts label, which is the amount in the finished food product. Manufacturers are required to provide such records to an appropriate regulatory official upon request during inspection. Manufacturers are also 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 or synthetic non-digestible carbohydrate that are not listed in the definition of dietary fiber will have the option of submitting a citizen petition to FDA to request the agency amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber, by demonstrating the physiological benefits of the isolated or synthetic non-digestible carbohydrate to human health. In addition, if the isolated or synthetic non-digestible carbohydrate is the subject of an authorized health claim, FDA would consider the carbohydrate to be a dietary fiber with a beneficial physiological effect

to human health and would amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber. If the citizen petition is granted, or if the isolated or synthetic non-digestible carbohydrate is the subject of an authorized health claim, then the non-digestible carbohydrate is considered to meet the definition of dietary fiber and the definition would be amended to include the dietary fiber in the listing of dietary fibers that must be included in the total amount of dietary fiber declared on the Nutrition or Supplement Facts label by food manufacturers who manufacture food products that contain the isolated or synthetic non-digestible carbohydrate. The record requirements are 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. 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 is in compliance with the requirements of §§ 101.9(g) and 101.36(f).

We require that firms make and keep certain records necessary to verify the amount of the nutrients in the finished food product. The Nutrition Facts Label 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 Nutrition Facts Label rule would require manufacturers to, upon request during an inspection, 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, information from recipes or formulations, batch records, or other appropriate verification records that contain the required information to verify the nutrient content in the final product.

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

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

Type of Declaration/ 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]	31,283	1	31,283	1	31,283
Dietary Fiber/ § 101.9(c)(6)(i)[2]	31,283	1	31,283	1	31,283
Soluble Fiber/ § 101.9(c)(6)(i)(A)[2]	31,283	1	31,283	1	31,283
Insoluble Fiber/ § 101.9(c)(6)(i)(B)[2]	31,283	1	31,283	1	31,283
Dietary Fiber/ § 101.9(c)(6)(i)	28	1	28	1	28
Vitamin E/ § 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
Folate/Folic Acid/ § 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
Total					187,726
Total Initial Hours					187,726
New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					187,942

[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 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 final 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 final 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, we estimate the recordkeeping burden of the Nutrition Facts Label rule to be 1 hour per manufacturer as estimated in Table 1.

Under the Nutrition Facts Label rule, the declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate that all roughly 31,283 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. We estimate that there are currently approximately 28 isolated or synthetic non-digestible carbohydrates that are not listed in the definition of dietary fiber.[46] Once a citizen petition is filed by a manufacturer related to a particular isolated or synthetic non-digestible carbohydrate is granted or denied, or the carbohydrate is the subject of an authorized health claim, and the dietary fiber is listed in the definition of dietary fiber, the use of the dietary fiber as an ingredient in any food product must be included in the total amount of dietary fiber declared in nutrition labeling for such product.

[46] We have no way of estimating the number of isolated or synthetic non-digestible carbohydrates that will be discovered in the future.

Thus, it is estimated that 28 manufacturers would incur a recordkeeping burden associated with filing a citizen petition to amend the listing of dietary fiber related to an isolated or synthetic non-digestible carbohydrate that is not currently listed in 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 conservatively estimate that all roughly 31,283 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 Nutrition Facts Label 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 Nutrition Facts Label 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 187,942 recordkeeping burden hours for the covered establishments under the Nutrition Facts Label rule, as reported in Table 1.

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) a combination of both naturally occurring and added sugars (2) a mixture of non-digestible carbohydrates that do and do not meet the 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: Under the Nutrition Facts Label rule, we require that firms provide records upon request during an inspection that they use to verify the declared amounts of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid on the Nutrition Facts or Supplement Facts label.

The 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, non-digestible carbohydrates that both do and do not meet the 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/ 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]	31,283	1	31,283	1	31,283
Dietary Fiber/ § 101.9(c)(6)(i)[2]	31,283	1	31,283	1	31,283
Soluble Fiber/	31,283	1	31,283	1	31,283

§ 101.9(c)(6)(i)(A)[2]					
Insoluble Fiber/ § 101.9(c)(6)(i)(B)[2]	31,283	1	31,283	1	31,283
Vitamin E/ § 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
Folate/Folic Acid/ § 101.9(c)(8)[3]	31,283	1	31,283	1	31,283
Total					187,698
Total Initial Hours					187,698
New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					187,914

[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 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 Nutrition Facts Label 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 conservatively 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. Built into the estimate of 1 hour is the range from 0 hours, for some covered manufacturers that do not need to maintain records, to a larger number of hours for some covered manufacturers, such as those who produce fermented foods, that may require more time to gather or produce the necessary records. As shown in Table 2, the initial reporting burden for covered establishments is 187,698 hours. Also, in accordance with our previous estimate of the number of newly introduced products that would be covered by the requirements 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 187,914 reporting burden hours for the covered establishments under the Nutrition Facts Label rule, as estimated in Table 2.

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]

CFR Section	Number of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs (in billions of 2014$)
101.9 and 101.36	31,283	26	813,358	2	1,626,716	$2.47

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

We have estimated that the burden associated with the Nutrition Facts Label rule would be a burden created by the need for food manufacturers to revise their nutrition labels. We

estimate that the third party disclosure burden would be approximately 2 hours per disclosure, for a total burden of 1,626,716 hours.

Third party disclosure burden for manufacturers:

The incremental time burden for reviewing labels to assess how to bring them into compliance with the requirements of the Nutrition Facts Label rule 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 estimate that about 31,283 manufacturers representing about 813,358 UPCs, with an average disclosure of 26 (813,358/31,283), would be covered under the Nutrition Facts Label rule. 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 RIA, we have estimated the capital cost to be $2.47 billion (2014$).

B. Serving Size Rule

This 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.

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 RACCs; Serving Size for Breath Mints; and Technical Amendments

Reporting Requirements

None.

Recordkeeping Requirements

None.

Third-Party Disclosure Requirements

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

Description: In major part, the Serving Size rule revises §§ 101.9 and 101.12 to (1) amend the definition of a single serving, (2) require a second column of nutrition information per package for products that contain at least 200 and up to and including 300 percent of the applicable RACCs, as well as per unit for discrete units in multi-serving packages in which each unit contains at least 200 percent and up to and including 300 percent of the applicable RACCs, (3) update, modify, and establish RACCs 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 many instances, will require changes to the nutrition information that is presented on the Nutrition Facts label of retail food products. Preexisting §§ 101.9 and 101.12 are approved by OMB in accordance with the PRA under OMB control number 0910-0381. The Serving Size rule will modify the information collection associated with preexisting §§101.9 and 101.12 by adding to the burden associated with the collection by requiring the following manufacturers to make changes to their product labels: those whose

retail food products are labeled with a serving size that is inconsistent with the provisions of the final rule, and those whose retail food products would be required to use DCL.[47] 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 billions of 2014$)
101.9 and 101.12	13,452	25	336,300	2	672,600	$1.00
Total Initial Hours and Capital Costs					672,600	$1.00
New Products	500	1	500	2	1,000	$0.01
Total Recurring Hours and Capital Costs					1,000	$0.01
Total Burden Hours and Capital Costs					673,600	$1.01

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

Under §§ 101.9 and 101.12, some manufacturers of retail food products would need to make a labeling change to modify the serving sizes and other nutrition information based on changes to what products may be or are required to be labeled as a single serving or based on updated, modified, or established RACCs. Additionally, some manufacturers would need to change their product labels to add a second column of nutrition information per package or per discrete unit as part of the Nutrition Facts label. The third-party disclosure burden consists of the

[47] Included in this burden are the labeling costs that result from changes in the eligibility to bear nutrient content claims or health claims (e.g., the cost of removing a claim from labeling or adding a required disclaimer).

setup time required to design a revised label and incorporate it into the manufacturing process. The third-party disclosure burden for the Serving Size rule is estimated in Table 1.

Based upon our knowledge of food labeling, we estimate that the affected manufacturers 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 requirements of the Serving Size rule. Each label redesign would require an estimated 1 additional hour per UPC, for a total of 2 hours per UPC.

We estimate that about 13,452 manufacturers would initially be affected by the Serving Size rule and that about 336,300 products would initially be required to be relabeled, for an average of 25 (336,300/13,452) products per respondent. The total initial third-party disclosure burden of 672,600 hours is reported in Table 1. The final column of Table 1 gives the estimated initial capital cost of the relabeling associated with the Serving Size rule. Based on the RIA, we estimate the initial capital cost to be approximately $1 billion (2014$).

The Serving Size rule generates recurring burdens related to the requirement that some manufacturers undertake an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims and also to the requirement that some manufacturers undertake a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required.[48] We estimate that about 500 new products would be affected by these requirements each year, and that the required third party disclosure burden would be 2 hours per product, for an annual recurring third party

[48] The Serving Size rule does not otherwise generate any recurring burdens 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.

disclosure burden of 1,000 hours. Based on the RIA, we estimate the annual recurring capital cost to be approximately $0.01 billion (2014$).

Adding the recurring burden from new products to the initial burden for existing products results in a total of 673,600 third party disclosure burden hours and $1.01 billion (2014$) in capital costs as reported in Table 1.

The information collection provisions in the Nutrition Facts Label rule and the Serving Size rule have been submitted to OMB for review as required by Section 3507(d) of the PRA of 1995.

Before the effective date of the Serving Size final rule and the Nutrition Facts Label final rule, we will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the rules.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

References

1 RTI International. "2014 FDA Labeling Cost Model." Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.

2 RTI International. "Reformulation Cost Model." Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela Coglaiti, Shawn Karns, and Catherine Viator. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.

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

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

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

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

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

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

9 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.

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

11 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.

12 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.

13 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.

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

15 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.

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

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

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

19 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.

20 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/.

21 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.

22 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.

23 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.

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

25 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.

26 National Center for Health Statistics. Health, United States, 2011: With Special Feature on Socioeconomic Status and Health. Hyattsville, MD. 2012.

27 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.

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

29 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.

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

31 National Cancer Institute. Food Sources of Energy Among U.S. Population, 2005 – 2006. Risk Factor Monitoring and Methods. Control and Population Sciences. National Cancer Institute; 2010.

32 Palisade Corporation. @Risk for Excel. Version 6.1.2: Professional Edition. 2013.

33 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.

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

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

36 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.

37 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.

38 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.

39 Brill, A. The Long-Term Returns of Obesity Prevention Policies. Robert Wood Johnson Foundation. April, 2013. Available at: http://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf405694.