DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2012–N–1210]

RIN 0910–AF22

Food Labeling: Revision of the Nutrition and Supplement Facts Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The updated information is consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States, and corresponds to new information on consumer understanding and consumption patterns. The final rule updates the list of nutrients that are required or permitted to be declared; provides updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishes nutrient reference values specifically for these population subgroups; and revises the format and appearance of the Nutrition Facts label.

DATES: *Effective date:* The final rule becomes effective on July 26, 2016. *Compliance date:* The compliance date of this final rule is July 26, 2018 for manufacturers with $10 million or more in annual food sales and July 26, 2019 for manufacturers with less than $10 million in annual food sales. See section III, Effective and Compliance Dates, for more detail. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of July 26, 2016.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–5429, email: *NutritionProgramStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary

Purpose of the Regulatory Action

We are amending our regulations for the nutrition labeling of conventional foods and dietary supplements to help consumers maintain healthy dietary practices. Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)) specifies certain nutrients to be declared in nutrition labeling, and authorizes the Secretary of Health and Human Services to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section.

The final rule revises our regulations to provide updated nutrition information on the label and to improve how the nutrition information is presented to consumers.

Summary of the Major Provisions of the Regulatory Action in Question

The final rule revises the Nutrition Facts label by:

- Removing the declaration of ''Calories from fat'' because current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases;
- Requiring the declaration of the gram amount of ''added sugars'' in a serving of a product, establishing a Daily Reference Value (DRV), and requiring the percent Daily Value (DV) declaration for added sugars;
- Changing ''Sugars'' to ''Total Sugars'' and requiring that ''Includes 'X' g Added Sugars'' be indented and declared directly below ''Total Sugars'' on the label;
- Updating the list of vitamins and minerals of public health significance. For example, the final rule requires the declaration of vitamin D and potassium and permits, rather than requires, the declaration of vitamins A and C;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts and Supplement Facts labels to increase the prominence of the term ''Calories;''
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances. For example, because there are no analytical methods that can distinguish between dietary fiber (soluble and insoluble fiber) and nondigestible carbohydrates that do not meet the definition of dietary fiber; added and naturally occurring sugars or the various forms of vitamin E; or folate and folic acid, the final rule requires manufacturers to make and keep certain written records to verify the declarations of dietary fiber, added sugars, vitamin E, and folate and folic acid in the labeling of the food associated with such records. The final rule requires these records to be kept for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. A similar requirement exists with respect to added sugars in foods subject to non-enzymatic browning and fermentation because there are no analytical methods that can determine the amount of added sugar in specific foods containing added sugars alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and fermentation. However, for manufacturers of such foods who are unable to reasonably approximate the amount of added sugars in a serving of food to which the records requirements apply, the final rule allows manufacturers to submit a petition to request an alternative means of compliance; and
- Establishing a compliance date of 2 years after the final rule's effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the final rule's effective date. (For more details, see part III.)

The final rule is the result of significant stakeholder engagement. We received nearly 300,000 comments, conducted several consumer studies and made those studies publicly available, and, in light of new scientific recommendations (particularly for added sugars), issued a supplemental notice of proposed rulemaking.

Elsewhere in this issue of the **Federal Register**, we have published a final rule that amends the definition of a single-serving container, requires dual column labeling for certain containers, updates the reference amounts customarily consumed and serving sizes for several food product categories, and amends the serving size for breath mints.

Costs and Benefits

We have developed one final regulatory impact analysis (FRIA) for this final rule as well as the final rule entitled ''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.'' The FRIA discusses key inputs in the estimation of costs and benefits of the changes finalized by the rules and assesses the sensitivity of cost and benefit totals to those inputs. The two nutrition labeling rules—which have a compliance date of 2 years after the final rule's effective date for manufacturers with $10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than $10 million in annual food sales—have impacts, including the sign on net benefits, that are characterized by substantial uncertainty. The primary sensitivity analysis shows benefits having the potential to range between $0.2 and $2 or $5 billion, and costs ranging between $0.2, $0.5 and $0.8 billion (annualized over the next twenty years, in 2014 dollars, at seven percent interest).[1]

TABLE 1—SUMMARY OF THE PRIMARY SENSITIVITY ANALYSIS OF THE COSTS AND BENEFITS OF THE FINAL RULES

[in billions of 2014$]

	Benefits (Low)	Benefits (Mean)	Benefits (High)	Costs (Low)	Costs (Mean)	Costs (High)
Present Value						
3%	$2.8	$33.1	$77.7	$2.3	$4.8	$8.6

[1] 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 the regulatory impact analysis.

TABLE 1—SUMMARY OF THE PRIMARY SENSITIVITY ANALYSIS OF THE COSTS AND BENEFITS OF THE FINAL RULES—Continued

[in billions of 2014$]

	Benefits (Low)	Benefits (Mean)	Benefits (High)	Costs (Low)	Costs (Mean)	Costs (High)
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. Three percent annualizing factor = 14.88. Seven 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).

I. Background

In general, under section 403(q) of the FD&C Act, a food is deemed misbranded unless its label or labeling bears nutrition information for certain nutrients. To implement section 403(q) of the FD&C Act, we have issued regulations related to:

- Declaration of nutrients on food labeling, including nutrients that are required or permitted to be declared and the format for such declaration;
- Label reference values for use in declaring the nutrient content of a food on its label or labeling;
- Two types of reference values, Reference Daily Intakes (RDIs) for vitamins and minerals and DRVs for certain nutrients, which are used to declare nutrient contents as percent DVs on the Nutrition Facts label;
- Exemptions for certain specified products; and
- A simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling can be used.

These regulations are at § 101.9 (21 CFR 101.9).

Elsewhere in this issue of the **Federal Register**, we are publishing a final rule that amends the definition of a single-serving container, requires dual column labeling for certain containers, updates the reference amounts customarily consumed and serving sizes for several food product categories and amends the serving size for breath mints.

In addition, section 403(q)(5)(F) of the FD&C Act imposes specific requirements that relate to the labeling of dietary supplement products. Accordingly, our food labeling regulations, at §§ 101.9(j)(6) and 101.36, establish requirements for nutrition labeling of dietary supplements.

A. Legal Authority

We are updating the Nutrition Facts label and Supplement Facts label, as set forth in this final rule, consistent with our authority in section 403(q) of the FD&C Act. Section 403(q)(1) of the FD&C Act states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling and identifies specific nutrient and calorie information required in labeling. Section 403(q)(2)(A) of the FD&C Act gives the Secretary, and by delegation, FDA, the discretion to require, by regulation, nutrition information about nutrients other than those specified in section 403(q)(1) of the FD&C Act to assist consumers in maintaining healthy dietary practices. Section 403(q)(2)(B) of the FD&C Act permits the Secretary, and by delegation, FDA, to remove information relating to a nutrient required by section 403(q)(1) or 403(q)(2)(A) of the FD&C Act if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. Consistent with these authorities, we are revising certain nutrient declarations in the Nutrition Facts label and Supplement Facts label. In addition, FDA's authority includes section 2(b)(1) of the Nutrition Labeling and Education Act of 1990 (NLEA) (21 U.S.C. 343 note). Specifically, section 2(b)(1)(A) of the NLEA requires nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Section 2(b)(1)(A) of the NLEA also states that such information should be consistent with current scientific knowledge about nutrients and health. We are changing DVs (RDIs and DRVs, as applicable) for some nutrients, and these values are used to calculate the percent DV for use on food labels. The use of reference values based on current science and the use of such values to calculate the percent DV can help consumers understand the nutrition information and its relative significance in a total daily diet. Furthermore, section 2(b)(1)(C) of the NLEA requires that the regulations permit the label or labeling of food to include nutrition information which is in addition to the information required by section 403(q) of the FD&C Act and ''which is of the type described in subparagraph (1) or (2) of such section . . . .'' We are changing the voluntary declaration of certain nutrients in the Nutrition Facts label consistent with this authority.

Other relevant authorities include sections 701(a), 403(a)(1) and 201(n) of the FD&C Act (21 U.S.C. 371(a), 21 U.S.C. 343(a)(1), and 21 U.S.C. 321(n), respectively). Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980)).

We are relying on our authority under sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act to establish record requirements to support nutrient declarations in labeling for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid, under certain circumstances, so that we can determine compliance with labeling requirements and take enforcement action as needed. For these nutrients, there is no official method of analysis of the Association of Official Analytical Chemists (AOAC) International or other reliable or appropriate analytical procedure, otherwise required by § 101.9(g), available for us to quantify the declared amount of the nutrient, under certain circumstances. Section 101.9(g) sets forth the standards for accuracy of the amount statements of nutrients on food labels. Failing to accurately state the amounts of nutrients on the label under

§ 101.9(g) would result in a product being misbranded. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains. Moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, when a food product contains dietary fiber (whether soluble, insoluble, or a combination of both) and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, we are requiring manufacturers to make and keep certain written records to verify the amount of added non-digestible carbohydrate that does not meet the definition of dietary fiber. When vitamin E is present in a food as a mixture of *all rac*-α-tocopherol acetate and RRR-α-tocopherol, we are requiring manufacturers to make and keep written records to verify the amount of *all rac*-α-tocopherol acetate added to the food and RRR-α-tocopherol in the finished food. When a mixture of folate and folic acid is present in a food, we are requiring manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food. When added sugars as well as naturally occurring sugars are present in a food, we are requiring manufacturers to make and keep records to verify the declared amount of added sugars in the food. Finally, we are requiring manufacturers to make and keep records to verify the declared amount of added sugars in specific foods, alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and/or fermentation.

The final rule's record requirements for these nutrients are designed to ensure that the nutrient declarations are accurate, truthful, and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The records we are requiring are only for foods for which an adequate analytical method is not available. The records will allow us to verify the declared amount of each nutrient and that such amount is truthful and not misleading. Thus, the records requirements will help in the efficient enforcement of the FD&C Act.

The authority granted to FDA under sections 701(a), 403(q), 403(a)(1) and 201(n) of the FD&C Act not only includes the authority to establish records requirements, but also includes access to such records. Without such authority, the nutrient declarations for these specific nutrients that we have determined are necessary to assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act are, practically speaking, not enforceable. Without access to such records, we would not know whether the amount declared on the label or in the labeling of these nutrients, under the circumstances described, is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Failure to make and keep records and provide the records to us, as described in § 101.9(g)(10) and (11), would result in the food being misbranded under sections 403(q) and 403(a)(1) of the FD&C Act.

B. Need To Update the Nutrition Facts and Supplement Facts Labels

We first issued regulations related to the Nutrition Facts label in 1993 and amended them in 1995 (to establish new DVs and to update the DVs (60 FR 67164, December 28, 1995)) and in 2003 (to address the declaration of *trans* fats (68 FR 41434, July 11, 2003)). From July 2003 to November 2007, we also issued three advance notices of proposed rulemaking (ANPRMs) seeking public comment on issues relevant to updating the Nutrition Facts label. These ANPRMs sought comment on:

- Data that could be used to establish new nutrient content claims about *trans* fatty acids; to establish qualifying criteria for *trans* fat in nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart healthy food choices. We also requested comments on whether we should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts label or as a disclosure statement in conjunction with claims to enhance consumer understanding about cholesterol-raising lipids and how to use the information to make healthy food choices (68 FR 41507, July 11, 2003). We later extended the comment period (69 FR 20838, April 19, 2004) to receive comments that considered the information in the 2004 meeting of the Nutrition Subcommittee of the Food Advisory Committee which addressed whether the available scientific evidence supported listing the percent DV for saturated fat and *trans* fat together or separately on the Nutrition Facts label and what the maximal daily intake of *trans* fat may be;
- The prominence of calories on the food label (70 FR 17008, April 4, 2005) (the 2005 ANPRM). We took this action in response to recommendations from the Obesity Working Group established by the Commissioner of Food and Drugs to develop an action plan to address the growing incidence of obesity in the United States. The 2005 ANPRM, in part, requested comments on whether giving more prominence to the declaration of calories per serving would increase consumer awareness of the caloric content of the packaged food and whether providing a percent DV for total calories would help consumers understand the caloric content of the packaged food in the context of a 2,000 calorie diet. We also requested comments on questions concerning the declaration of ''Calories from fat;'' and
- The revision of reference values and mandatory nutrients (72 FR 62149, November 2, 2007) (the 2007 ANPRM). The 2007 ANPRM requested comment on various aspects of nutrition labeling, including new reference values we should use to calculate the percent DV in the Nutrition Facts and Supplement Facts labels and factors we should consider in establishing such new reference values. We also requested comments on whether we should require that certain nutrients be added or removed from the Nutrition Facts and Supplement Facts labels.

Additionally, between 1993 and 2013, we received 12 citizen petitions asking us to make various changes to the Nutrition Facts and Supplement Facts labels. For example, some petitions asked us to permit the use of a different term on the Nutrition Facts label, while others sought changes in definitions, values (such as caloric values or the DV for a specific nutrient), or the inclusion of more information on the Nutrition Facts label.

Yet, as we considered the issues raised in the ANPRMs and the citizen petitions, the public health profile of the U.S. population changed, and new

information became available about nutrient definitions, reference intake values, and analytical methods. New dietary recommendations also were published. We reconsidered what nutrients we should require or permit to be listed on the Nutrition Facts label and what nutrient reference intake values we should use as a basis for calculating the percent DVs in food labeling. We also considered corresponding changes to the Supplement Facts labels. Consequently, in the **Federal Register** of March 3, 2014 (79 FR 11879), we issued a proposed rule to amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label and to help consumers maintain healthy dietary practices. The preamble to the proposed rule discussed, in some detail, the reasons why we felt it necessary to update the Nutrition Facts and Supplement Facts labels (see 79 FR 11879 at 11884 through 11889). In brief, the preamble to the proposed rule discussed:

- Rates of chronic disease, such as cardiovascular disease, diabetes, and cancer, and changes in obesity rates (79 FR 11879 at 11885);
- Dietary recommendations, consensus reports, and national survey data, such as the Institute of Medicine (IOM) Dietary Reference Intakes Reports (which resulted in the development of a set of reference values known collectively as Dietary Reference Intakes (DRIs) (id. at 11885 through 11887). The DRIs themselves consist of four categories of reference values: (1) The Estimated Average Requirement (EAR); (2) Recommended Dietary Allowance (RDA); (3) Adequate Intake (AI); and (4) Tolerable Upper Intake Level (UL) (id.). The preamble to the proposed rule explained that the EAR is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group and that EARs are used for assessing the statistical probability of adequacy of nutrient intakes of groups of people. The RDA is an estimate of the average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group and is set using the EAR. In general, the RDA is the EAR plus two times the standard deviation of the EAR. The RDA is used to plan nutrient intakes for individuals to ensure a low probability of inadequacy. The AI is the level determined for an essential nutrient or a nutrient that is beneficial for human health when there is insufficient evidence to calculate an EAR for that nutrient, and therefore insufficient evidence on which to establish an RDA. AIs can be based on a variety of data, including scientific evidence about the essentiality of a nutrient (*i.e.,* choline, biotin, fluoride), experimental data on risk reduction of chronic disease (*i.e.,* dietary fiber, potassium), and median intakes of a nutrient using national survey data (*i.e.,* vitamin K, pantothenic acid, chromium, manganese, linoleic acid, and α-linolenic acid). Although there is less certainty about an AI value than about an RDA value, the AI is similarly designed to cover the needs of nearly all individuals. The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. The UL is not intended to be a recommended level of intake, but is used to assess the risk of adverse health effects from excessive nutrient intake. As intake above the UL increases, so does the potential for risk of adverse health effects (id. at 11885 through 11886). The preamble to the proposed rule also discussed the Dietary Guidelines for Americans (DGA); the DGA is developed jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services and provides key recommendations on dietary patterns and quantitative intake recommendations with respect to micronutrients and macronutrients (id. at 11886). Although the preamble to the proposed rule discussed the DGA that was issued in 2010, in February 2015, the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC Report) became publicly available. While the DGAC Report is not a DGA itself (because the Federal government must determine how to use the information in the DGAC Report to develop the 2015–2020 version of the DGA), the DGAC Report contains scientific information on specific nutrients and vitamins as well as a review of the underlying scientific evidence. For example, the DGAC Report contains scientific evidence related to a daily intake recommendation for added sugars. In the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule with respect to the scientific evidence in the DGAC Report pertaining to added sugars and the possible inclusion of added sugars to the Nutrition Facts and Supplement Facts labels.
- Consumer use and understanding of the Nutrition Facts label (79 FR 11879 at 11887). The preamble to the proposed rule discussed, among other things, the frequency at which consumers use food labels and the purposes for which they consulted food labels (id.). The preamble to the proposed rule also noted that consumer research data suggested that, despite widespread use of food labels, certain elements of the Nutrition Facts label ''may need improvement'' (such as consumer understanding of the concept of percent DVs) (id.). We also stated that we intended to continue performing research during the rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label as well as to help inform consumer education (id.).
- Other considerations, including the focus of the Nutrition Facts label itself and practical limitations (id. at 11887 through 11888). For example, we noted that the Nutrition Facts label information is to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease. However, we also said that we were considering the large proportion of the U.S. population that is at risk for chronic disease as we proposed changes to the Nutrition Facts label's content and format (id. at 11887). Simultaneously, we recognized that there is not room on the label for all information that may be related to maintaining healthy dietary practices and that space constraints on the label of most foods make it impractical to declare all essential nutrients (id. at 11888). We added that having a large amount of information on the label could interfere with consumers' abilities to use the information that has the greatest public health significance and that, given the amount and format of information that we require on the label, limits to the voluntary information on the label are necessary so that voluntary information does not clutter the label, does not mislead, confuse, or overwhelm the consumer, and does not take away prominence of and emphasis on the required information (id.).

The preamble to the proposed rule also discussed the citizen petitions and ANPRMs (id. at 11888 through 11889) as influencing our development of the proposed rule. Additionally, as stated earlier in part I.B, in the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule to establish a DRV of 10 percent of total energy intake from added sugars, require the declaration of the percent DV for added sugars on the label, and to provide text for the footnotes to be used on the Nutrition Facts label. The

supplemental proposed rule also provided additional data and information to support the declaration of added sugars on the label and made our consumer research regarding the footnote text and added sugars declarations publicly available.

II. Comments to the Proposed Rule and the Supplemental Proposed Rule, Our Responses, and a Description of the Final Rule

A. Introduction

The proposed rule would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label. In brief, the proposed rule would (among other things):

- Require the declaration of ''Added Sugars'' on the label. ''Sugars'' include both ''added sugars'' and sugars that are naturally occurring in food. The proposed rule would require the declaration of ''Added Sugars'' indented under ''Sugars'' so that both would be listed;
- Remove the requirement for declaring ''Calories from fat.'' Current research shows that the total fat in the diet is less important than the type of fat. In addition, our consumer research shows that removal of the declaration of ''calories from fat'' has no effect on consumers' ability to judge the healthfulness of a product;
- Revise the nutrients of public health significance that must be declared on the label. The proposed rule would require the declaration of vitamin D and potassium. Vitamin D is important for its role in bone development and general health, and intakes among some population groups are inadequate. Adequate potassium intake is beneficial in lowering blood pressure, and intakes of this nutrient are also low among some population groups. The proposed rule also would no longer require mandatory labeling for vitamin C or vitamin A because data indicate that deficiencies are not common. Voluntary labeling for vitamins C and A would be allowed; and
- Revise DVs for certain nutrients that are either mandatory or voluntary on the label. Examples include calcium, sodium, dietary fiber and vitamin D. Some DVs are intended to guide consumers about maximum intake—saturated fat, for example—while others are intended to help consumers meet a nutrient requirement—iron, for example. DVs are used to calculate the percent Daily Value (% DV) on the label, which helps consumers understand the nutrient information on the product label in the context of the total diet. We considered revisions to the DVs based on scientific evidence related to recommendations published by the IOM and other reports such as the DGA. In addition to changing some DVs, the proposed rule would change the units used to declare vitamins A, E, and D from ''international units,'' or ''I.U.'' to a metric measure, milligrams or micrograms, and also would include the absolute amounts in milligrams or micrograms of vitamins and minerals, in addition to the % DV, on the label.

The proposed rule also would change the appearance of the label itself by highlighting key parts of the label that are important in addressing current public health problems. For example, the proposed rule would:

- Highlight the caloric content of foods by increasing the type size and placing in bold type the number of calories and servings per container;
- Shift to the left of the label % DV. The % DV is intended to help consumers place nutrient information in the context of a total daily diet;
- Declare the actual amount, in addition to % DV, for all vitamins and minerals when they are declared;
- Change ''Amount Per Serving'' to ''Amount per ___'', with the blank filled in with the serving size in common household measures, such as ''Amount per 1 cup'';
- Replace the listing of ''Total Carbohydrate'' with ''Total Carbs'' and add an indented listing of ''Added Sugars'' directly beneath the listing for ''Sugars;''
- Right justify the actual amounts of the serving size information;
- Reverse the order of ''Serving Size'' and ''Servings Per Container'' declarations; and
- Remove the existing footnote that describes the DVs for 2,000 and 2,500 calories to provide more space to better explain the percent dietary value.

The proposed label changes were intended to help consumers maintain health dietary practices, and we based the updated information on current data on associations between specific nutrients and chronic diseases or health-related conditions in the United States and on new information regarding consumer understanding of the label and consumption patterns.

We provided a 90-day comment period for the proposed rule. In the **Federal Register** of May 27, 2014 (79 FR 30055), we extended the comment period by 60 more days after receiving multiple requests to extend the comment period. In the **Federal Register** of May 29, 2014 (79 FR 30763), we announced a public meeting to discuss the proposed rule, as well as the proposed rule on serving size requirements, and to solicit oral stakeholder and public comments and to respond to questions about the proposed rules. Additionally, as we stated in part I.B, in the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule to establish a DRV of 10 percent of total energy intake from added sugars, to require the declaration of the percent DV for added sugars, and to provide text for the footnotes to be used on the Nutrition Facts label. The supplemental proposed rule also provided additional information to support the declaration of added sugars on the label and made our consumer research regarding added sugars declarations and the footnote text publicly available. We also reopened the comment period for the purpose of inviting public comment on two consumer studies we added to the administrative record (80 FR 44302). The two consumer studies pertained to proposed changes to the format of the Nutrition Facts label and to consumers' interpretations of information on the Nutrition Facts label. Collectively, with respect to the proposed rule, the supplemental proposal, and the related **Federal Register** documents, we received nearly 300,000 comments from consumers, foreign governments, industry, trade associations, professional societies, academia, health professionals, and other government agencies.

We discuss the issues raised in the comments on the proposed rule and supplemental proposed rule and also describe the final rule, in part II. We preface each comment discussion with a numbered ''Comment,'' and each response by the word ''Response'' to make it easier to identify comments and our responses. We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

Incorporation by Reference

Additionally, the final rule incorporates by reference the ''Official Methods of Analysis of the AOAC International,'' 19th Edition. The ''Official Methods of Analysis of AOAC International'' (AOAC Methods) is a comprehensive collection of chemical and microbiological methods of analysis. The AOAC Methods have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and

fitness for purpose. Each method includes specific instructions for performing the chemical analysis of a substance in a particular matrix.

Although the 19th Edition of the AOAC Methods was available for purchase from AOAC when we drafted the proposed rule, the reference has since been sold out at AOAC INTERNATIONAL. Copies, however, can be obtained or downloaded from secondary sources, and the final rule identifies one such source. However, we do not endorse any particular secondary source or reseller and note that other resellers also may have the 19th Edition of the AOAC Methods for sale.

B. General Comments

Some comments raised issues that were general in nature or affected multiple parts of the rule.

Additionally, one foreign government agency, Health Canada, provided factual information and comments on various aspects of its review and update of nutritional information on the Canadian food label. Health Canada did not advocate a particular outcome or did not provide comments on possible changes or suggestions to our proposed rule.

1. Comments Seeking an Education Campaign or Program

(Comment 1) Several comments suggested that we develop a well-funded, coordinated, multi-component consumer education campaign to promote and explain the new Nutrition Facts label, the changes to the label, and the use of the label to help consumers to make healthier food and beverage choices. Many comments suggested that we coordinate our consumer education campaign with other Federal government Agencies including the Centers for Disease Control and Prevention (CDC), other parts of the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), State health departments, and non-government entities, including food manufacturers, retailers, and non-profit organizations with an interest in nutrition and health.

Several comments suggested that our education campaign emphasize calories because knowledge of calories is important for rolling back the obesity epidemic. Other comments would focus on sodium because of its contribution to cardiovascular disease or on nutrients (such as added sugars) that would be on the Nutrition Facts label for the first time and nutrients (such as total fat) for which the science has changed significantly.

Several comments noted that, although some revisions (such as the declaration of *trans* fatty acids and the declaration of food allergens) have been made to nutrition labeling since implementation of the NLEA, there have not been changes to the label of the magnitude in the proposed rule. The comments said, therefore, that public outreach, through avenues such as Webinars, town hall meetings, and social media, will be a key component of the nutrition labeling modernization effort. A few comments suggested that the consumer education program should be informed by any relevant consumer research. Several comments noted that there is consumer confusion over the meaning of percent DV and consumer research had found that consumers do not understand or know how to use the DVs; thus, the percent DV should be a key area in which to focus consumer education efforts. One comment specifically stated that percent DV/added sugars disclosure will create substantial consumer confusion that does not exist today and that we would need to provide consumer education in attempt to overcome the confusion. Several comments stated that education is needed to help consumers understand the meaning of percent DVs, with inclusion of a brief footnote on packages, but additional consumer education should be done online.

Several comments suggested that, although the education campaign is important for all consumers to know about, understand, and use the revised Nutrition Facts label, an education campaign should primarily be designed to reach consumers who are least likely to understand and use the label, including lower income consumers, communities with diverse languages and literacy levels who are also more likely to suffer from many obesity- and nutrition-related chronic diseases than those with higher incomes and education. The comments stated that we should use multiple and culturally relevant communication channels and messengers, and we should field test our messages to ensure they are relevant and compelling for audience segments. One comment noted that a Canadian study (Ref. 1) found that participants were significantly less likely to correctly assess the Nutrition Facts label for calorie and nutrient information if they reported lower educational attainment, lower income, or non-white ethnicity. The comment also stated that the 2012 IOM report on front-of-pack labeling (Ref. 2) found that ''a lack of nutrition knowledge is a major barrier to effective use of the [Nutrition Facts label] and may actually lower the motivation of some consumers to use the nutrition information on the label,'' and that ''some racial groups . . . are less likely . . . to use and understand nutrition labels, primarily because of lack of time to read labels and lack of understanding of the nutrition information.'' The comment stated that working with other health departments and organizations could help extend our educational resources to all rural and urban communities. Another comment suggested that, to be most effective, we should incorporate lessons learned on how individuals from various subpopulations interpret the new label design. The comment noted that such education needs to accommodate individuals at various levels of educational achievement and with cultural and ethnic diversity.

A few comments suggested that we conduct the education campaign after the final rule's publication and before the rule's compliance date. One comment suggested that our recommendations be publicized to groups who interact with the public at least 3 months before implementation of the new Nutrition Facts label style and elements to allow for preparation of curricula and development of local educational and media efforts.

One comment suggested that, similar to our earlier public service campaigns such as ''The Real Cost'' campaign targeting youth tobacco use, we have a unique ability to get the attention of the public and shape understanding about the risks of lifestyles habits and choices. Other comments suggested that we integrate the education campaign with preexisting consumer education programs and initiatives, including the USDA's Supplemental Nutrition Assistance Program Education (SNAP-Ed) (the nutrition promotion and obesity prevention component of SNAP), school-based nutrition education programs, and grocery store labeling and education initiatives, such as the Boston Public Health Commission's ''Re-Think Your Drink'' campaign. One comment suggested that we develop a similar outreach campaign as ''Read the Label'' to enable Americans to understand the revised label and its uses.

One comment noted that, while nutrition education has been shown to have a positive impact on consumers' dietary choices and patterns, multiple studies suggest that education alone is not adequate to change consumer behavior around healthy eating for a sustained amount of time. The comment suggested that, for education efforts to be effective and sustainable, they should be combined with policy, systems, and environmental changes that support healthful choices. For example, food

environmental changes, such as increased availability of and access to healthful foods, combined with education efforts, have been found to be significantly more effective in changing consumer behavior in the long run.

(Response) We agree that a consumer education and outreach campaign will assist in making the new food label a successful tool in continuing to help consumers to make healthy food and beverage choices. Currently, we have available a collection of various educational materials (*e.g.,* videos, an array of public education materials and brochures (in English and Spanish)) on numerous nutrition topics, including materials on the Nutrition Facts label (*e.g.,* ''Read the Label,'' Make Your Calories Count, Sodium: Look at the Label) (Ref. 3). These materials are intended for educators, teachers, health professionals (*e.g.,* dietitians, physicians, and nurses) as well as for general consumers. Our intent is to update our existing educational materials and create new educational opportunities to explain how to use the label to help consumers make healthy dietary choices, with an emphasis on each of the new changes of the label. We intend to continue to work on and to create new partnership opportunities with other Federal government Agencies including other parts of the Department of Health and Human Services, USDA, State health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations that have an interest and responsibilities in nutrition education and health promotion. These partnerships will help us develop and disseminate our educational materials that will ease the transition to the revised nutrition label and help consumers to understand and use the label to make well-informed dietary choices. Through our work with both government and non-government entities, our continued goal is to increase consumers' knowledge and effective use of the new Nutrition Facts label and to ensure that consumers have accurate and adequate resources, materials, and information for making healthy food and beverage choices. Furthermore, we intend to continue a variety of activities such as conduct and report on existing and planned food labeling research; to develop education initiatives at the national and local levels; to build labeling education exchanges; and to integrate food labeling education into existing programs (*e.g.,* USDA-school-based nutrition education programs). We plan to continue to build partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, lower incomes, minorities, and various subpopulations (*e.g.,* children, older subpopulation, women of childbearing age) as well as to the general public.

As for the comments stating that the percent DV should be a key area to focus consumer education efforts, and that the disclosure of ''% DV/Added sugars'' will create substantial consumer confusion, we will continue to provide education and outreach to consumers about using the Nutrition Facts label to make healthful dietary choices. (We also note that the comments' use of the term ''confusion'' is, itself, misplaced; a more appropriate characterization would be whether some consumers we tested ''understand'' or ''misunderstand'' the declaration of added sugars. However, because the comments used the term ''confusion,'' for convenience, we will use the same term in this response as well as in other responses on the subject of added sugars, consumer research, and education, in reference to the findings that some consumers we tested seemed to misunderstand that the term ''added sugars'' referred to a subcomponent of total sugars on the label.) The changes in the ''new'' label will be highlighted and clarified through these education and outreach endeavors. We are not planning to focus educational activities on the ''% DV/Added Sugars'' disclosure of the Nutrition Facts label in isolation. Instead, education and outreach will focus on a number of aspects of the label to enhance its use and understanding by consumers.

As for the comment stating that education efforts should be combined with policy, systems, and food environmental changes that support healthy dietary choices, we understand that combining the Nutrition Facts label education efforts with other policies may be more effective in supporting healthy dietary choices; however, many policies, such as consumer access to or increased availability of healthful foods, are not under our purview and are outside the scope of this rulemaking. As part of supporting access to healthy foods, we continue to encourage food product reformulation, such as reducing sodium content in the food supply.

2. Comments Linking the Nutrition Facts Label to Specific Diseases

(Comment 2) Many comments recommended mandatory declaration of specific nutrients (*e.g.,* phosphorous, added sugars, potassium) on the Nutrition Facts label because, according to the comments, these nutrients are or may be helpful to persons with an existing acute or chronic disease (*e.g.,* heart disease, chronic kidney disease, diabetes). According to the comments, mandatory declaration of the specific nutrient would be helpful for the management of specific diseases or conditions.

(Response) While the Nutrition Facts label information has never been, nor is it now, targeted to individuals with acute or chronic disease (*e.g.,* diabetes, chronic kidney disease or cardiovascular disease (CVD)), consumers with these types of diseases may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions. However, the nutrient declaration and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease.

3. Use of Household Measures

(Comment 3) Many comments recommended that the amount of total fat, carbohydrate, sugars, added sugars, protein, and sodium be declared in common household measurements (*e.g.* teaspoons) instead of or in addition to grams (g). The comments said that the metric system has not been widely adopted in the United States, and the average consumer is more familiar with household measurements than with grams. The comments also said that, if the purpose of the information on the label is to help consumers understand the actual amount of nutrients in a food product, the declaration of these nutrients in grams defeats the intended purpose of the label because consumers cannot conceptualize gram amounts. One comment suggested that we include an icon that would allow the consumer to visualize a gram and that we could use a teaspoon for such an icon. Another comment suggested using ounces instead of or in addition to grams because consumers can understand this information more easily than gram amounts. The comment also recommended stating on the label that there are 28 grams in an ounce and 448 grams in a pound.

(Response) We decline to require the declaration of total fat, carbohydrate, sugars, added sugars, protein, and sodium in household measurements or in ounces. Using a volume measure rather than a weight measurement for total fat, carbohydrate, sugars, added sugars, and protein would provide inaccurate information. The gram is a measure of mass or weight while a teaspoon is a measure of volume. The

gram weight of different carbohydrates, fats, and proteins is different. For example, a teaspoon of sucrose or table sugar weighs 4.2 grams, but a teaspoon of corn syrup weighs 7.3 grams (Ref. 4) and has 1.5 grams of water and 5.1 grams of sugar.

Additionally, many ingredients provide multiple nutrients, so it may not be possible for manufacturers to determine the volume contribution that each ingredient provides towards the various macronutrients. For example, salt is composed of sodium and chloride. Other ingredients, such as baking soda, contain sodium. It would be very difficult for a manufacturer to determine the volume of sodium contributed by both salt and baking soda in a food such as a cookie.

We also reiterate that the gram weight is a more precise measurement. When it comes to some nutrients, particularly added sugars and sodium, most products contain a fraction of a teaspoon.

Additionally, dietary recommendations for total fat, total carbohydrate, sugars, added sugars, protein, and sodium are provided in grams and milligrams (mg) (Ref. 5). The declaration of these nutrients in household measurements would make it more difficult for consumers to compare the amount of the nutrient in a serving of a product to current dietary recommendations.

As for the comments suggesting the declaration of teaspoon amounts in addition to grams, there is limited space available on the label, especially for small packages and dual column labeling (see part II.Q). Adding a teaspoon amount before or after the gram declaration of the nutrients could make it more difficult to read the information on the label. Therefore, we decline to allow for voluntary declaration of household measurements of total fat, carbohydrate, sugars, added sugars, protein, and sodium.

Finally, with respect to declaring nutrients in ounces or pounds, we decline to revise the rule as suggested by the comment. Many products contain an ounce or less of food per serving. If ounces or pounds were declared on the label for these nutrients, fractions would have to be declared. The gram weight of a nutrient is a more precise measurement than ounces or pounds.

4. Impact on Other Regulations

(Comment 4) Several comments expressed concern that revision of the RDIs would necessitate revisions to other regulations for nutrient content claims and health claims. Several comments noted that many products (such as juices and dairy products) that are now eligible to make nutrient content claims for nutrients that are increasing (such as potassium, calcium, vitamin D, and vitamin C) would no longer be able to do so. Other comments expressed concern that standards of identity for yogurt, milk, and cheeses might need to be updated. Other comments noted that food additive regulations for the addition of calcium and vitamin D to juice would need to be reevaluated; some comments suggested that we delay finalizing the rule until we update our rules on nutrient content claims.

(Response) We will address, as appropriate and as time and resources permit, the impact on our other regulations that are outside the scope of this rulemaking in separate rulemaking actions. While we do intend to revisit our regulations for nutrient content claims at a later date to determine if changes are necessary, we recognize that changes to the list of nutrients declared on the Nutrition Facts label or the RDIs or DRVs of nutrients could affect the ability of some products to bear certain nutrient content or health claims. We also recognize that changes to the RDIs for calcium, for example, may impact certain other regulations, including our food additive regulations in § 172.380 (21 CFR 172.380), where the use of vitamin D is based on a product containing a certain percentage of the RDI for calcium.

We also do not agree to delay finalizing this rule until we provide any updates to our rules on nutrient content claims. The RDIs are based on how much of a nutrient should be consumed to meet nutrient needs and not based on eligibility to make a nutrient content claim.

(Comment 5) One comment said we should try to finalize all the anticipated changes to the food package labels simultaneously, including Nutrition Facts label, a front-of package panel, and health claims so that a consumer education program about the revised Nutrition Facts label also could explain all changes at one time, thereby minimizing consumer confusion and maximizing resources available for education.

(Response) We do not agree that the rule should be delayed until we provide any updates to rules on health claims or any possible rule on front of pack labeling. The pace at which each individual rulemaking activity proceeds may be affected by our resources and other priorities; consequently, it would be impractical to defer action on this final rule until we complete other possible regulatory actions.

5. Consumer Research

In the preamble to the supplemental proposed rule (80 FR 44303 at 44305 through 44306), we discussed, among other things, information on two consumer studies (80 FR 44303), and in the **Federal Register** of July 27, 2015 (80 FR 44302), we reopened the comment period for the proposed rule for inviting public comments on two additional consumer studies. These four consumer studies, conducted in 2014 and 2015, were randomized controlled experimental studies with English-speaking adult consumers: (1) The Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars (''the added sugars study''); (2) the Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats (''the footnote study''); (3) the Experimental Study of Proposed Changes to the Nutrition Facts Label Formats (''the format study''); and (4) the Eye-tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking (''the eye-tracking study''). All study participants were adults 18 years of age or older. The overarching purpose of these studies was to explore how and to what extent different presentations of the label and its components (*e.g.,* different formats of the entire Nutrition Facts label or different formats of how added sugars may be declared on the label) may affect consumer responses to the presentations. In addition, the added sugars study was conducted to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. In the following paragraphs, we briefly describe the methodology and key findings of each study and discuss the characteristics and proper use of the study data and findings.

The added sugars study was a randomized, controlled, Web-based experiment conducted in July and August of 2014 to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. At the time the research was designed, we were not aware of any previous studies of consumer responses to added sugars information. We

engaged in this research to help inform our potential consumer education efforts if added sugars were declared on the Nutrition Facts label. The research design did not include a percent Daily Value for added sugars on the food label or the ingredient listing that will appear on packages and therefore did not provide data on how those pieces of information would affect consumer responses to an added sugars declaration. Nevertheless, the study achieved its intended objectives of providing an initial understanding of potential consumer reactions to added sugars declarations on Nutrition Facts labels.

Participants (n = 6,480) self-administered the study on their own computers and were randomly assigned to view mock-ups of one of three formats of the current Nutrition Facts label: (1) The ''Added Sugars'' format, in which an added sugars declaration was indented below a ''Sugars'' declaration; (2) the ''Total Sugars + Added Sugars'' format, in which an added sugars declaration was indented below a ''Total Sugars'' declaration; and (3) the ''Current'' format, in which ''Sugars,'' but not added sugars, was declared on the label. While viewing their assigned label images, participants answered questions on their ability to recognize and compare nutrient amounts on the Nutrition Facts label and their judgments about the foods' overall healthfulness and relative nutrient levels. The Nutrition Facts label images were accompanied by a product identity caption (*e.g.,* ''Frozen Meal'' or ''Cereal''), but no front panel or brand name, either fictitious or real. The study was designed as a controlled experimental study that employed random assignment in order to establish causal relationships between test conditions and consumer responses. Because the study was not intended to generate population estimates, participants were selected from members of an online consumer panel in the United States. To recruit a diverse study sample, quotas were constructed with the aim of making the sample's distributions of age, gender, education, race/ethnicity, and census region resemble that of the U.S. population as closely as possible.

The added sugars study found that, while added sugars declarations increased the ability of some participants to identify those products with less added sugars and to determine the quantity of added sugar in a food, the declarations decreased the ability of some participants to correctly identify the quantity of total sugars in a food. The ''Total Sugars + Added Sugars'' format appeared to help participants better comprehend the total amount of sugars in a food than the ''Added Sugars'' format. More details about the study methodology, tested label formats, and results can be found in an Administrative File entitled ''Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB No. 0910–0764)'' (Docket FDA–2012–N–1210).

The footnote study was a randomized, controlled, Web-based experiment conducted concurrently with the added sugars study. The footnote study included 3,866 participants who were different participants from those in the added sugars study but selected from the same online consumer panel using the same sampling methodology as that used in the added sugars study. The purpose of the footnote study was to explore consumer responses to various formats for the footnote area of the Nutrition Facts label, including those that provide information such as various definitions for percent Daily Value, a succinct statement about daily caloric intake, and general guidelines for high and low nutrient levels. Participants self-administered the study on their own computers and were randomly assigned to view a mock-up of one of seven Nutrition Facts label formats. Five of these Nutrition Facts formats included modified footnotes; one included the current footnote, and one included no footnote at all. The footnotes displayed variations of information such as a description of percent Daily Value, a succinct statement about daily caloric intake, or a general guideline for interpreting percent Daily Values, or noted nutrients whose daily intake should be limited. While viewing a label, participants answered questions about their judgments of the foods' overall healthfulness and levels of vitamin A, vitamin C, dietary fiber, fat, and sodium. After rating the product's nutritional attributes, participants who viewed labels that included one of the five modified footnotes or the current footnote were asked to rate the footnote statement's understandability, usefulness, believability, and helpfulness for the following dietary tasks: Comparing products, planning a healthy diet, determining the healthfulness of a food, and deciding how much of a food to eat.

The footnote study found that all five footnote options produced similar perceptions and judgments relative to the current footnote and the no-footnote control. Nevertheless, all five modified footnotes were rated as easier to understand than the current footnote. Footnote 1 was perceived to be more believable than the current footnote. Footnote 1 stated the following: ''2,000 calories a day is used for general nutrition advice. * The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet.'' More details about the study methodology, tested label formats, and results can be found in an Administrative File entitled ''Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats (OMB No. 0910–0764)'' (Docket FDA–2012–N–1210).

The format study was a Web-based study conducted in February–March, 2015, to explore consumer responses to: (1) Three different formats of the Nutrition Facts label (the Current format, the Proposed format, and the Alternative format discussed in the proposed rule) (80 FR 11879), with each format embodying all current label elements or most of the potential changes to them as outlined in the proposed rule (*e.g.,* the prominence of the calorie declaration, the position of the percent Daily Value column); (2) the location of the percent Daily Value column (right or left side of the label); (3) column type (single-column, dual-column, and dual-calorie); (4) location of sodium declaration on the Proposed single column label; and (5) the declaration of voluntary vitamins and fats (voluntary vitamins, voluntary fats, and both vitamins and fats). A total of 5,430 consumers participated in the format study; they were recruited from the same online consumer panel with the same sampling methodology as in the added sugars and the footnote studies. As in the added sugars study and the footnote study, participants were randomly assigned to view different Nutrition Facts label mock-ups and answer questions about their: (1) Perceptions of the healthfulness and levels of nutrients of a product; (2) identification of which product in a pair of products was considered healthier; (3) accuracy of identifying the amount of nutrients per serving and per container and number of servings per container; and (4) perceptions of the understandability, usefulness, believability, and helpfulness of the label for various dietary tasks such as comparing products and deciding how much of a food to eat.

We did not find many significant or consistent effects of these label variations on the answers to the questions we asked. However, there were some notable and statistically significant differences when comparing

the current, single-column Nutrition Facts label with the % DV on the right (the ''Current label''), the single-column Nutrition Facts label with the % DV on the left (which we had proposed (the ''Proposed label'')), and an alternative, single-column label with the % DV on the left (the ''Alternative label''). Respondents were more accurate in identifying the grams of saturated fat and the % DV for sodium using the single-column Proposed label (% DV left) compared to the single-column Current label (% DV right). Respondents were more accurate in identifying the grams of sugars per serving using the single-column Current label (% DV right) compared to the single-column Proposed (% DV left) or single-column Alternative label (% DV left), and they were more accurate in identifying the grams of sugars per container using the single-column Current label (% DV right) compared to the single-column Proposed label (% DV left). Finally, respondents were more accurate in identifying the grams of added sugars with the single-column Proposed label (% DV left) as compared to the single-column Alternative label (% DV left) (respondents assigned to view the Current label were not asked this question). Among the Proposed labels with % DV on the left (single-column, dual-column, and dual-calorie), we found that dual-column labeling significantly improved respondents' ability to identify the amount of nutrients in the entire container. More details about the study methodology and results can be found in an Administrative File entitled ''Experimental study of proposed changes to the Nutrition Facts label formats (OMB No. 0910–0774)'' (Docket FDA–2012–N–1210).

The eye-tracking study, conducted in January–March, 2015, was to explore whether and to what extent most of the potential label changes as outlined in the proposed rule (80 FR 11879), in their totality, may increase consumer attention to various label elements (*e.g.,* calories, number of servings) and lessen consumer effort in searching for specific label information. In addition, the eye-tracking study explored how the difference in the location of the percent Daily Value column may cause any changes in consumer attention to various label elements. A total of 160 English-speaking adult consumers in four cities (Washington, DC, Chicago, IL, Boston, MA, and San Francisco, CA) participated in the eye-tracking study. They were recruited by telephone and the sample was composed of some degree of diversity in socio-demographic characteristics and experience with the Nutrition Facts label. Due to an unexpected issue during recruiting, the eye-tracking study did not include any participants who were 35 years of age or younger. We asked study participants to come to a central location in each city to view mock-ups of three label formats (the Current format, the Proposed format and the Alternative format) (80 FR 11879) on a computer screen, recorded participants' eye-movement data to examine and compare the degree of attention paid to some of the possible label changes and the level of effort participants used to perform three categories of task (browsing a label, searching for specific information on a label such as the amount of sodium per serving in a product, and identifying which of a pair of products they would choose for a given purpose such as if they were to buy a healthier product for themselves). Labels used in this study were borrowed or adapted from the format study.

The eye-tracking study showed few statistically significant differences between the Current and the Proposed formats or between their variants. Among these differences, no one single format or variant consistently stood out as the ''best'' format in terms of degree of participant attention to label information, level of effort in using label information, or accuracy of information search or dietary choices. Many of the format differences pertained to two specific label components: (1) Sodium, carbohydrate, and protein; and (2) vitamins and minerals. There was little evidence that the Proposed format led participants to re-allocate their attention to or effort spent on different label components while browsing a label or making the dietary choices. More details about the study methodology and results can be found in an Administrative File entitled ''Eye-tracking experimental study on consumer responses to modifications to the Nutrition Facts label outlined in the Food and Drug Administration's proposed rulemaking (OMB No. 0910–0774)'' (Docket FDA–2012–N–1210).

For all four studies, we employed a randomized controlled experimental approach. According to the Office of Management and Budget (OMB), when Federal Agency research questions involve trying to determine whether there is a causal relationship between two variables or whether a program caused a change for participants, the Agency will need to employ an experimental or quasi-experimental design (rather than other approaches such as population surveys) to demonstrate how the study design will allow the Agency to determine causality (Ref. 6).

We chose to conduct the added sugars, the footnote, and the format studies using a Web-based approach with mock-ups of the Nutrition Facts label and footnote. The Web-based approach is quicker in administration and data collection and more efficient in including participants from many different parts of the country than other modes of data collection such as in-person interviews. The approach also reduces administrative errors in terms of assignment of labels for different participants. We used mock-ups of the label and footnote rather than real food packages because the approach helps the studies accomplish their goal of exploring consumer responses to differences in the presentation of the label rather than of a food package, which includes other components such as the front panel, the ingredient list, and imageries. The presence of these other label elements can weaken a study's ability to obtain key information on the label and the footnote to answer its research questions.

All studies used non-probability samples recruited from either members of the public at selected geographic locations with a certain degree of diversity in sociodemographic characteristics (*i.e.,* age, gender, education, race/ethnicity), as in the eye-tracking study, or members of a commercial online consumer panel with the sample's sociodemographic characteristics matched to that of the general population, as in the added sugars, the footnote, and the format studies; in all these cases, an individual's probability of being selected into a sample was unknown. In particular, the online panel recruitment methodology was based on the opt-in approach, a non-probability sampling technique. In contrast to probability sampling in which every individual has some chance of being selected to participate in a study, not all individuals have some chances of being selected in a study. To ensure representativeness of selected participants of the population, it is necessary that everyone has a known probability and that no one is left out (Ref. 7). In addition, according to OMB's Guidance on Agency Survey and Statistical Information Collections, for the purpose of making estimates with measurable sampling error that represent a population, the sample must be selected using probability methods, where a subset of the population is chosen randomly such that each unit has a known nonzero probability of

selection (Ref. 6). Therefore, none of the studies could provide nationally representative population estimates of consumer understanding, behaviors, or perceptions, nor could their data be considered nationally representative.

The samples of our studies were not selected using a probability sampling method and the samples came from consumers in selected locations or an opt-in online consumer panel. Therefore, based on the AAPOR and OMB guidelines, we do not consider the findings of any of the four studies projectable to the general population.

The overarching purpose of our research was to explore how and to what extent different presentations of the label and its components may affect consumer responses to the presentations. The added sugars study also was conducted to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. We did not aim to use these studies to help us develop a label that will be understood by all consumers. We recognize that, regardless of how well a label is designed, there is always a certain proportion of consumers who encounter challenges in understanding and using the label.

In the **Federal Register** of July 27, 2015 (80 FR 44302), we added a description and our findings of these four studies to the administrative record, and we reopened the comment period for the sole purpose of inviting public comments on the eye-tracking and the format studies. We also published a supplemental proposed rule that discussed, among other things, information on the added sugars and the footnote studies (80 FR 44303). In response, many comments discussed our studies' findings, methodologies, and implications. Some comments provided new consumer research information related to issues examined in our studies, particularly the added sugars declaration. To the extent that the comments pertained to general issues involving our study results and methodologies, we address them here. We respond to comments related to research implications that are specific to the added sugars declaration or to format issues, such as the footnote, elsewhere in this document (see, *e.g.,* part II.H.3, ''Added Sugars,'' and part II.Q, ''Format'').

(Comment 6) While many comments referred to our research findings as part of the evidence used to support their positions, some comments suggested that we conduct additional consumer research on selected changes outlined in the proposed rule. The comments felt further research is needed because it is difficult to examine the effects of individual proposed changes based on our studies.

(Response) One of our missions is to assist in providing the public with the accurate, science-based information it needs to use medicines and foods to maintain and improve health (Ref. 8). The objective of the Nutrition Facts label is to provide nutrition information about products to help consumers in maintaining healthy dietary practices. Therefore, as part of our continuing effort to enable consumers to make informed dietary choices and construct healthful diets, we intend to, subject to program priorities and resource availability, conduct more consumer research to help enhance the usefulness and understandability of the label.

In the format and the eye-tracking experimental studies, we chose to examine the combined effects of most of the changes outlined in the proposed rule, in totality. Nevertheless, in both studies, we also examined selected individual changes where we thought original consumer research would be helpful. For example, we were interested in the effect of the location of the percent Daily Value (left or right) independent of other format elements and therefore studied that change on all three label formats (Current, Proposed, and Alternative) (in both the format and the eye-tracking studies). We also were interested in the effect of column type (single-column, dual-column, and dual-calorie) independent of other label format changes and therefore studied that on all three label formats (in the format study). We also were interested in some other possible label format changes and therefore chose to study the effects of moving the location of sodium declaration on the Proposed single column label (in the format study), as well as the declaration of voluntary vitamins and fats (voluntary vitamins, voluntary fats, and both vitamins and fats) (in both the format and the eye-tracking studies). We believed the original consumer research on these topics was more useful than on other topics. Therefore, we took a hybrid approach of studying the differences between the Current, Proposed, and Alternative formats in totality and as well as in isolation for selected individual changes.

(Comment 7) Some comments questioned whether participants in our studies generally or as assigned in individual conditions were representative of the consumers in the nation. The comments stated that such representativeness was important for assessing the effects of the proposed label format changes on consumer understanding and use of the label. In particular, the comments were concerned that the lack of such representativeness, for example, the absence of participants 35 years of age and younger in the eye-tracking study, would render results imprecise or misleading. Some comments also encouraged us to obtain nationally representative samples of the population for future consumer research studies.

(Response) While we recognize that our study samples are not nationally representative, we disagree that the use of such samples would render our findings imprecise or misleading. The purpose of our studies was to investigate and compare how different presentations of label information may cause different responses by consumers. In other words, we sought to understand the causal relationships between the label presentations and consumer response rather than develop nationally representative estimates of the prevalence or extent of various responses. Therefore, our primary consideration in the study design was internal validity (*i.e.,* the validity of the causal relationships) rather than external validity (*i.e.,* the extent that the results can be generalized to the population or to presentations other than those studied). Even though we focused on internal validity, we recognized that, to make the study findings more robust, it was important that the studies included participants from different segments of the population in terms of education, gender, race/ethnicity, and geographic regions. Moreover, the causal relationships we examined were not necessarily particular to certain segments of the population, and our samples included consumers with a wide range of label reading and use practices.

We doubt the absence of study participants aged 35 years and under in the eye-tracking study, which was due to an unexpected issue in recruiting participants from this segment, would have led us to reach noticeably different conclusions about the label formats. While all of the eye-tracking participants were over age 35, they were diverse in many other important factors that the literature suggests may be related to label viewing and use, such as gender, education, race/ethnicity, label reading practices, attitudes toward the label, and nutritional interest (Refs. 9–11).

(Comment 8) One comment said that the use of terms such as ''healthy'' and ''healthier'' in our studies represented a misuse of a defined nutrient content claim. The comment also noted that consumers have different interpretations of the term ''healthy'' and that these interpretations may be based on considerations that are different from those defined for the claim ''healthy'' in FDA regulations. In addition, the comment said that the use of the term ''healthy'' in the eye-tracking study was a cue to participants that there is a correct answer and the criterion was ''healthy.''

(Response) In the consumer studies we conducted for informing this rulemaking, research participants were presented with and asked to respond to a Nutrition Facts label. Neither the front panel of a package nor the ingredient list was provided to participants. In our studies, the questions that asked participants to assess products' healthfulness served as one type of measure of potential consumer reactions to the tested Nutrition Facts label formats and content modifications. These questions were not connected to the regulatory meaning of a ''healthy'' claim, which usually appears on the front panel of a package, and we disagree that the healthfulness questions in our studies reflect ''a misuse,'' as asserted in the comments, which mischaracterize the purpose of the healthfulness questions in the studies we conducted.

We agree, in part, and disagree, in part, that the use of the term ''healthy'' in the eye-tracking study was a cue to participants that there was a correct answer and the criterion was ''healthy.'' We agree that this term was used in the study to prompt participants to use ''healthy'' as the criterion in deciding their response to the task of choosing which of two products they thought was healthier for themselves. The primary purpose of this design was to examine whether and how different label presentations would lead to differences in participant attention to various parts of a label if participants were considering a healthy dietary choice. The accuracy of choice was of less interest in this design. In addition, one of the products presented to the participants always had lower content of calories, total fat, saturated fat, sodium and sugars than the other, so the ''correct'' choice was unambiguous. Therefore, we do not believe that the study design would have biased the answers participants gave in this task.

(Comment 9) One comment suggested that we conduct studies that are not electronically based so that we may have more reliable data that can contribute to a more successful solution.

(Response) The comment did not explain why data collected non-electronically are more reliable than data collected electronically. We believe the Web-based approach is appropriate for the purposes of our studies. Furthermore, the comment did not assert that our study results were necessarily flawed because we collected data electronically.

(Comment 10) One comment asked us to clarify a conclusion reported in the preamble to the supplemental proposed rule that when participants viewing Nutrition Facts labels without added sugars declarations could not accurately determine the amount of added sugars in the products and that many participants who viewed Nutrition Facts labels without added sugars declarations assumed that the more nutritious products in the study had less added sugars (80 FR 44303 at 44306). The comment asked us to clarify the preceding statement because it further noted that another document, namely, ''Experimental Study of Proposed Changes to the Nutrition Facts Label Formats,'' stated that ''respondents assigned to view the Current label were not asked to identify the grams of added sugars.'' The comment questioned how we were able to arrive at the conclusion referenced in the supplemental proposed rule, reasoning that the two statements appear contradictory, as participants in the format study who viewed the Current label were not asked questions regarding the amount of added sugars.

(Response) The two statements are not contradictory because the two statements refer to different studies. Due to the different purposes of the studies, the format study did not ask participants who were assigned to the Current label about the amount of added sugars, whereas the added sugars study did. We used results from the added sugars study, rather than findings from the format study, to arrive at the conclusion stated in the supplemental proposed rule.

(Comment 11) One comment asked if we balanced the sample for demographic characteristics in the added sugars and format studies.

(Response) In the added sugars and format studies, we did balance our samples on key demographic characteristics. We selected our samples by matching their key demographic characteristics (*i.e.,* age, gender, education, race/ethnicity, and census region) to that of the U.S. population.

(Comment 12) Some comments said that the order in which we assigned label formats to participants in the eye-tracking study could have affected the participants' responses. The comments attributed the concern to the design that showed all participants the Current label in the first set of tasks and showed the Proposed or Alternative labels randomly in the second set of tasks, rather than showing the three labels to three randomly assigned groups of participants in one set of tasks. The comments further stated that the design choice was not explained.

(Response) We acknowledge that the design could potentially have yielded different results than a design that randomly assigned participants to the three formats. We chose our design because the Current Nutrition Facts label has been on products for approximately 20 years and most, if not all, consumers have had exposure to or used the label. Consumers have likely developed their own patterns of reading and use of the Current label. Furthermore, the objective of the study was to explore whether and how much the two label formats outlined in the proposed rule would help raise consumer attention to certain label elements and reduce reading efforts. The design we chose recognized that participants would carry their own patterns of reading and using the Current label into tasks based on the Proposed and the Alternative labels. To the extent that the patterns could have varied between participants, each participant's responses to the Current label in the first set of tasks was used as her/his own baseline when we examined the responses to the Proposed or the Alternative labels in the second set of tasks. This approach, in turn, could minimize the within-subject differences between study participants and help reveal the true differential effects of label format on attention and efforts. Correspondingly, we applied the difference-in-difference analysis for this purpose. Therefore, although our design could have produced different results than a design that randomly assigned participants to the three label formats, we believe our design is appropriate under the particular circumstances.

(Comment 13) One comment said that the sample size of the eye-tracking study was too small to produce reliable empirical evidence. The comment also said that, despite the study's claim that the sample represented a wide variety of demographics, the claim is misleading because the South and Midwest regions were not included and 69 percent of the sample had a college or advanced degree.

(Response) We disagree with the comment. Our sample size calculations

suggested that the numbers of participants included in various statistical tests were sufficient to achieve the conventional degree of statistical power of at least a medium effect size for the non-parametric analyses we conducted. This is particularly true in terms of key outcome measures during label browsing (proportion of participants who noticed a label component at least once, length of time it took participants to notice a label component for the first time, proportion of total label viewing time spent on a label component, proportion of total number of notices spent on a label component), during information search (proportion of participants who identified target information, length of time it took participants to find target information, number of notices of target information before it was found), and during product identification (length of time it took participants to enter a choice, proportion of participants who selected a given label, proportion of participants who noticed a label component at least once on either of a pair of labels, proportion of total number of notices spent on a label component, and proportion of total label viewing time spent on a label component). Additionally, as shown in the study report, the participants varied in education attained, gender, race/ethnicity, and geographic locations. Thus, contrary to what the comment said, the sample did include a wide variety of demographics.

(Comment 14) Some comments questioned certain design aspects of how the format experimental study tested the different Nutrition Facts label formats. In particular, some comments said that the overall study design was complex and that 29 labels were too many to test at once and recommended a simpler design. One comment said that questions related to calories per serving and number of servings were comparatively less important because they appeared later in the questionnaire. In addition, the comment asked why the subjective numeracy questions, which asked participants to self-rate their aptitude for working with fractions and percentages, appeared at the beginning of the questionnaire.

Other comments questioned why certain topics were not included as part of the questionnaire. For example, one comment noted that, although the term ''% DV'' was used in place of ''% Daily Value'' in the Proposed and Alternative label formats, there were no questions specific to this change in the study. The comment also asked why there were not more direct questions about serving size. In addition, one comment said that the study report did not include respondents' perceptions of each label's ''helpfulness.''

(Response) The main purpose of the format study was to compare consumer use and understanding of Current, Proposed, and Alternative label formats (in their totality). Additionally, the study was designed to test the effects of the location of Percent Daily Value, column type (single- vs. dual-column vs. dual-calorie), location of sodium declaration on the Proposed single-column label, and declaration of voluntary vitamins and fats on the Proposed label. Given the priorities chosen, we carefully designed the study, including the necessary number of test labels, to ensure that the study could provide adequate statistical power to test hypotheses related to the priority topics. Thus, the overall study design and number of labels were appropriate.

Moreover, we disagree with the comment stating the questions about calories per serving and number of servings appeared later in the questionnaire and were less important. These questions appeared in the first half of the questionnaire. In addition, with respect to the comment on the order of questions related to subjective numeracy, we conducted the cognitive interviews with the subjective numeracy questions at the beginning of the study and found that the overall flow of the questionnaire was working well. We did not use these questions to screen participants in or out of the study.

With respect to comments related to questions not included in the format study, we narrowed our questions to the purpose of the study. For example, although we did not include specific questions to assess consumer understanding of the terms ''% DV'' and ''% Daily Value, '' we assessed the effects of the location of Percent Daily Value through a question that used the definition of % Daily Value as part of the question. Specifically, we included a question asking respondents the percentage of sodium for the day in a serving of a product to see how the labels compared in helping respondents find the % Daily Value. In addition, the focus of this study was not on consumer use and understanding of the meaning of serving size and therefore did not include a specific question about it. Instead, we focused on how the label formats affected consumers': (1) Perceptions of the healthfulness and levels of nutrients of a product; (2) identification of which product in a pair of products was considered healthier; (3) accuracy of identifying the amount of nutrients per serving and per container and number of servings per container; and (4) perceptions of the understandability, usefulness, believability, and helpfulness of the label for various dietary tasks such as comparing products and deciding how much of a food to eat.

Lastly, we disagree with the comment that we did not report on respondents' perceptions of label ''helpfulness.'' We reported on respondents' perceptions of ''helpfulness'' for each set of label comparisons in the ''Label preference'' rating.

(Comment 15) Some comments asked us to conduct additional analyses with the format experimental study on the Nutrition Facts label formats data. Some comments requested that we provide an analysis specifically comparing the single-column Current label format to the dual-column Proposed label format. Another comment asked us to provide the results related the effect of adding absolute values to the vitamins and minerals as was found on the Proposed and Alternative labels. One comment asked why we did not include an analysis of the number of servings per container.

(Response) In the notice on Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Reopening of the Comment Period as to Specific Documents (80 FR 44302), we reported on the results of our consumer study ''Experimental Study of Proposed Changes to the Nutrition Facts Label Formats'' related to key aspects of the changes we proposed to the format of the nutrition label. The comparisons suggested by the comments could be made through additional analyses of the data we collected. While we reported the effects of the format types within the same column type and the column-type within the same format type, we did not report the comparison between the Current single-column format and Proposed dual-column format. Such an analysis would not have provided us with information on the differences in formats in which we were most interested. However, for our own interest, we have since conducted that analysis and the results do not provide any new information related to our consideration of the format of the nutrition label. The results of this analysis seem to corroborate our main finding related to the effects of dual-column labeling compared to single-column labeling as described in table 7 of our June 30, 2015 memo to the file (Ref. 12). As reported in that memo, the Proposed dual-column label (% DV left) scored higher than the Proposed single-column label (% DV left) on the Total correct per container measure.

Similarly, in the new comparison, the Proposed dual-column label (% DV left) scored higher than the Current single-column label (% DV right) on that same measure. The new comparison demonstrates that the Proposed dual-column (% DV left) also scored higher on the Total Correct per serving measure than the Current single-column (% DV right) label.

In addition, the purpose of our evaluation of consumer views about how high or low the product is in a vitamin or mineral when absolute values were provided, compared to a label without this information, was to understand how some consumers perceive different numbers associated with various units of measure. In response to the comment on our findings on absolute amounts, we did complete a review of that aspect of the data, and the results do not provide any new information related to our consideration of the declaration of absolute amounts for some or all nutrients (Ref. 13)). The study did not address how consumers use or understand absolute amounts for following dietary advice. Participants who viewed the different label conditions were asked to rate on a 5-point scale (1 = none or very little; 5 = a lot) how much of various nutrients they thought were in one serving of the product. Because the questions asked participants to offer their subjective perception, rather than report the absolute amount for a nutrient, no rating offered could be judged as correct or incorrect. Instead, the ratings simply provided information about how pairing the correct absolute nutrient amount with the correct % DV affected participants' perceptions.

Further analysis found that there was no difference in correctly identifying the number of servings per container between the single-column labels, the dual-column labels, or between the Current single-column (% DV right), and the Proposed dual-column (% DV left) (Ref. 13). Thus, none of these formats had any influence on how participants identified the number of servings per container, and therefore, did not provide any new information related to our consideration of the servings per container.

(Comment 16) One comment mentioned an eye-tracking study that the comment did to examine and compare participants' attention to the Nutrition Facts label either in its current format or in the proposed format. The comment stated that the study did not find significant differences between the two formats either in attention to the label in its totality or in terms of the vitamins and mineral section nor in healthful food choices made. The comment also stated that moving the percent Daily Value column to the left side of the label reduced participants' attention to the percent Daily Value information. In addition, the comment suggested that more noticeable changes to the label format, such as using traffic light colors, or descriptors, such as ''high'' or ''low,'' may have a greater impact on attention and choice than the changes we proposed.

(Response) We decline to comment on the findings because the comment did not provide sufficient details about how the study was designed and analyzed.

As for other possible changes of the label that the comment speculated might affect consumer attention and food choices, *e.g.,* traffic light colors or text descriptors, such issues are outside of the scope of this rulemaking.

(Comment 17) One comment said that FDA's added sugars study seemed to be unduly focused on whether consumers could correctly identify added sugars and how identification of added sugars affected overall judgment of the product. The comment also stated that the study design steered participants to think specifically about added sugars throughout the survey, potentially leading them to judge the labels on the amount of added sugars.

(Response) We disagree that the design of the added sugars study unduly emphasized, or otherwise steered participants to focus on, added sugars beyond a level necessary to meet the key objectives of the study. A primary focus of FDA's added sugars study was to explore participants' understanding of Nutrition Facts labels that include added sugars declarations relative to participants' understanding of Nutrition Facts labels that do not include added sugars declarations. Although the primary objectives of the study pertained to added sugars declarations, we used a variety of measures to assess a range of participant reactions to the different labels. For example, we asked participants to evaluate foods' overall healthfulness as well as the levels of various nutrients such as saturated fat, sodium, dietary fiber, and others, in addition to added sugars.

(Comment 18) One comment noted that the added sugars study varied the experimental conditions in an unbalanced way, making it difficult to make inferences about the experimental conditions. The comment also said that we did not keep the caloric value consistent across products and, therefore, did not isolate the effect of the added sugars declarations separately from the effect of calories. The comment also noted that, in Appendix A of the FDA study report about the results of the added sugars study (Ref. 14), the ''most nutritious'' frozen meal had more calories, sodium, fat, and saturated fat, and lower iron and vitamin C than the ''least nutritious'' frozen meal.

(Response) Because the comment does not specify what was ''unbalanced'' in the experimental conditions and what specific inferences were therefore precluded, we do not have sufficient information to respond to this comment. We disagree that the study did not isolate the effect of added sugars declarations separately from the effect of calories because that is in fact what the experimental design achieved. In other words, by randomly assigning participants to different experimental conditions, we were able to compare participant responses in experimental conditions that were treated identically in all respects other than the display of added sugars information, thus isolating the effect of added sugars declarations from the effect of other experimental factors, such as calorie information.

Regarding Appendix A of the FDA study report (Ref. 14), there was a typographic error on the nutrition profiles for the frozen meals. Meal 1 should have been labeled the ''least nutritious,'' whereas Meal 3 should have been labeled the ''most nutritious.'' This typographic error, however, did not in any way affect the rest of the study description or reported findings.

(Comment 19) One comment noted that in table 8 of the added sugars study report (Ref. 14), the mean ''usefulness'' score for those viewing the control format was 3.93, whereas the mean ''usefulness'' score for those viewing the added sugars declaration format was 3.97. The comment stated that the report noted a significant difference between these scores and requested clarification.

(Response) The comment is incorrect. The report indicated that there was no statistically significant difference between the two means in question.

(Comment 20) One comment stated that the voluntary responses from study participants during the debriefing phase of the eye-tracking study showed that consumers had difficulties using the Current label and did not understand terms such as saturated fat and *trans* fat.

(Response) We disagree that the indicated responses showed that consumers have difficulties using the Current label and do not understand terms such as saturated fat and *trans* fat. The comment did not interpret this finding in context. The full statement in our study report is ''When asked, most participants did not report having difficulties using the Current format as

long as they knew what to look for on the label (table 25) (Ref. 15). Some, however, mentioned that they did not understand some of the information on the label, such as fats and *trans* fat, or had problems with the small font size of the information'' (eye-tracking study memo in the re-opener, July 27, 2015, p. 25). Contrary to the comment, the report states that most of the study participants did not have difficulties using the Current label, and only some said they did not understand fats and *trans* fat.

C. Comments on Legal Issues

Several comments addressed legal issues. Some comments asserted that FDA cannot compel an added sugars declaration in nutrition labeling under the First Amendment. We also received comments that questioned whether our proposed requirement for an added sugars declaration and certain other proposed requirements are consistent with the requirements in the Administrative Procedure Act (APA) and our authority under the FD&C Act. In addition, we received comments questioning our authority to require and access records related to the declarations for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid. Other comments raised miscellaneous legal issues.

1. First Amendment

Many comments on the proposed requirement to include an added sugars declaration on food labels related to our ability to compel such speech under the First Amendment. Some comments supported our proposed requirement for the declaration of added sugars as factual, uncontroversial information, based on the application of the First Amendment test set forth in *Zauderer* v. *Office of Disciplinary Counsel of Supreme Court,* 471 U.S. 626 (1985). Most comments raising First Amendment arguments did not support the proposed declaration, but differed in their assertion of the applicable First Amendment test. Many comments asserted that the proposed declaration did not satisfy the Zauderer test, while other asserted that it failed under the test set forth in *Central Hudson Gas & Electric Corp.* v. *Public Service Comm'n,* 447 U.S. 557 (1980). Still others asserted that the proposed declaration was subject to, and failed to satisfy, strict scrutiny review.

(Comment 21) Some comments said the added sugars declaration is not subject to the test in *Zauderer,* or, even if subject, does not meet such test. Specifically, one comment stated that *Zauderer* does not apply to misleading statements or statements that are subject to misinterpretation. Other comments said that because there is already a declaration for total sugars and there is no material difference, or scientific rationale, for distinguishing between added and intrinsic sugars, including no ''sufficient nexus to consumer health,'' the declaration of added sugars is not purely factual and uncontroversial information for which the First Amendment test in *Zauderer* would apply. One comment stated that because added sugars are not chemically distinct from natural sugars and do not have different health effects, the declaration of added sugars would be false and misleading and the Agency could not compel it under the First Amendment. Several comments stated there are no physiological distinctions between added and naturally occurring sugars, and therefore, no connection to consumer health on which to compel such speech.

(Response) The disclosure of added sugars is factually accurate nutrition information and industry's interest in not disclosing such factual information is minimal. In *Zauderer,* the Supreme Court explained that ''[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a speaker's] constitutionally protected interest in not providing any particular factual information in his advertising is minimal'' (see 471 U.S. at 651 (internal citations omitted)). Providing consumers the amount of added sugars in a serving of food ''does not offend the core First Amendment values of promoting efficient exchange of information'' and ''furthers, rather than hinders, the First Amendment goal of the discovery of the truth and contributes to the efficiency of the 'marketplace of ideas' '' (*Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 113 through 114 (2d Cir. 2001). As a result, government requirements to disclose factual commercial speech are subject to a more lenient constitutional standard than that set forth under the Central Hudson framework (*Zauderer,* 471 U.S. at 651). Under *Zauderer,* the government can require disclosure of factual information in the realm of commercial speech as long as the disclosure provides accurate, factual information; is not unjustified or unduly burdensome; and ''reasonably relate[s]'' to a government interest (id.).

The required added sugars declaration readily satisfies the *Zauderer* test. First, the declaration of added sugars, which is being finalized in this rule, provides accurate disclosures of factual commercial information about the amount of added sugars contained in a food. The required disclosure requires only facts about the product (*Am. Meat Inst.* v. *United States,* 760 F.3d 18 (D.C. Cir. 2014) (''country-of-origin labeling qualifies as factual, and the facts conveyed are directly informative of intrinsic characteristics of the product AMI is selling'')). This required labeling will help facilitate the free flow of commercial information by providing a declaration of added sugars on food labels, and does not ''prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion'' (*Zauderer,* 471 U.S. at 651 (quoting *W. Va. State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943))).

As for the comments stating that there is no material difference or scientific rationale for distinguishing between total sugars and added sugars, or between added sugars and naturally occurring sugars, these comments relate to our rationale for why an added sugars declaration will assist consumers to maintain healthy dietary practices and not to whether the declaration is factual and accurate information. We address these comments in part II.H.3.i. The added sugars declaration conveys factual and accurate information about the amount of added sugars in a serving of food.

Second, the required added sugars declaration is not unduly burdensome. Factual nutrition information for a number of other nutrients is currently required to be provided on packaged foods. The space that is occupied by the indented line for the ''Includes 'XX' g Added Sugars'' declaration, below the ''Total Sugars'' declaration does not increase the size of the existing Nutrition or Supplement Facts label, given changes made elsewhere to the label, such as reducing the size of the footnote in the label. We also note that, as discussed in our economic analysis (Ref. 16), the cost to manufacturers is reduced from that in the proposed rule under the compliance timelines in the final rule which will allow most manufacturers to make revisions to the label during regularly scheduled label changes for their products.

Third, the required added sugars declaration is reasonably related to our government interests in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices, and thus amply satisfies the remaining element of the *Zauderer* test. Providing consumers with information about the added sugars content of food would promote the

public health by ensuring they have information to assist them in meeting nutrient needs within calorie limits and to assist them in constructing a healthy dietary pattern that is limited in added sugars to reduce the risk of CVD. As explained in the preamble to the proposed rule (79 FR 11879 at 11903), Americans consume too many calories from solid fats and added sugars, which makes it difficult for consumers to meet nutrient needs within their calorie limits. The 2010 DGA noted that solid fats and added sugars contribute a substantial portion of calories (35 percent) in the American diet, with 16 percent on average from added sugars. Recommended calorie limits for most consumers, as set forth in the 2010 DGA, can only reasonably accommodate 5 to15 percent of calories from solid fats and added sugars combined (id.). While it is true that excess calorie consumption from any source can lead to weight gain, the statistics on calorie consumption from solid fats and added sugars suggest that, for many consumers, added sugars contribute to excess calorie intake. In fact, the 2010 DGA also noted that excess calories from solid fats and added sugars have implications for weight management (id.). Moreover, there is strong evidence showing that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake (id.).

The 2015 DGAC report further contributed to the scientific support for the added sugars declaration. For the first time, the 2015 DGAC conducted a systematic review of the relationship between dietary patterns and health outcomes. The DGAC found a strong association of a dietary pattern characterized, in part, by lower consumption of sugar-sweetened foods and beverages relative to a less healthy dietary pattern and reduced risk of CVD. We reviewed and considered the evidence that the 2015 DGAC relied upon, including an existing review from the Nutrition Evidence Library (NEL) Dietary Patterns Systematic Review Project as well as the NHLBI Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group (''NHLBI Lifestyle Evidence Review'') (Ref. 17) and the associated American Heart Association (AHA)/American College of Cardiology (ACC) Guideline on Lifestyle Management to Reduce Cardiovascular Risk (''Lifestyle Management Report'') (Ref. 18). The diet quality of the general U.S. population ''does not meet recommendations for vegetables, fruit, dairy, or whole grains, and exceeds recommendations, leading to overconsumption, for the nutrients sodium and saturated fat and the food components refined grains, solid fats, and added sugars.'' While intake levels of added sugars still remain high at an average of 13.4 percent of calories among the U.S. population, the amount of added sugars available for the calorie ranges covered by the USDA Food Patterns (1,000 to 3,200 calories) ranges from only 4 to 9 percent (Ref. 19).

The scientific evidence, and other data and information, supports the need for an added sugars declaration to promote the public health.

In addition, the declaration of added sugars provides information that is material because, without the declaration of added sugars, consumers would not have access to information about the amount of added sugars in a serving of food. The current ''Sugars'' declaration on the label does not provide information on how much added sugars are present in a food, nor does the ingredient listing. The contribution of naturally occurring sugars and added sugars cannot be determined based on the ''Sugars'' declaration that includes both types of sugars. In addition, although ingredients are listed in order of predominance by weight (21 CFR 101.4), the ingredient information is not a substitute for the gram amount of added sugars. An ingredient listing would not enable the consumer to understand the amount of added sugars in grams and therefore, the contribution of the food to the daily dietary recommended limit of less than 10 percent of calories from added sugars.

Added sugars are found in many foods in the marketplace. Consumers are likely to be aware that added sugars are present in some sweet foods, such as sugar-sweetened beverages and candy, but in other foods, such as sweetened grains, mixed dishes, condiment, gravies, spreads, and salad dressings, the presence of added sugars is not as obvious. The majority of food sources of added sugars are beverages (excluding milk and 100 percent fruit juice), snacks, and sweets; however, 22 percent of food sources of added sugars are from other categories of foods such as grains, mixed dishes, dairy, condiments, gravies, spreads, salad dressings, fruits and fruit juice, and vegetables (Ref. 20). Small amounts of added sugars that are contributed to diet by a wide variety of foods can add up over the course of the day and can make it difficult for an individual to eat sufficient amounts of foods from the basic food groups to meet nutrient needs without exceeding the amount of calories they need in a day for weight maintenance. Because added sugars are in such a wide variety of foods in the food supply, consumers need to have information on the label so that they can consider the amount of added sugars in both foods that supply large amounts of added sugars as well as those that supply smaller amounts when constructing a healthy dietary pattern that contains less than 10 percent of calories.

Without the declared amount of added sugars, consumers would be denied access to the information they need to reduce the intake of added sugars to the recommended daily limit. As discussed in our response to comment 159, added sugars is a material fact, within the meaning of section 201(n) of the FD&C Act. Mandatory labeling that provides information about the contribution to daily caloric intake of added sugars is necessary to ensure that full, factual information is imparted to consumers so they have access to the information needed to follow a healthy dietary pattern and will not be misled in purchasing decisions because they have no information about added sugars content and further could not calculate it based on the other information on the label—total sugars content or ingredient labeling.

Furthermore, the declaration of added sugars is also reasonably related to the government's interest in providing information needed to assist consumers in maintaining healthy dietary practices by providing them with information about added sugars content in a serving of food to construct diets containing more nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars to less than 10 percent calories. Survey data show that consumers use the Nutrition Facts label and the percent Daily Value at point-of-purchase and review the nutrient contribution of food (Refs. 21–23) products. Thus, by requiring the added sugars declaration on the Nutrition Facts label, we will give consumers a tool they need to include added sugars as part of a healthy dietary pattern that avoids excess calories from added sugars and is associated with a reduced risk of CVD.

Some comments asserted that *Zauderer* is limited to cases where the government interest is in preventing consumer deception. Case law interpreting *Zauderer* clarifies that the government need not establish that compelled disclosure will prevent consumer deception for the *Zauderer* standard to apply. In *American Meat Institute,* the court held that ''[t]he language with which *Zauderer* justified its approach . . . sweeps far more

broadly than the interest in remedying deception'' 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc). In reaching the conclusion that the applicability of *Zauderer* extends beyond regulations in which the government is attempting to mandate a disclosure to remedy deception, the court focused on the ''material differences between disclosure requirements and outright prohibitions on speech,'' (id. at 21 (quoting *Zauderer,* 471 U.S. at 650)), the fact that ''the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed,'' (id. (quoting *Zauderer,* 471 U.S. at 652 n.14)), and the fact that ''[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a] constitutionally protected interest in not providing any particular factual information in his advertising is minimal,'' (id. (citing *Zauderer,* 471 U.S. at 651)). The court found that, ''[a]ll told, *Zauderer*'s characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception'' (id.). Several other circuits concur (see *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294, 297 through 298, 310, 316 (1st Cir. 2005); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 133 (2d Cir. 2009); *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 115 (2d Cir. 2001) (affirming use of the ''reasonable-relationship *Zauderer* standard when the compelled disclosure at issue . . . was not intended to prevent 'consumer confusion or deception' ''); *Disc. Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 556 (6th Cir. 2012) (holding that ''*Zauderer*'s framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception'')).

(Comment 22) One comment stated the proposed declaration of added sugars violates the First Amendment because the requirement is not reasonably related to a legitimate regulatory interest. Another comment asserted that an added sugars declaration would not assist consumers in maintaining healthy dietary practices. Another comment stated that even if the declaration of added sugars was purely factual and not controversial, the declaration is ''unjustified and unduly burdensome'' (citing *Zauderer,* 471 U.S. at 651), where there is no scientific evidence that added sugars contributes to obesity or heart disease and there is no recommended daily allowance.

(Response) As explained in our response to comment 21, the required added sugars declaration assists consumers in maintaining healthy dietary practices and is reasonably related to our government interests in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices. Furthermore, we disagree with the comment suggesting that the added sugars declaration is unjustified and unduly burdensome because ''no scientific evidence exists to support FDA's assumption that added sugars contribute to obesity or heart disease'' and due to the lack of a DV for added sugars. To the extent the comment suggests we were relying on a specific nutrient-disease relationship between added sugars and obesity or heart disease in the general population, the comment misunderstands our rationale for the declaration. We stated that our scientific basis for the added sugars declaration, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition or a physiological endpoint (see 79 FR 11879 at 11904). Although we recognized that U.S. consensus reports do not support a cause and effect relationship between added sugars consumption and risk of obesity or heart disease (id.), we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars to healthy dietary patterns, and the impact to public health from such patterns. In the latter, we included a proposed DV for the added sugars declaration.

(Comment 23) One comment stated that the disclosure of added sugars is disclosure of factually accurate nutritional data and analogized the disclosure to the disclosure of allergens under the Federal Food Allergen Labeling and Consumer Protection Act (FALCPA). The comment said that Congress imposed requirements for nutrient and allergen disclosures so consumers can make ''safer, healthier, and more informed choices about the foods they eat'' and not because food labels were deceptive without the information. The comment cited *Zauderer* and *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 113 through 114 (2d Cir. 2001) for support that industry's interest in not disclosing such factual information is minimal. The comment also stated that we articulated a rational basis for requiring consumers to maintain healthy dietary practices (citing *N.Y. State Rest. Ass'n* v. *N. Y. City Bd. of Health,* 556 F.3d 114, n.21 and at 136 (2d Cir. 2009), and *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294 (1st Cir. 2005)).

(Response) We agree that the disclosure of added sugars is factually accurate nutrition information and that industry's interest in not disclosing such factual information is minimal. We also agree that Congress imposed nutrition labeling requirements to help consumers have access to information that would assist them in choosing healthy diets. Congress prescribed that foods subject to the nutrition-label requirements are ''deemed to be misbranded'' if they do not provide nutrition labels as required (see section 403 and 403(q) of the FD&C Act). Congress also has indicated that labeling's failure to provide certain material information is to be taken into account in determining whether such labeling is misleading (see section 201(n) of the FD&C Act). We do not respond to the portion of the comment on Congress' intent with respect to allergen labeling under FALCPA because it is outside the scope of this rule.

(Comment 24) One comment stated the added sugars labeling is not to provide purely factual information to prevent consumer deception, but to shape consumer behavior.

(Response) As explained in the preamble to the proposed rule (see 79 FR 11879 at 11905), the added sugars declaration will provide information to consumers on the amount of added sugars in a serving of food. We recognize that added sugars can be a part of a healthy dietary pattern when not consumed in excess amounts. The purpose of the added sugars declaration is not to discourage the consumption of the class of foods that contain added sugars, but rather to increase consumer understanding of the quantity of added sugars in foods to enable the consumer to understand the relative significance of the contribution of added sugars from a serving of a particular food in the context of the total daily diet. A consumer may or may not elect to reduce the consumption of certain foods with added sugars, based on his or her individual need and dietary choice. The declaration provides purely factual information so that consumers will have access to the information they need about the amount of added sugars in a food, and that they are not able to obtain from the current nutrient declaration of ''Sugars'' or ''Total Sugars'' alone.

Through our consumer education, we plan to help consumers understand the changes we are making in the final rule and how the information can assist them to include a variety of foods in their daily diet so that they understand how to achieve a healthy dietary pattern.

(Comment 25) One comment stated the added sugars declaration would compel misleading labeling because it would mislead consumers into believing that a sweetened dried cranberry is less healthy than a naturally sweetened dried fruit, due to the cranberry's added sugar content.

(Response) The comment seems to refer to the consumer research data related to consumer perceptions of ''healthful'' that we discuss in our response to comment 184. We do not agree that the results in our added sugars study or the results submitted by comments on consumer perceptions support the assertion that an added sugars declaration would compel misleading labeling. As we have stated, a consumer's belief, opinion, or previous exposure to information about added sugars and their impact to health, whether based on science or not, may affect how a consumer may view a food with an added sugars declaration. These factors can influence how a consumer perceives the factual statement about the amount of added sugars on a label and may result in some consumer confusion and misunderstanding about the food containing the added sugars that is not based on the declaration itself, but instead, on the consumer's own misperceptions. For example, a consumer may erroneously think a food, which can be part of a healthy dietary pattern, is not ''healthful'' because it contains some amount of added sugars. This is likely not unique to added sugars. Consumers obtain information from a number of sources, previous experiences, or in response to specific health concerns. For example, there is a large body of data and information on other nutrients to limit, *e.g.,* saturated fat, cholesterol, and sodium, which may influence consumer perception of how ''healthful'' a food may be. A consumer may choose to avoid all or most sources of food with sodium or saturated fat present, or present in a certain amount, based on their beliefs or specific dietary needs.

A consumer's lack of understanding about what added sugars are or how to use the added sugars declaration to limit added sugars intake does not mean the factual declaration of the amount of added sugars in a serving of food is misleading. Consumers need more, not less, information about the added sugars content of a food to learn how to understand and use the information in planning a healthy dietary pattern. Furthermore, the term ''unhealthful'' when describing a food with added sugars is a relative term and must be viewed in the context of the day's total dietary intake. For example, a food with a high amount of added sugars may be understandably viewed as ''unhealthful'' because, if consumed, it may result in overconsumption of added sugars for the day. We need to correct the misperceptions consumers may have about added sugars and provide them with information they need to include a variety of foods in their diet, as part of a healthy dietary pattern, so they can understand how to include added sugars in their diets at levels less than 10 percent of calories to avoid overconsumption. We intend to educate consumers on the changes to the food label, and in particular, to the declaration of added sugars so that consumers can expand their food choices to include nutrient dense foods, such as cranberries with added sugars, and still achieve a healthy dietary pattern.

(Comment 26) Another comment stated that an added sugars declaration and percent DV will compel false information on the label because the amount of added sugars will need to be overstated on yeast-leavened products, in violation of the First Amendment.

(Response) We disagree that an added sugars declaration on yeast-leavened products will need to be overstated and therefore compel false information on the label. We allow for reasonable deficiencies in foods generally for label amounts of calories, sugars, added sugars, saturated fat, *trans* fat, cholesterol and sodium, within current good manufacturing practices (see final § 101.9(g)(6)). Furthermore, as we have stated in our response to comment 200, we recognize that labeling of added sugars in products that undergo fermentation and non-enzymatic browning may not be exact, but that manufacturers of most products that participate in these reactions should be able to provide a reasonable approximation of the amount of added sugars in a serving of their product based on information in the literature and their own analyses. To the extent a manufacturer has reason to believe the amount of added sugars in a serving of food may be significant enough to impact the label declaration by an amount that exceeds the reasonable deficiency acceptable within current manufacturing practice, and is unable to reasonably approximate the amount of added sugars in a serving of food, the manufacturer may submit a petition to request an alternative means of compliance.

(Comment 27) One comment stated that, even if the added sugars declaration is not false or misleading, *Zauderer* still would not apply to the requirement to include a % DV for the declaration of added sugars because the % DV is not designed to prevent consumer fraud or deception. The comment stated it is not clear whether consumers know what the % DV represents. The comment suggested that the mere declaration may lead a consumer to consider added sugars as ''inherently dangerous.''

(Response) We disagree with the suggestion that, if the % DV is not designed to prevent consumer fraud or deception, *Zauderer* would not apply. As we explained in our response to comment 21, the *Zauderer* test is not limited in this way. Moreover, we are unclear as to the comment's basis for its assertion that consumers would consider added sugars as ''inherently dangerous.'' The comment provided no data or information for its assertion. We consider that view, should it exist, to be a consumer misperception. We plan to address consumer misperceptions about added sugars as part of our consumer education effort.

(Comment 28) Some comments asserted that the test in *Zauderer* is not applicable to the added sugars declaration and that *Central Hudson* provides the appropriate test with which to evaluate the declaration under the First Amendment.

(Response) While we disagree that the required added sugars declaration should be subject to the *Central Hudson* standard, it would nonetheless be Constitutional under the standard set forth in *Central Hudson.* If the *Central Hudson* standard were applicable to the required added sugars declaration, we would need to identify a ''government interest [that] is substantial,'' establish that ''the regulation directly advances the government interest asserted,'' and show that the regulation ''is not more extensive than is necessary to serve that interest'' (*Central Hudson,* 447 U.S. at 566). Under the *Central Hudson* test, we have the discretion to ''judge what manner of regulation may best be employed'' to serve the substantial government interest (see *City of Cincinnati* v. *Discovery Network, Inc.,* 507 U.S. 410, 416 n.12 (1993) (citing *Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989))).

(Comment 29) Some comments stated there is no substantial government interest for which we can require an added sugars declaration under *Central*

Hudson because there is no material difference between added and intrinsic sugars in food. One comment stated that ''scientific studies have not sufficiently shown that FDA has a substantial interest in preventing consumer intake of added sugars.'' Another comment stated that FDA's interest in compelling an added sugars declaration is not substantial where there is no causal relationship between added sugars and risk of chronic disease, but only evidence of a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD. The comment further stated that, just as there is no substantial government interest for added sugars, there is no such interest for total sugar content or for the percent DV for added sugars; the comment stated there is no material health or safety difference between a food with added sugars as compared to naturally occurring sugars.

(Response) We disagree that we have no substantial government interest to support the declaration of added sugars. We have an interest in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices. Promoting the public health is part of our mission to ensure, in part, that foods are properly labeled (section 1003 of the FD&C Act (21 U.S.C. 393)). In addition, for over 20 years, we have had a substantial government interest in ensuring that consumers have access to information about food on the nutrition label that is truthful and not misleading, and an interest in ensuring that nutrition information will assist consumers in maintaining healthy dietary practices. Based on the more recent scientific evidence on reducing added sugars consumption as part of a healthy dietary pattern, we have a substantial interest in ensuring the accuracy and completeness of added sugars information in labeling. Our government interests are substantial and supported as such (*Rubin* v. *Coors Brewing Co.,* 514 U.S. 476, 485 (1995) (recognizing that the government has a substantial interest in promoting the health of its citizens); see also, *Am. Meat Inst.* v. *U.S. Dep't Agric.,* 760 F.3d 18 (D.C. Cir. 2014) (en banc) (finding the context and history of disclosures in labeling by USDA one of several interests to support a substantial government interest under *Central Hudson*); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health* (556 F.3d 114, 134 (2d Cir. 2009) (finding the promotion of ''informed consumer decision-making so as to reduce obesity and the diseases associated with it'' through posting of calorie content information on menus to be a substantial government interest)).

We also disagree that there is no material difference between added and intrinsic sugars for purposes of achieving a healthy dietary pattern to avoid excess discretionary calories from added sugars and reduced risk of chronic disease. As we discuss in our response to comment 143, there is a strong association with respect to the consumption of a healthy dietary pattern characterized, in part, by a lower intake of sugar-sweetened foods and beverages, and a reduced risk of CVD, compared to less healthy dietary patterns with higher intakes of added sugars. Foods that are composed of naturally occurring or intrinsic sources of sugars, *e.g.,* fruits and vegetables, are distinct from the category of sugar-sweetened foods and beverages and are not food categories recommended to be reduced as part of the healthy dietary pattern. Furthermore, evidence and conclusions from the 2010 DGA support the conclusion that consumption of excess calories from added sugars can lead to a less nutrient-dense diet. With respect to the comments related to the scientific support for the added sugars declaration, we disagree that a causal relationship must be shown between added sugars and a risk of chronic disease (*e.g.,* a dose-response relationship between a nutrient and risk of disease) before we can make the requisite finding under section 403(q)(2)(A) of the FD&C Act that added sugars would assist consumers in maintaining healthy dietary practices (see part II.H.3.a). No such dose-response requirement exists in section 403(q) of the FD&C Act or in implementing regulations. Furthermore, the comment's characterization that ''scientific studies have not sufficiently shown that FDA has a substantial interest in preventing consumer intake of added sugars'' mischaracterizes the purpose of the nutrient declaration. We are not ''preventing'' consumer intake of added sugars. Instead, we are providing factual, accurate information to the consumer about the amount of added sugars in serving of food to enable consumers to understand and use the information to make informed dietary choices and construct their daily diets.

(Comment 30) One comment said that consumer interest alone does not make information material and consumer interest is not a substantial government interest, and therefore, the added sugar declaration cannot be compelled under the First Amendment.

(Response) We are not requiring the declaration of added sugars based on consumer interest. We are requiring an added sugars declaration to provide information to assist consumers with food purchases that can reduce their intake of added sugars and enable them to achieve a healthy dietary pattern. A healthy dietary pattern, characterized in part by lower amounts of added sugars than that found in the U.S. general population's dietary pattern, is strongly associated with a reduced risk of chronic disease (*Disc. Tobacco & Lottery, Inc.* v. *United States,* 674 F.3d 509, 564 (6th Cir. 2012) (finding a reasonable relationship between tobacco warning statements and a government interest in ''promoting greater public understanding of the risks''); *Sorrell,* 272 F. 3d at 115 (finding a rational relationship between the state's goal of reducing mercury contamination and required label disclosures on mercury-containing light bulbs). The required declaration of added sugars is consistent with the First Amendment and our authority in sections 403(a), 201(n), 403(q)(2)(A) and 701(a) of the FD&C Act.

(Comment 31) Some comments questioned how an added sugars declaration would directly advance the government interest related to consumer health. One comment stated that, even if FDA had a substantial government interest, FDA has not shown that the declaration directly advances that interest (citing *Central Hudson,* 447 U.S. at 566) and to a ''material degree'' (citing *Florida Bar* v. *Went For It, Inc.,* 515 U.S. 618, 626 (1995)) because FDA has not shown there would be any ''discernable effect on consumer behavior'' and that FDA must demonstrate that an added sugars declaration is related to ''its desired change in consumer behavior or an improvement in consumer health.'' Another comment cited *Edenfeld* v. *Fain,* 507 U.S. 761 at 770 through 771 (1993), stating that FDA will not be able to carry the burden to ''demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'' The comment stated that we have not and cannot demonstrate a concrete harm in the absence of a mandatory added sugars declaration.

(Response) The added sugars declaration directly advances our government interests in promoting consumer health, preventing misleading labeling, and assisting consumers in maintaining healthy dietary practices. As we explain in our response to comment 137, Americans consume too many calories from solid fats and added sugars, which replace nutrient-dense foods and make it difficult for consumers to achieve the recommended

nutrient intake while controlling their calorie intake. Consumers can only reasonably accommodate 5 to 15 percent of calories from solid fats and added sugars combined, yet the 2015 DGAC found intakes from added sugars alone at approximately 13.4 percent. Excess calories from solid fats and added sugars have implications for weight management. Moreover, there is strong evidence showing that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake.

The scientific evidence shows that, although there is moderate evidence of an association with healthy dietary patterns (with lower added sugars) compared to less healthy patterns and measures of increased body weight or obesity, type 2 diabetes, cancer, and congenital anomalies, there is a strong association of a dietary pattern characterized, in part, by lower consumption of sugar-sweetened foods and beverages, relative to a less healthy dietary pattern found in the general U.S. population, and reduced risk of CVD. Thus, the scientific review supports that a healthy dietary pattern that is characterized by a lower consumption of added sugars, not a lower consumption of naturally occurring sugars, is strongly associated with a reduced risk of CVD.

The declaration of added sugars would provide consumers with information about the amount of added sugars in a food product that is currently absent from the label. The failure to disclose the amount of added sugars in a product is an omission of a material fact. The reasonable consumer would expect that the information on the label would give them the most important nutrition information, relative to the need to construct a healthy dietary pattern that limits the excess consumption of added sugars. The omission of added sugars runs counter to that expectation, impeding rational consumer choice. A healthy dietary pattern, when compared to the current dietary pattern in general U.S. population, is associated with a reduced risk of CVD and avoids excess discretionary calories from added sugars and solid fats. Consumers need information about added sugars in all foods, not just those that contain a certain threshold level or that are found in select food categories (*e.g.,* beverages) to reduce overall intake of added sugars in the diet. Consumers can use the declared amount of added sugars to compare products and make food selections to achieve a healthy dietary pattern that is associated with a reduced risk of CVD. Therefore, the added sugars declaration is required to ensure that the labeling is not misleading.

Consumers need to understand the amount of added sugars in food to understand the relative contribution of the food to total dietary intake. The percent DV provides information on how much added sugars in a serving of food contributes to the recommended limit of less than 10 percent calories from added sugars. As we explain in our response to comment 21, consumers use the Nutrition Facts label at point-of-purchase and review the nutrient contribution of food products to help them choose products and compare products. By providing this information, consumers can have the information they need to achieve a healthy dietary pattern that is characterized by lower levels of added sugars through a lower total consumption of sugar-sweetened foods and beverages. A healthy dietary pattern is also characterized by a higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat and refined grains. In addition, the declaration of added sugars on the nutrition label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct daily diets containing nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars to less than 10 percent calories. Thus, by providing this information on the food label, we can directly and materially advance an interest in promoting public health, preventing misleading labeling, and assisting consumers in maintaining healthy dietary practices. We have sufficient support to demonstrate that the declaration directly advances our government interests, including scientific support for the added sugars declaration, evidence to support consumer use of the label, and expert opinion to support consumer understanding of the added sugars declaration based on changes made to the proposed declaration (see *Florida Bar* v. *Went For It, Inc.,* 515 U.S. 618, 628 (1995) (justifying speech restrictions ''by reference to studies, and anecdotes pertaining to different locales altogether . . . or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense' '') (citations omitted)).

We disagree with the comment's assertion that we must show a ''discernable effect on consumer behavior'' and that we must demonstrate that an added sugars declaration is related to a ''desired change in consumer behavior or an improvement in consumer health.'' Achieving specific changes in consumer behavior and/or health are not the government interests we assert, and the law does not require that these specific showings be made. We note that, to the extent the comment suggests we need a connection to consumer health for purposes of the added sugars declaration, we have described that relationship in the proposed rule, the supplemental proposed rule, and the final rule.

(Comment 32) One comment acknowledged the strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced CVD risk. However, most comments questioned how an added sugars declaration would directly advance our government interest to assist consumers to maintain healthy dietary practices and focused on health outcomes for which they say there is only moderate or no direct evidence of an association between added sugars consumption and a disease or health-related condition. For example, some comments stated there is no evidence that added sugars has an impact on obesity, and therefore, a declaration would not assist consumers to maintain healthy dietary practices. Another comment said that a link to added sugars intake and health based on the 2010 DGA is flawed, citing to a statement in the preamble to the proposed rule that added sugars do not contribute to weight gain more than any other source of calories (79 FR 11879 at 11904) even though the 2010 DGA recommendation is to reduce the intake of calories from added sugars. Other comments focused on the evidence in Chapter 6 of the DGAC Report, which the comments describe as ''moderate'' evidence, to support a specific relationship between added sugars and disease risk. The comments appeared to suggest that we are relying only on evidence in Chapter 2 Part D of the 2015 DGAC Report to support our basis for the added sugars declaration, and not the moderate evidence in Chapter 6. One comment suggested the moderate evidence provides a lower level of scientific certainty to support a reasonable fit between the disclosure and FDA's government interest.

(Response) The comments focusing on evidence related to a specific relationship between added sugars intake in the general U.S. population and a direct link to obesity to support a mandatory declaration of added sugars

may have overlooked the discussion in the preamble to the proposed rule (79 FR 11879 at 11904). We are not establishing or relying on a direct link to obesity from added sugars intake for the general population. There is adequate evidence that the U.S. population consumes excess calories from added sugars, above the discretionary calories permitted within a recommended caloric intake (id. at 11903). The 2010 DGA supports the need for an added sugars declaration to provide the information necessary for consumers to identify the contribution of discretionary calories from added sugars, which are consumed in excess by the general U.S. population based on recommended calorie limits, to their daily diet in order to reduce their intake of added sugars to within recommended calorie limits. While it is true that excess calories from any source leads to weight gain, we know that the U.S. general population consumes added sugars in excess of the recommended limit of less than 10 percent of calories. Moreover, we have additional support for the declaration of added sugars, as lower intakes of sugar-sweetened foods and beverages were part of a healthy dietary pattern that was found to be strongly associated with a decreased risk of CVD (see part II.H.3.a and II.H.3.b). Furthermore, we disagree we are mischaracterizing the evidence on which we rely because we do not cite to moderate evidence in the 2015 DGAC. Although the evidence concerning a cause and effect relationship between added sugars intake and reduced risk of a disease is still emerging, there is a strong association found for a healthier dietary pattern, characterized in part by a reduced intake of overall added sugars compared to less healthy dietary patterns like those consumed by the general U.S. population, and reduced risk of CVD.

(Comment 33) One comment said that we have not identified any direct relationship between the added sugars declaration and an interest in helping consumers to maintain healthy dietary practices by reducing added sugars consumption. The comment questioned the strong association found between dietary patterns and risk of CVD in the 2015 DGAC Report, based on criticisms by FDA of menu modeling to establish DRVs in the preamble to the proposed rule (79 FR 11895 at 11896).

(Response) To the extent the comment asserts we must have a direct relationship between a nutrient and a reduced risk of disease before the nutrient is eligible for mandatory labeling under section 403(q)(2)(A) of the FD&C Act, we disagree for the reasons we set forth in our response to comment 58. Furthermore, the analysis that was conducted related to dietary patterns and health outcomes that is discussed in Chapter 2 of the 2015 DGAC Report is not based on modeling of dietary patterns, but rather on a review of diet quality studies where dietary quality indices were used to assess how adherence to a healthy dietary pattern is associated with health outcomes (Ref. 19). Therefore, statements that we have made in the past related to food pattern modeling do not apply to the evidence that we considered related to healthy dietary patterns that are characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy dietary patterns and CVD risk.

(Comment 34) One comment stated that consumer research demonstrates that, while an added sugars declaration may allow consumers to determine the amount of added sugars in a product accurately and compare products based on the amount of added sugars and percent DV contribution, the evidence does not demonstrate that consumers would maintain healthy dietary practices or that consumer understanding of a product's healthfulness is improved. Another comment suggested that we must demonstrate that a % DV disclosure for added sugars would have a ''direct and material effect on consumer behavior.'' The comment said there is no evidence that consumers understand the % DV and how to use the information for the added sugars declaration.

(Response) We interpret the comments as questioning how an added sugars declaration (and percent DV) would directly advance our government interest to assist consumers to maintain healthy dietary practices. The comments may misunderstand our authority under section 403(q)(2)(A) of the FD&C Act. Section 403(q) of the FD&C Act gives us the discretion to require a nutrient declaration when we determine that the information is necessary to assist consumers to maintain healthy dietary practices. The determination is based on a review of the scientific evidence and other available data and information related to the need for the nutrition information to be available to the consumer as part of the Nutrition Facts label. The declaration places the information in the hands of the consumer so that the consumer can make a judgment about whether to purchase a given food based on the nutrient content and can understand the relative significance of the information in the context of a total daily diet (see our response to comment 33). Our government interest does not rest on the notion that there must be some percent of consumers who we know will modify their diet to consume more or less of a nutrient before we can compel a label declaration for that nutrient or the percent DV. Consumers do not know the amount of added sugars in foods without a required declaration. Furthermore, the comment may misunderstand that the nutrition information on Nutrition Facts label is to assist consumers in understanding the relative significance of the information in the context of a total daily diet and does not require a threshold level of a change in consumer behavior before the nutrient can then be required on the nutrition label. The final rule does not define when a food is ''healthy'' based on the amount of added sugars in a serving of the food; instead, through the Nutrition Facts label, we are providing information about the amount of added sugars so that consumers can understand the relative significance of a food's contribution to the total added sugars intake in the context of the total daily diet and use that information to decide what foods to choose as part of that dietary intake for the day.

(Comment 35) One comment stated the added sugars declaration must be understandable to directly advance the government interest to assist consumers to maintain healthy dietary practices. The comment said the added sugars study provides only weak evidence that consumers understand the declaration. The comment cited our statements in the supplemental proposed rule and study memorandum that acknowledge that a number of participants were confused about the distinction between sugars and added sugars on the labels studied and that some participants identified a more nutritious product with more added sugars as less healthy.

(Response) We considered the results from our consumer research on the added sugars declaration, in addition to consumer research on the declaration submitted in comments (see part II.B.5). As a result of the findings showing that some consumers may be confused by the juxtaposition of total sugars followed by added sugars indented below total sugars, we revised the declaration to address those concerns. We now include the word ''Total'' before ''Sugars'' and use the phrase ''Includes ''XX'' g Added Sugars'' indented below ''Total Sugars'' to mitigate the observed misunderstanding by some consumers to add the total and added sugars values together. With the change to the declaration, we expect that consumers will understand that

added sugars are a component of total sugars (see our response to comment 188). We also considered results showing that some consumers may perceive products with more added sugars as less healthy (see our responses to comments 55 and 184) and plan to address consumer perceptions as part of our consumer education. The factual declaration of the amount of added sugars in a serving of food is not misleading based on consumer perceptions about whether a food with added sugars is ''unhealthful.''

(Comment 36) One comment said that we must identify the public harm caused by not declaring added sugars, demonstrate how the declaration will alleviate this harm, and show this is the least intrusive approach to comport with a company's constitutional protection of its right to free speech. The comment also said that we must show there is a different or greater harm from added sugars that is not present for the same level of naturally occurring sugars.

(Response) We discuss how the added sugars declaration comports to the *Central Hudson* analysis, including why added sugars are distinguished from naturally occurring sugars, in our response to comment 29. *Central Hudson* requires the regulation to be no more extensive than necessary to serve the asserted government interest (*Central Hudson,* 447 U.S. at 566). This standard does not require the government to employ ''the least restrictive means'' of regulation or to achieve a perfect fit between means and ends (see *Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). Instead, it is sufficient that the government achieve a ''reasonable'' fit by adopting regulations '' 'in proportion to the interest served.' '' (id. (quoting *In re R.M.J.,* 455 U.S. at 203)). The requirement of narrow tailoring is satisfied ''so long as the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation'' (*United States* v. *Albertini,* 472 U.S. 675, 689 (1985)). The added sugars declaration will give consumers a tool they need to include added sugars as part of a healthy dietary pattern—information that would not be readily available absent the regulation.

(Comment 37) One comment took exception to the fact that the requirement for added sugars labeling is for all foods and not limited to a smaller subset of foods that account for the majority of added sugars consumption (*e.g.,* sweetened beverages), and thus, is ''more extensive than necessary to serve [the government] interest'' (citing *Central Hudson,* 447 U.S. at 566).

(Response) We disagree. The required added sugars declaration is no more extensive than necessary to serve its purpose (see *Central Hudson,* 447 U.S. at 566). Again, this standard does not require the government to employ ''the least restrictive means'' of regulation or to achieve a perfect fit between means and ends, but rather a ''reasonable'' fit by adopting regulations '''in proportion to the interest served''' (*Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). Moreover, the required disclosure does more to advance our interests to promote public health, prevent misleading labeling, and assist consumers in maintaining healthy dietary practices than a disclosure that was limited to a subset of foods. Added sugars are used in a variety of foods from all food categories. For example, although some foods, such as sugar-sweetened beverages, may contain more added sugars relative to other beverages, that does not mean that a consumer is going to consume only those sugar-sweetened beverages that contain the most added sugars, and therefore, would only need added sugars information on the foods that contain some higher threshold of added sugars. Furthermore, the percent DV of less than 10 percent of calories from added sugars pertains to all calorie sources of added sugars, not just those categories that contain a certain higher amount of added sugars per serving of food relative to other foods in the same or similar food category. Therefore, a consumer needs to understand the contribution of all sources of added sugars in his or her diet to reduce calories from added sugars to less than 10 percent of the total. Those foods with fewer added sugars consumed over the course of a day can add up to levels that may meet or exceed 10 percent of total calories. Moreover, for some food categories, consumers may not even recognize the food as one that contributes added sugars to the diet (*e.g.,* condiments, sauces, canned fruits and vegetables, and some snacks), much less, the relative contribution. Limiting the required disclosure to only certain foods that exceed a certain level of added sugars before a declaration is required would undermine our efforts in getting information needed for making informed food purchases into the hand of consumers to enable them to achieve a healthy dietary pattern. In addition, the required disclosure is not unduly burdensome in that it is a factual disclosure confined to one line on the Nutrition Facts label and will enable consumers to understand the information in the Nutrition Facts label and how the contribution of added sugars from a food fits into the daily diet.

(Comment 38) One comment questioned whether the use of the Nutrition Facts format was too restrictive under the First Amendment for conveying nutrition information about a product, noting that Congress did not prescribe a particular format or means by which to convey nutrition information. The comment stated that section 403(q) of the FD&C Act provides that a food will be misbranded ''unless its label or labeling bears nutrition information.'' The comment suggested that nutrition information conveyed through labeling that does not physically accompany the product, such as at the point of purchase, on the Internet, or through a smart phone application, would be a less prescriptive means of conveying the required information.

(Response) To the extent the comment suggests a completely different approach to conveying nutrition information that is separated from, and not on, the food label itself, by use of a smart phone, Internet, or posted somewhere in the store, the comment provided no data or information to support why those approaches would assist consumers as well as, if not better, than having the information on the label itself at point-of-purchase. Not all consumers own smart phones or computers, or even if they did, would necessarily take these electronic devices to the store to research the nutrient profile of each food they are considering to purchase. It also is unclear how added sugars and other nutrient information in the Nutrition Facts label would be accessed by posting in the aisles or somewhere else in the store for the number of foods stocked within each area or how a consumer would find the information that matched the product picked up off the shelf. The Nutrition Facts label provides product-specific information that is readily accessible to the consumer at point-of-purchase in the store, when consumers would use the information to understand the nutrient content and compare products for purposes of deciding whether to purchase the product. Because the comment's suggested alternative would be less effective than the required disclosure in advancing the relevant government interests, we disagree with the comment.

(Comment 39) One comment stated the compelled disclosure of added sugars is more extensive than necessary to serve ''a speculative interest by FDA.'' The comment suggested that an

interest to help consumers select diets that are nutrient rich, where foods high in solid fats and added sugars do not displace food with greater nutrient density, could be served by consumer education and not a listing of added sugars.

(Response) We disagree our interest is speculative. We have substantial government interests in promoting the public health, preventing misleading labeling, and assisting consumers to maintain healthy dietary practices. These interests are supported by the science and our 20-plus year history of the use of the Nutrition Facts label to convey accurate, truthful, non-misleading information about the nutrient content of a food to the consumer at point-of-purchase. We do not consider consumer education alone to be a reasonable alternative to the declaration on the label because consumers need to know the amount of added sugars in specific foods, not simply general concepts, and to understand how to incorporate added sugars into a healthy dietary pattern. Providing the gram amount of added sugars in a serving of food on the label, which is the same information provided for other nutrients on the label, is sufficiently narrowly tailored to advance our interests in providing nutrition information to promote the public health, prevent misleading labeling, and assist consumers in maintaining healthy dietary practices. The nutrition information will be readily available to consumers at point-of-purchase which is the time and place that is critical to a consumer's purchasing decision and considering the relative significance of the information in the context of their total daily diet. Because the proposed alternative would be less effective than the required disclosure in advancing the relevant government interests, we disagree with the comment.

(Comment 40) One comment stated an added sugars declaration does not seem to fit the requirements under *Central Hudson* to directly advance the government interest asserted or not be more extensive than necessary to serve that interest because: (1) The current label already provides information on nutrient density and total sugar content; (2) there is no consumer research showing that consumers understand the meaning and role of added sugars; (3) there is no nutritional or physiological difference between added and naturally occurring sugars; and (4) other sources of excess calories would contribute to weight gain.

(Response) We have explained, in our response to comment 39, why the added sugars declaration directly advances our substantial government interests. We also explained, in our response to comment 39, why the added sugars declaration is not more extensive than necessary to serve our government interests. We disagree that the current label provides information on nutrient density because, although the current label provides information on total sugar content, it does not provide information on added sugars content which is information consumers need to understand to avoid the excess contribution of empty calories. To the extent the comment suggests that we would need consumer research showing that consumers understand the meaning and role of added sugars before we require a declaration of added sugars, we disagree. The FD&C Act does not require us to establish that consumers have a level of understanding about a nutrient before we can compel disclosure of that nutrient on the label. In fact, the label is the means by which the consumer can access new nutrition information that we have determined is necessary to maintain healthy dietary practices.

(Comment 41) One comment stated that added sugars declaration is subject to strict scrutiny (citing *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218 (2015)) because of discrimination between added and naturally occurring sugars. The comment stated that the two categories of label declarations for added sugars and naturally occurring sugars is a content-based regulation of speech. In particular, the comment stated that cranberries and other fruit to which sugar is added are nutritionally comparable to fruit that contains only natural sugars, so a declaration of added sugars would mislead consumers into believing the products without added sugars are healthier. The comment said there is no compelling government interest, and the declaration is not narrowly tailored, where the added sugars are listed in the ingredient statement. The comment said a footnote could be provided to clarify the sugars are added for palatability.

(Response) We disagree that the added sugars declaration is subject to strict scrutiny under *Reed* v. *Town of Gilbert. Reed* involved a town sign code, which involves ''quintessential public fora'' (*McLaughlin* v. *City of Lowell,* 2015 U.S. Dist. LEXIS 144336 (D. Mass. Oct. 23, 2015)). *Reed* does not apply to commercial speech, which is the only type of speech at issue here (see, *e.g., CTIA—The Wireless Ass'n* v. *City of Berkeley,* Cal., Civ. No. 15–2529 (EMC), 2015 U.S. Dist. LEXIS 126071 *31 through 33 (N.D. Cal. Sept. 21, 2015) (''[A]s the Supreme Court has emphasized, the starting premise in all commercial speech cases is the same: The First Amendment values commercial speech for different reasons than non-commercial speech, and nothing in its recent opinions, including *Reed,* even comes close to suggesting that that well-established distinction is no longer valid.''); *Chiropractors United for Research & Educ., LLC* v. *Conway,* 2015 U.S. Dist. LEXIS 133559 (W.D. Ky. Oct. 1, 2015) (''Because the New Solicitation Statute constrains only commercial speech, the strict scrutiny analysis of *Reed* is inapposite.''); *San Francisco Apt. Ass'n* v. *City & Cnty. of San Francisco,* 2015 U.S. Dist. LEXIS 150630 (N.D. Cal. Nov. 5, 2015) (''*Reed* is inapplicable to the present case, for several reasons, including that it does not concern commercial speech.''); *Cal. Outdoor Equity Partners* v. *City of Corona,* 2015 U.S. Dist. LEXIS 89454 (C.D. Cal. July 9, 2015) (''*Reed* does not concern commercial speech''); *Timilsina* v. *West Valley City,* 2015 U.S. Dist. LEXIS 101949 (D. Utah June 30, 2015) (''Because the parties agree this case concerns commercial speech and the *Central Hudson* applies, the Court need not address how the regulation would fare under [Reed]'')). Moreover, *Reed* involved review of ''content-based *restrictions* on speech'' (*Reed,* 135 S. Ct. at 2231). Here, we are requiring the *disclosure* of factual information, which is properly reviewed under the standards articulate in *Zauderer* and its progeny (*Sorrell,* 272 F.3d at 113 to 114 (''Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.' '')). The added sugars declarations, together with the other nutrient declaration on the nutrition label, contribute to the marketplace of ideas by providing information that may help consumers to use and understand the amount of added sugars, along with the other nutrients listed, in constructing a healthy dietary pattern to reduce the risk of chronic disease and achieve a calorie intake that limits excess intake of empty calories from unhealthy types of fats and from added sugars.

With respect to the comment's assertion that products with different

added sugars content would mislead consumers into believing the products without added sugars are healthier, we explain in our discussion of consumer research in part II.H.3.g why the findings of some consumer perceptions about what is ''healthy'' does not mean that the added sugars declaration is misleading. Furthermore, we also explain, in our response to comment 21, why the ingredient listing is not sufficient to convey the amount of added sugars in serving of a product. With respect to the use of a footnote or other language on the palatability of a food without added sugars, we are not setting forth requirements in this final rule on labeling information about this practice, and any labeling information must be truthful and not misleading. Lastly, as we explain in our response to comment 28, we disagree that we do not have a substantial government interest or that the added sugars declaration is not narrowly tailored.

(Comment 42) One comment stated that an added sugars declaration is inconsistent with the First Amendment because it would send a message with which the manufacturer disagrees. The comment said it is the total number of calories consumed, not the type of calories consumed, which determines the potential for weight gain. Another comment stated that a strict scrutiny test should be applied to the added sugars declaration because the declaration is ''an inherently subjective, judgmental statement in the guise of a purely factual declaration.'' The comment stated that the declaration is ''designed to convey the unsupported opinion that added sugars are somehow more adverse to health than sugars that occur naturally.'' Another comment stated that an added sugars declaration would compel food producers to tell their consumers that avoiding added sugars is a meaningful factor in maintaining healthy dietary practices, which producers do not believe to be true, and requires a higher level of scrutiny to support (citing *United States* v. *United Foods,* 533 U.S. 405, 411 (2001)). Some comments said that we have conceded that the declaration is not meaningful based on statements we made in the preamble to the proposed rule (79 FR 11879 at 11903 through 11904) about added sugars, *e.g.,* that added sugars are not chemically different than natural sugars, and there is lack of scientific agreement on the effects from added sugars to health outcomes and contribution to weight gain compared to other calorie sources.

(Response) The declaration of added sugars is an assertion of fact in the context of a commercial communication; it is not subjective, judgmental, or a matter of opinion. Courts have rejected similar arguments from industry attempting to assert that heightened scrutiny should be applied to regulation of commercial speech (see, *e.g., N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 134 (2d Cir. 2009) (rejecting argument that menu calorie content disclosures be subject to strict scrutiny review); *Discount Tobacco,* 674 F.3d at 525–27 (rejecting argument that strict scrutiny applied to tobacco warnings, as a compelled '' 'subjective and highly controversial' marketing campaign expressing its disapproval of their lawful products'')). In contrast, *United Foods* (533 U.S. 405 at 411), which concerned the payment of subsidies for speech that was disfavored, has no bearing on the nutrient declaration for added sugars.

The scientific evidence on which we rely relates to dietary patterns and impact to health from consumption of a healthy dietary pattern characterized, in part, by a reduced added sugars intake. Added sugars are distinguishable from naturally occurring sugars when consumed as part of a healthy dietary pattern compared to the current U.S. general population's dietary pattern. Indeed, the declaration of added sugars is not based on a specific relationship between added sugars and disease risk, contrary to what the comments suggest. We made that distinction clear in the preamble to the proposed rule (79 FR 11879 at 11904) when we stated that our rationale to support an added sugars mandatory declaration in labeling is different from our rationale to support other mandatory nutrients to date which generally relates to the intake of a nutrient and a risk of chronic disease.

2. Administrative Procedure Act

(Comment 43) One comment said that we do not have the required reasonable basis to mandate the added sugars declaration because, unlike the differences between saturated fats and *trans* fat, there is no physiological distinction between added and naturally occurring sugars, no analytical methods to distinguish these sugars, inadequate evidence to support a direct contribution of added sugars to obesity or heart disease, and that our rationale does not relate to the intake of a nutrient and risk of chronic disease, health-related condition or physiological endpoint. Another comment cited specific statements we made related to added sugars and their link to obesity and other statements in which we have stated there is inadequate evidence to support the direct contribution of added sugars to obesity, suggesting that this is a reversal of the Agency position.

(Response) We disagree that we do not have a sufficient scientific basis to support an added sugars declaration. As we stated in our response to comment 21, a physiological distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. Nor is an analytical method specific to added sugars a prerequisite to mandatory declaration under this section (see the discussion in our response to comment 45). Furthermore, we explained in the preamble to the proposed rule that our scientific basis for the added sugars declaration for the general population, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition or a physiological endpoint (see 79 FR 11879 at 11904). Rather than relying on a causal relationship between added sugars to obesity or heart disease, we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars as part of healthy dietary patterns and the impact to public health from such patterns. Thus, the comments erroneously focused on the nutrient, added sugars, and its independent relationship to health in the general population rather than our rationale for mandatory declaration of added sugars as part of a healthy dietary pattern.

(Comment 44) One comment stated the added sugars declaration appears to be arbitrary and capricious because the rationale to support the added sugars declaration is dramatically different from the rationale to support other mandatory nutrients and the added sugars content of a food does not always reflect a food's nutritional value (such as yogurt) or convey information that is not otherwise available from the total sugars declaration. Another comment suggested that the supplemental proposed rule does not provide adequate notice and explanation for the departures from established precedent and must acknowledge the change and provide a reasoned explanation for the change (citing *Prevor* v. *FDA,* 895 F. Supp. 2d 90 (D.D.C. 2012) and *Paralyzed Veterans of Am.* v. *DC Arena L.P.,* 117 F.3d 579, 586 (D.C. Cir. 1997)).

(Response) We disagree with the comments that suggest the required added sugars declaration is arbitrary and capricious under the APA. For each nutrient we require be declared on the nutrition label, we consider whether the nutrient will assist consumers in

maintaining healthy dietary practices, consistent with our statutory authority in section 403(q) of the FD&C Act. We consider the scientific evidence related to that standard for each nutrient we consider for mandatory declaration. The scientific evidence on which we rely to make that determination for a particular nutrient may differ. With respect to added sugars, we considered the evidence related to a healthy dietary pattern that is associated with a reduced risk of CVD, consumption data showing that Americans are consuming too many calories from added sugars, evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children. Specifically, we explained that we were reconsidering whether to require the declaration of added sugars based on new data and information, including U.S. consensus reports and recommendations related to the consumption of added sugars, a citizen petition, and public comments (79 FR 11879 at 11902). We explained our rationale for requiring an added sugars declaration in the preambles to the proposed rule (79 FR 11879 at 11904 and the supplemental proposed rule (80 FR 44303 at 44308)). The evidence in the 2015 DGAC report, through the use of studies on diet quality, supports evidence of a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD. We also set forth in the supplemental proposed rule our rationale for use of the reference amount for added sugars of less than 10 percent total daily caloric intake (*id.*). Thus, we provided the requisite showing, consistent with our obligations under the APA, for why an added sugars declaration is necessary to assist consumers in maintaining healthy dietary practices (see *Home Care Ass'n of Am.* v. *Weil,* 799 F.3d 1084 (D.C. Cir. 2015) (stating the APA imposes ''no special burden when an Agency elects to change course'' and the ''reasoned explanation'' under the APA for an alternative approach includes an Agency awareness of the change in position and good reasons for the change (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)). We are not limited to one body of scientific evidence when exercising our discretion under section 403(q)(2)(A) of the FD&C Act; instead, we have broad discretion to consider the new scientific evidence and how nutrition information may impact human health.

Moreover, with respect to the comment that the added sugars declaration conveys no more information than one could obtain from the total sugars declaration, we disagree. As we explain in our response to comment 161, the added sugars declaration does convey information that is not otherwise available from the total sugars declaration. Furthermore, it is not clear why the comment suggests the added sugars content does not reflect a food's nutritional value (such as yogurt). The added sugars declaration reflects the contribution of that nutrient in a serving of the food. We agree that a food, such as yogurt, can provide nutritional value to the overall diet even though it contains added sugars. The added sugars declaration is one piece of information on the nutritional label to help inform the consumer about how the food fits into the overall dietary pattern so that the consumer can use that information to help achieve a healthy dietary pattern. The cases cited by the comment (*Prevor* v. *FDA,* 895 F. Supp. 2d 90 (D.D.C. 2012) and *Paralyzed Veterans of Am.* v. *D.C. Arena L.P.,* 117 F.3d 579, 586 (D.C. Cir. 1997) (overruled in part by *Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199 (2015))) involve questions related to interpretative rules. Therefore, we do not consider them to be applicable to this final rule, which is a legislative rule, for which we provided notice and an opportunity to comment.

(Comment 45) Some comments stated that the declaration of added sugars is inconsistent with FDA's approach on whether to declare other nutrients, specifically stearic acid, acetic, propionic and butyric acids, dietary fiber, and carbohydrates, and cited statements in the preamble to the proposed rule related to chemically distinct nutrients. The comments stated that our rationale for not labeling these other substances separately is based on the fact that these are not chemically distinct or are based on whether analytical techniques are available to verify the declared amount on the label. The comments said that we did not explain why we departed from our traditional approach for the added sugars declaration, and, therefore, our decision regarding the declaration of added sugars appears arbitrary and capricious under the APA (citing *Atchison, T. & S. F. R.* v. *Witchita Board of Trade,* 412 U.S. 800 (1973) and *Allentown Mack Sales and Serv.* v. *NLRB,* 522 U.S. 359 (1998)).

(Response) We disagree with the suggestion that we only consider requiring the mandatory declaration of a nutrient where the nutrient is chemically distinct from other nutrients or when there is an available analytical method to test the presence of the nutrient in a food. The comment cited particular statements in the preamble to the proposed rule in which we made reference to a nutrient's chemical definition, composition, or structure. However, the statements cited in the comment do not support the propositions asserted by the comment. We consider the need for a mandatory declaration based on whether the nutrient is necessary to assist consumers to maintain healthy dietary practices, consistent with our authority under section 403(q)(2)(A) of the FD&C Act, whereas the statements cited by the comment concern characteristics of nutrients that are not necessarily related to whether the nutrient can assist consumers to maintain healthy dietary practices. For example, as part of our discussion of stearic acid in the preamble to the proposed rule (79 FR 11879 at 11894), we did not agree to declare stearic acid as a nutrient rather than as part of the saturated fat declaration because saturated fat intake is based on scientific evidence related to the intake of all saturated fatty acids, including stearic acid, and the potential effects to human health from changes in the dietary intake of stearic acid on the risk of CVD remain unclear (79 FR 11879 at 11894 through 11895). Furthermore, we discussed, in response to a request in a petition requesting FDA to define total fat to exclude acetic, propionic, and butyric acids, based on the chemical differences of these acids from other fatty acids comprising total fat, that these acids were not chemically distinct based on the reasons set forth by the petitioner (79 FR 11879 at 11893). We further explained that the petitioner did not explain why we should define total fat based on physiological differences, even if such differences existed (*id.*). Thus, we examine, on a case-by-case basis, whether a nutrient is necessary to assist consumers to maintain healthy dietary practices.

Similarly, the statements the comment included for dietary fibers and carbohydrate classification are taken out of context and do not support the comment's proposition. We discussed the reasons for separating dietary fiber from the definition of total carbohydrate and determined, for several reasons, it was not necessary to change the calculation of carbohydrate by difference (79 FR 11879 at 11900). We also referenced the 2007 ANPRM in

which we were considering whether to classify carbohydrates by chemical definition or physiological effect (79 FR 11878 at 11901). While we recognized that analytical methods would distinguish carbohydrates based on chemical structure and not physiological effects, we determined that given the various components of total carbohydrate and different types of physiological effects of these components that, for the class of total carbohydrates, a definition based on physiological effects would not be a better approach than a chemical definition (*id.*). We did not consider an analytical method to be a necessary prerequisite to the declaration for carbohydrate. Thus, we have not limited ourselves to the need for a chemical distinction for a nutrient before we would consider the mandatory declaration of the nutrient under section 403(q)(2)(A) of the FD&C Act. For these reasons, we disagree with the comment's apparent assertion that we departed from a traditional approach related to requiring a nutrient be chemically distinct for mandatory labeling, and that therefore the added sugars declaration is somehow arbitrary and capricious under the APA.

(Comment 46) One comment stated that we would violate section 706(2) of the APA if we finalized a declaration for added sugars because the proposed declaration of added sugars was not reasoned decision making, where we did not complete the consumer study before proposing the required declaration. The comment cited references that would analogize this situation to one where an Agency relied on a defective or discredited study to support a rule (*e.g., St. James Hospital* v. *Heckler,* 760 F. 2d 1460, 1468 (7th Cir. 1985); *Almay, Inc.* v. *Califano,* 569 F.2d 674 (D.C. Cir. 1977), or where the study authors did not agree with the use of the research for a particular application relied on by an Agency (*Humana of Aurora, Inc.* v. *Heckler,* 753 F.2d 1579 (10th Cir. 1985)). With respect to the consumer research we conducted on added sugars, the comment asserted that, ''FDA in this situation recognized that such a study was essential'' and that without a consumer study, the factual basis for the requirement would be lacking (citing *Motor Vehicle Mfrs. Ass'n of United States* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)). The comment also said we failed to provide an adequate notice and opportunity for comment on the results of the consumer research study because the comment period would be closed before the study is completed (citing *Doe* v. *Rumsfeld,* 341 F. Supp. 2d 1 (D.D.C. 2004); *Service* v. *Dulles,* 354 U.S. 363 (1957); *Conn. Light & Power Co.,* v. *Nuclear Regulatory Com,* 673 F.2d 525, 530 through 531 (D.C. Cir. 1982); and *American Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 1009 through 1010 (D.C. Cir. 1991); *Small Refiner Lead Phase-Down Task Force* v. *Environmental Protection Agency,* 705 F.2d 506, 540 through 541 (D.C. Cir. 1983); *Sierra Club* v. *Costle,* 657 F.2d 298, 398 (D.C. Cir. 1981)).

(Response) We disagree that a consumer study related to the added sugars declaration is required before we can finalize a requirement to compel the declaration under section 403(q)(2)(A) of the FD&C Act. Our discretionary authority to require an added sugars declaration can be exercised if we determine the declaration is necessary to assist consumers to maintain healthy dietary practices. Our rationale for the declaration is supported by sufficient evidence set forth in the 2010 DGA and the 2015 DGAC Report, in part, related to the role of sugar-sweetened foods and beverages as part of a healthy dietary pattern compared to less healthy dietary patterns, and the relationship between healthy dietary patterns and risk of chronic disease. In addition, the evidence and conclusions from the 2010 DGA support that consumption of excess calories from added sugars can lead to a less nutrient-dense diet and that current consumption data show that Americans are consuming too many calories from added sugars. Moreover, there is strong evidence that greater intake of sugar-sweetened beverages is associated with increased adiposity in children. Furthermore, section 403(q) of the FD&C Act does not require us to complete a consumer study before we can make the finding in section 403(q)(2)(A) of the FD&C Act to require a nutrient declaration.

We explained why we were conducting consumer research in the preamble to the proposed rule. We discussed, in the context of the placement of added sugars on the label, our plan to conduct a consumer study to help enhance our understanding of how consumers would comprehend and use the new information and to publish the results of the consumer research when available (79 FR 11879 at 11952). We published the results of our consumer research in a supplemental proposed rule to present those study findings (80 FR 44303; July 27, 2015), and provided the raw data for the consumer study in response to requests for such data (80 FR 54446; September 10, 2015). Contrary to what the comment suggested, the consumer research studied consumer reactions to the declaration to help inform our future educational efforts related to food labeling and was not conducted for the purpose of determining whether we had the requisite scientific basis to declare added sugars under section 403(q)(2)(A) of the FD&C Act (80 FR 44303 at 44306). We consider consumer research helpful to understand how to best utilize our consumer education efforts when changes to the label are made. Moreover, in response to our findings from the ''Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars'' that showed some participants were confused by the total sugars declaration when added sugars was indented below total sugars, we considered these findings and comments received on the consumer research in making changes to the declaration of added sugars to reduce the potential for consumer confusion. With respect to the comment that we failed to provide an adequate notice and opportunity for comment on the results of the consumer research study, we note that this comment was submitted in response to the proposed rule published in March 2014, before the publication of the consumer research results in July 2015 and raw data in September 2015. Therefore, the cases to which the comment cites, concerning the need for notice and opportunity for comment, are moot. Furthermore, we are not relying on a defective or discredited study to support a rule or one where the study authors do not agree with the use of the research for a particular application relied on by the Agency and therefore do not need to address the cases cited in comments on these issues.

(Comment 47) One comment asserted that we did not provide an adequate legal justification for why we were not relying on the IOM DRI Report with respect to developing a DRI for added sugars and instead relying on evidence in the DGAC Report.

(Response) We disagree that we did not provide an adequate explanation for the DRV for added sugars, nor did the comment further explain the basis for its assertion. We explained why we were not relying on the IOM DRI Report in the preamble to the proposed rule (79 FR 11879 at 11906). Specifically, we explained that the IOM did not establish a DRI, such as a UL, for added sugars, nor did the IOM define an intake level at which an inadequate micronutrient intakes occur. Thus, there was no level for added sugars, based on the IOM review, on which we could rely for a reference amount. In the preamble to the

supplemental proposed rule (80 FR 44303 at 44308), we discussed the availability of the data and information from the 2015 DGAC Report to support a DRV for added sugars to below 10 percent of total energy intake based on the modeling of dietary patterns, current added sugars consumption data, and a published meta-analysis on sugars intake and body weight (*id.*). We tentatively concluded that the scientific information in the 2015 DGAC Report provided the basis on which we could rely to support a DRV reference point for the added sugars declaration (*id.*). We respond to comments in this final rule to further explain the basis for the added sugars declaration under our authority in section 403(q)(2)(A) of the FD&C Act.

(Comment 48) One comment questioned whether we provided stakeholders with an opportunity to provide meaningful comments. Specifically, the comment seemed to object to the period provided for comment on the raw data for the consumer studies, and the limited scope of the comment on the supplement proposed rule to the issues presented in that document. The comment stated that we have no authority to propose rules in a ''piecemeal fashion'' and must consider comments that address the impact of the final rule as a whole.

(Response) We consider the comment periods provided for the supplemental proposed rule (80 FR 44303; July 27, 2015) and the raw data on the consumer studies (80 FR 5446; September 10, 2015), to October 13, 2015 to be sufficient. The comment did not provide any basis for why the comment period did not provide a sufficient time during which meaningful comments could be submitted, nor did the comment provide a basis to support its assertion that we lack authority to issue a supplement to the proposed rule. The supplemental proposed rule (80 FR 44303) provided notice and an opportunity for comment on relevant new data and information for consideration in the final rule, including the findings of the consumer study on the added sugars declaration and footnote. Thus, there was adequate notice and an opportunity for comment on the issues. We considered the comments we received in response to the proposed rule and supplemental proposed rule when developing the final rule.

(Comment 49) One comment suggested that we are ignoring the section of the DGAC Report that focuses on scientific studies about the specific relationship between added sugars and CVD, for which there is moderate evidence, and referred to this as a ''blatant abuse of discretion.'' The comment stated that we are mischaracterizing the evidence related to a specific relationship between added sugars and CVD as ''strong'' rather than ''moderate'' and described this outcome as arbitrary and capricious and an abuse of discretion in violation of the APA. Other comments stated that the ''moderate'' evidence does not meet our standard of ''significant scientific consensus'' or the ''factual basis'' standard required (citing *Motor Vehicle Mfrs Ass'n* v. *State Farm Mut. Auto. Ins Co.,* 463 U.S. 29 (1983) and *A.L. Pharma, Inc.* v. *Shalala,* 62 F.3d 1484, 1491 (D.C. Cir. 1995)). One comment further stated the specific relationship between added sugars and CVD is moderate, and as such, the evidence is mixed and inconclusive and therefore such a change in policy will be overturned (citing *AFL–CIO* v. *Dole,* 745 F. Supp. 18, 21 (D.D.C. 1990) *rev'd on other grounds,* 923 F.2d 182 (DC Dir. 1991)).

(Response) The comments may not have considered or appreciated the evidence on which we rely for the added sugars declaration. There is scientific evidence demonstrating a strong association between a healthy dietary pattern characterized, in part, by a lower amount of sugar-sweetened foods and beverages and the reduced risk of CVD. The scientific evidence in Chapter 6 of the 2015 DGAC report, concerns an entirely different body of evidence based on an independent relationship of added sugars with chronic disease risk. The comments do not address the evidence of the strong association between a healthy dietary pattern (including, with regard to added sugars, lower intakes of sugar-sweetened foods and beverages), relative to less healthy dietary patterns, and reduced risk of chronic disease, set forth in Chapter 2 Part D of the 2015 DGAC report. Our reliance on this scientific evidence does not mean we abused our discretion, nor does it mean we are mischaracterizing the evidence. We are not relying on the scientific evidence with regard to the independent relationship of added sugars and specific chronic diseases as the basis to require an added sugars declaration, and we have described the basis for our required added sugars declaration and the evidence we rely on in the preamble to the proposed rule (79 FR 11879 at 11902 through 11905), the supplemental proposed rule (80 FR 44303 at 44307 through 44308) and this final rule.

(Comment 50) One comment asserted the DGAC report violates the National Nutrition Monitoring and Related Research Act of 1990 (NNMRRA) because there were no scientific studies reviewed by the DGAC on consumer comprehension of an added sugars declaration, and therefore, the recommendation for added sugars labeling was not based on a preponderance of the scientific and medical knowledge required under section 301(a) of the NNMRRA for information and guidelines in the report. The comment stated that FDA's reliance on the DGAC report for added sugars labeling therefore violates section 706(2) of the APA in that it lacks a factual basis and is thus arbitrary and capricious in violation of the APA. The comment also stated that the HHS and USDA violated section 5 of the Federal Advisory Committee Act (FACA) in creating the 2015 DGAC because the committee was not ''fairly balanced.'' The comment said that our reliance on the DGAC Report is arbitrary and capricious in violation of section 706(2) of the APA. Another comment said the proposed added sugars declaration and DRV violate FACA because the DGAC Report and the science supporting the requirements are not sufficiently reliable or objective.

(Response) We disagree that the required declaration of added sugars violates section 706(2) of the APA based on independent authorities in NNMRRA and FACA with respect to the 2015 DGAC Report. The mandatory added sugars declaration in nutrition labeling is based on our authority in section 403(q)(2)(A) of the FD&C Act and not on the separate and independent authority in NNMRRA. Contrary to what the comments stated, we considered and relied on the scientific evidence in the DGAC Report for the purpose of determining whether an added sugars declaration will assist consumers in maintaining healthy dietary practices, and did not rely on a DGAC Report recommendation. The comment concerning whether the 2015 DGAC Report violated section 301(a) of NNMRRA is separate and distinct from our authority under section 403(q)(2)(A) of the FD&C Act and outside the scope of this rule.

Moreover, with respect to the comments expressing concerns about section 5 of FACA in relation to the 2015 DGAC Report, we reviewed the available scientific evidence to determine whether to require an added sugars declaration, based on our authority in section 403(q)(2)(A) of the FD&C Act. We included, in our review, evidence from the 2015 DGAC Report, the 2010 DGA, NHANES data on U.S. consumption patterns, and other data and information. The DGAC selection and review process is an interagency

process that includes HHS and USDA and is outside the scope of this rule.

(Comment 51) One comment stated that we should further consider the effects of the definitions (such as dietary fiber) and Daily Values on existing nutrient content and health claims authorized under section 403(r) of the FD&C Act. The comment stated that claims for certain foods that currently qualify for a claim may no longer qualify, and the comment stated it anticipated that restrictions may include claims that are part of brand names and trademarks, and therefore, implicate First Amendment and Fifth Amendment ''takings'' issues. The comment further stated that, without a thorough evaluation of these ''collateral implications'' the final rule ''would fall short of administrative law requirements'' (citing *Prometheus Radio Project* v. *FCC,* 373 F.3d 372, 420–21) (3d Cir. 2004) and *Sprint Corp.* v. *FCC,* 315 F.3d 369, 377 (D.C. Cir. 2003)).

(Response) In the preamble to the proposed rule (79 FR 11879 at 11889), we recognized that changes to the list of nutrients declared on the label and changes to the RDIs and DRVs of nutrients could affect whether some foods that contained a nutrient content or a health claim prior to the publication of the final rule would no longer meet a defined term or eligibility requirement to make the claim. We stated that we plan to evaluate the impact of any changes in a final rule on other FDA regulations and address them, as appropriate, in a future rulemaking (*id.*). To the extent the comment suggests we must consider impacts to food products that currently declare certain non-digestible carbohydrates as dietary fiber, but that may no longer be able to declare these carbohydrates as dietary fiber based on the definition of ''dietary fiber'' in the final rule, we provided notice and an opportunity to comment on the proposed definition and have responded to comments in this final rule.

To the extent the comment suggests we must enlarge the scope of this rulemaking to consider what specific food products may no longer qualify for a nutrient content or health claim, or may include claims that are part of brand names, we disagree. The final rule concerns changes to the nutrient declarations in the Nutrition Facts label and Supplement Facts label under our authority in section 403(q) of the FD&C Act. The final rule does not include within its scope nutrient content claim or health claim regulations we promulgated under our independent authority in section 403(r) of the FD&C Act. Our decision on what RDI or DRV we select for a nutrient for purposes of nutrition labeling to ensure the information will assist consumers in maintaining healthy dietary practices is distinct from, and would precede a decision on, how to define a term for a nutrient content claim or establish an eligibility criterion for a health claim. Therefore, we are not obligated to consider changes to the requirements for nutrient content claims or health claims in this final rule (see *Home Box Office, Inc.* v. *FCC,* 567 F.2d 9, 36 n. 58 (D.C. Cir. 1977), *cert. denied,* 434 U.S. 829 (1977) (''In determining what points are significant, the 'arbitrary and capricious' standard of review must be kept in mind . . . only comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule cast doubt on the reasonableness of a position taken by the agency.'')).

For example, we have established a number of defined terms for nutrient content claims based on the percent of the DV provided in a reference amount customarily consumed for food that bears the claim (*e.g.,* ''high'' and ''good source'' in 21 CFR 101.54). Any changes we may consider to the definition of those terms based on changes made to the DV in this final rule would be in a separate rulemaking, consistent with our authority in section 403(r) of the FD&C Act. We plan to evaluate the impact of any changes on other FDA regulations and address, as appropriate, those impacts in a future rulemaking. Furthermore, the comment suggesting there may be restrictions in using claims that include brand names and trademarks did not provide any further explanation. To the extent there are such circumstances, those would be considered in a separate rulemaking where we consider such claims. Lastly, the cases cited by the comment concern the distinction between an interpretive rule and a legislative rule and are inappropriate to this final rule, which is a legislative rule for which we provided notice and an opportunity to comment.

3. Federal Food, Drug, and Cosmetic Act

We are updating the Nutrition Facts label and Supplement Facts label, as set forth in this final rule, consistent with our authorities in sections 403(q), 403(a)(1) and 201(n), and 701(a) of the FD&C Act.

(Comment 52) Some comments questioned whether the declaration of added sugars to limit consumption of added sugars was a material fact under sections 403(a) and 201(n) of the FD&C Act. One comment stated that we must demonstrate that the absence of a declaration of added sugars on the nutrition label would be misleading to consumers.

(Response) The declaration of added sugars is a material fact under sections 403(a) and 201(n) of the FD&C Act, as we explain in our response to comment 159. Under section 201(n) of the FD&C Act, labeling is misleading if it fails to reveal facts that are material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed or under conditions of use as are customary or usual.

Here, we have determined that the evidence shows that healthy dietary patterns associated with a decreased risk of chronic disease are lower in added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened foods and beverages are associated with increased adiposity in children. Furthermore, the scientific evidence supports limiting added sugars intake to less than 10 percent of total calories. We note that this limit was adopted as a recommendation in the 2015–2020 DGA. The current intake of discretionary calories from added sugars in the U.S. population is excessive. The excess intake of calories from added sugars displaces the calories from other foods that are needed as part of a healthy dietary pattern in order to reduce the risk of CVD. Without information on the amount of added sugars in a serving of a food, consumers would not be able to determine the amount of added sugars in particular foods, and therefore would not have the information they need to place a particular food in the context of their total daily diet to construct a healthy dietary pattern that contains less than 10 percent of calories from added sugars. Thus, the amount of added sugars in a food is a material fact with respect to the consequences which may result from the use of the article under the conditions of use prescribed or under conditions of use as are customary or usual.

Moreover, section 403(q) of the FD&C Act gives us the authority to require nutrient declarations that we have determined provide information that will assist consumers to maintain healthy dietary practices.

(Comment 53) Some comments said the declaration of added sugars is itself misleading. The comments highlighted statements in the preamble of the proposed rule that there is no physiological difference between added sugars and those sugars that are intrinsic to food and there is no scientifically supported quantitative intake

recommendation for added sugars on which a DRV for added sugars can be derived and that U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease (79 FR 11879 at 11905 through 11906). Another comment stated that because added sugars are not chemically distinct from natural sugars or have different health effects, the declaration of added sugars would be false and misleading.

(Response) We disagree that the declaration of added sugars is misleading. The statutory basis for requiring an added sugars declaration is whether the Secretary, and by delegation, FDA, determines that the nutrient should be included in the labeling of food for the purpose of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The statutory framework does not require that the nutrient be linked in isolation to any particular chronic diseases nor does it specify that the nutrient must be physiologically unique. Furthermore, we have determined that there is a scientifically supported basis for requiring a DRV of 10 percent for added sugars. We address questions as to the specific scientific basis for that DRV in part II.H.3. The inclusion of this DRV and the other issues described by the comment do not make the declaration of added sugars misleading. The declaration of added sugars is a factual statement of the amount of this nutrient in the product.

(Comment 54) One comment said that the declaration of added sugars, as applied to cranberry juice products that are nutrient dense and sweetened for palatability, presents the same issue related to misleading labeling under section 403(a)(1) of the FD&C Act, where foods naturally free or low in a nutrient that bear a claim of ''free'' or ''low'' must be labeled as a food that is low in that nutrient (''broccoli, a fat free food'') to avoid implying the food has been altered as compared to foods of the same type. The comment said that requiring an added sugars declaration on a cranberry juice product that has fewer total sugars than juice containing all natural sugars is misleading because it implies the cranberry product with added sugars is less nutritious and generally unhealthy (citing *United States* v. *Ninety-Five Barrels,* 265 U.S. 438, 442–443 (1924) and *United States* v. *An Article of Food . . . ''Manischevitz . . . Diet Thins,''* 377 F.Supp. 746 (E.D.N.Y. 1974)). The comment expressed concern that a shopper would focus on the added sugars declaration and not the total sugars declaration.

(Response) The listing of added sugars, which is a subset of the amount of total sugars, is not misleading. It is the factual statement of the amount of added sugars in a product and the declaration of added sugars is one of a number of nutrient declarations on the label which consumers can use to assist them in maintaining healthy dietary practices. We disagree that the declaration of added sugars is equivalent to the need to clarify that all broccoli is fat-free when making a fat-free claim about broccoli. First, the declaration of the amount of added sugars is not a claim, it is a required declaration. A package of broccoli would be required to declare 0 grams of fat on the Nutrition Facts label without any additional explanation (§ 101.9(c)(2)). Furthermore, the two cited cases cited by the comment are not relevant to the requirement to state the factual declaration of the amount of added sugars in a product. The Supreme Court in *Ninety-Five Barrels* was discussing a label of an imitation product that claimed to contain the actual ingredient. The *Manischevitz Diet Thins* case was addressing a product using the name ''diet'' that had the same calories and overall nutritional profile as the regular non-diet product. Both cases found these specific terms used were misleading and noted that the FD&C Act condemned statements that mislead about the make-up of the product. The declaration of added sugars provides more information to consumers about the nutritional make-up of the product to use to help them maintain healthy dietary practices. Consumers may have perceptions or preferences about a number of nutrients, and which nutrients they focus on in choosing food may vary. As we discuss in our response to comment 184, whether consumers regard a product as healthy can be a combination of many factors, and we intend to engage in education and outreach efforts to help consumers understand the role of the added sugars declaration and other aspects of the revised Nutrition Facts and Supplement Facts labels.

(Comment 55) One comment stated that the declaration of added sugars on cranberry juice, even if true, is ''grossly misleading'' under sections 403(a)(1) and 201(n) of the FD&C Act because of a failure to reveal the material fact that the human body processes added sugars and naturally occurring sugars in the same way. The comment said that consumers will falsely regard the cranberry juice as less healthy when compared to other fruit juices that have all naturally occurring sugars. The comment suggested an alternative method for labeling to ensure the added sugars declaration is no longer misleading. The alternative method would apply to ''nutritious products made from unpalatable fruits'' and would remove the indented Added Sugars declaration such that ''The grams and percent of daily value for added sugars in a dried unpalatable fruit (a fruit in its raw state has total sugars of less than 5 percent and an average Brix-to-acid ration of six or less), and a juice product made with at least 27 percent juice of an unpalatable fruit, that is sweetened for fruit palatability and contains total sugars comparable to naturally sweetened dried fruits and 100 percent fruit juices, may be declared by an asterisk next to the declaration of total sugars with a footnote at the bottom of the nutrition facts panel that shall state: '**Total sugars include sugars added for fruit palatability.' ''

(Response) We disagree with the comment stating that the lack of difference in the way the body processes added versus naturally occurring sugars is a material fact with regard to the rationale for the added sugars declaration. The added sugars declaration is intended to assist consumers in maintaining healthy dietary practices based on the recommendation to decrease consumption of added sugars and the impact of a diet that includes high amounts of added sugars on chronic disease measures. We have addressed the consumer research on cranberry juice in our response to comment 184 and disagree that the added sugars declaration on cranberry juice misbrands the product. While we have modified the declaration of added sugars in the final rule, we have determined that no additional labeling is needed, as discussed in our response to comment 184.

(Comment 56) One comment stated that the term ''nutrient'' is not defined in the FD&C Act or FDA regulations and that it is reasonable for Congress to have intended the term to refer to substances that are chemically and structurally distinct from each other, with different physiological effects, and not based on whether the substance is added or inherent to a food. For these reasons, the comment suggested added sugars are not an additional nutrient within the context of section 403(q)(2)(A) of the FD&C Act. The comment referred to the listing of nutrients in section 403 of the FD&C Act (*e.g.,* total fat, saturated fat, cholesterol, sodium) as scientifically or chemically distinct substances and that the nutrients listed in section

403(q)(1)(D) and (E) of the FD&C Act are not distinguished based on whether they are added or inherent to a product. Furthermore, the comment said that the fact that verification of the added sugars declaration cannot be achieved through objective testing and requires records is another reason why Congress did not intend added sugars to be a nutrient (citing *Util. Air Regulatory Group* v. *EPA,* 134 S. Ct. 2427 (2014)). Another comment stated that we do not have the statutory authority to require the declaration of added sugars because they are not ''additional nutrients'' and are part of total sugars.

(Response) We disagree with the comments that added sugars is not compatible with the term ''nutrient'' in sections 403(q)(2) and 403(q)(1)(D) of the FD&C Act. With regard to the argument that it cannot be an additional nutrient if it is a component of total sugars or if it is not chemically distinct from total sugars, section 403(q)(1)(D) of the FD&C Act includes several nutrients that are subcomponents of other nutrients on the list, so the comments' arguments that each nutrient currently required is chemically distinct or that each nutrient is not a subcomponent of another listed nutrient is simply not correct. Total fat includes saturated fat, and total carbohydrates include sugars and dietary fiber. As these nutrients were all required by Congress to be declared on the label, we further disagree that Congress intended the nutrients to all be chemically and structurally distinct from each other and to have distinct physiological effects. Furthermore, the House committee report for the NLEA (H.R. 3562) (Report 101–538, June 13, 1990 at page 14) states that the Secretary may provide definitions of the nutrients required under 403(q)(1)(D) or 403(q)(2) of the FD&C Act, and we have done so consistent with the public health and based on sound scientific principles.

Additionally, the specific concerns and recommendations about added sugars' contribution to the daily diet that are distinct from total sugars has led to the requirement for the declaration of added sugars, consistent with the stated statutory purpose of assisting consumers to maintain healthy dietary practices. Nutrient content claims are defined in § 101.13(b) as claims that expressly or implicitly characterize the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36. We have a ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' nutrient content claim regulation (§ 101.60(c)(2)), supporting the fact that added sugars are considered to be a nutrient under the FD&C Act.

Also, we disagree that, because records would be needed to enforce the added sugars declaration, Congress did not intend that added sugars be considered a nutrient. Congress did not include any reference to ''objective testing'' or how enforcement would occur in the statutory language with regard to what nutrients should be declared on the label. The only criterion discussed in the statutory provision for adding a nutrient to the label is whether it will assist consumers in maintaining healthy dietary practices. Thus, the comment's reference to *Util. Air Regulatory Group* v. *EPA,* where the Supreme Court determined that an Agency had applied a more general definition to a statutory provision with a more narrow meaning given the context of the program, is also misplaced in this context. There is no context in the specific statutory provision about which nutrients should be declared on the label that indicates that it should be limited to nutrients that can be ''objectively measured.''

(Comment 57) Some comments stated the added sugars declaration does not assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act because it misleads consumers into believing that products without added sugars, but with the same or greater calories and total sugars, are healthier if the product contains naturally occurring sugars. Some comments considered our past statements, including that added sugars are not chemically distinct from naturally occurring sugars and added sugars are not independently and directly linked to any disease, health-related condition such as obesity, or physiological endpoint, to support the proposition that the added sugars declaration would not assist consumers in maintaining healthy dietary practices by providing consumers information to construct diets that are nutrient dense and reduce calorie intake from added sugars.

(Response) We do not agree that the declaration of added sugars misleads consumers based on our consumer research results and those results submitted in the comments in response to questions about how ''healthy'' a product is that contains added sugars. The declaration of added sugars provides information about the amount of a single nutrient that consumers can use as part of their decisions in building a healthy dietary pattern. We are requiring the declaration of added sugars because a dietary pattern characterized, in part, by larger amounts of added sugars is associated with greater risk of CVD than a healthy dietary pattern that includes less added sugars. Therefore, inclusion of added sugars above and beyond what is naturally present in foods that are part of a healthy dietary pattern is a public health concern. The declaration is needed for consumers to be able to identify the amount of added sugars in a serving of a product in order to fit that product into their total daily diet.

Added sugars are not chemically different than sugars that are naturally present in foods, and one should not avoid all foods that are relatively higher in added sugars than others. Consumers can eat a healthy diet that includes added sugars, but, in order to carefully choose foods so that the overall diet is not high in added sugars relative to calorie needs, it is important to consider the amount of added sugars in a serving of a product and how the added sugars content of that product should be balanced with other food choices.

(Comment 58) One comment stated that an added sugars declaration is not related to the purpose of the NLEA because it does not help consumers reduce the risk of a diet-related disease (citing House Committee Report 101–538, 101st Congress, 2nd Sess., 13 through 14 and the Congressional Record (136 Cong. Rec. H5836 101st Cong. 2nd Sess. (July 30, 1990 at 19 and 21)), S. 16610 Cong. Rec. (Oct. 24, 1990)). The comment referenced statements from the preamble to the proposed rule related to our rationale for other mandatory nutrient declarations that relate to the intake of a nutrient that is specifically related to the risk of chronic disease, health-related condition, or a physiological endpoint. Another comment stated that the purpose of our added sugars declaration is to help consumers with dietary planning and is not reasonably related to the requirements and purpose of the statute.

(Response) First, we note again that the statutory language in section 403(q)(2) of the FD&C Act is that a nutrient can be required for the purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. This statutory basis is how we determined to propose the mandatory declaration of added sugars. Furthermore, the statements cited by the comment relating to the Congressional history of the NLEA are taken out of context and inappropriately limit the scope of the NLEA and its nutrient declaration requirements. The purpose statement at the beginning of the House

Committee Report that the comment referenced actually states, ''The purpose of this legislation is to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods'' (House Committee Report 101–538, 101st Congress, 2nd Sess., 7). The comment's reference to the statements on the House floor by Congressman Madigan excluded the most relevant point about his more narrow bill with respect to specific chronic disease outcomes, that ''Chairman Waxman has graciously included much of the language in my bill in this comprehensive nutrition labeling bill'' (136 Cong. Rec. H5836 101st Cong. 2nd Sess. (July 30, 1990, at H5843). The statement from Senator Hatch seemingly focused on chronic disease also follows the more general statement by his co-sponsor Senator Metzenbaum that described the broader focus on healthy dietary practices, stating, ''By providing the public with better nutrition information, this bill makes a major step forward in enabling consumers to select foods to protect and improve their health'' (136 Cong. Rec. No. 147, S. 16607 101st Cong. 2nd Sess. (Oct 24, 1990, at S. 16608)).

While the preamble to the proposed rule discussed a different framework than an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint in the general population, added sugars are part of a dietary pattern linked to health effects and has been discussed in the recent DGA. In 2010, the scientific evidence supported a key DGA recommendation to reduce consumption of added sugars because of their effect on health due to the inability to eat excess added sugar and consume necessary nutrients within recommended calorie limits. In 2015, the DGAC Report included evidence that diets that included high amounts of added sugars were linked to increased risk of CVD compared to dietary patterns that included lower consumption of added sugars. The declaration of added sugars squarely fits within the statutory framework to assist consumers to maintain healthy dietary practices.

(Comment 59) One comment said we cannot rely on section 403(q)(2)(A) of the FD&C Act to support an added sugars declaration where we do not rely on an added sugars content of a food to determine if the food is ''healthy'' consistent with the nutrient content claim requirements for ''healthy'' in 21 CFR 101.65(d)(2). The comment seemed to assert that finalizing a requirement for an added sugars declaration, where the term ''healthy'' requires no limitation on added sugars content, is arbitrary and capricious under section 706(2) of the APA (5 U.S.C. 706(2)) and a violation of section 403(q)(1)(D) the FD&C Act (also citing *Frisby* v. *HUD,* 755 F.2d 1052, 1055 through 1056 (3d Cir. 1985) for the proposition that the Agency must follow its own regulations). Another comment stated that added sugars content is not included in the nutrient content claim for ''healthy,'' and, therefore, an added sugars declaration would not assist consumers in maintaining healthy dietary practices.

(Response) We are relying on our authority in section 403(q)(2)(A) of the FD&C Act to require the declaration of added sugars, and the only consideration for that statutory provision is whether the declaration will assist consumers to maintain healthy dietary practices. The *Frisby* case cited by the comment is not relevant because the definition of the voluntary ''healthy'' claim under section 403(r) of the FD&C Act does not bear on the determination of whether to require a declaration on the nutrition facts label, and we plan to revisit claims, including the healthy claim, after we finish this rulemaking. Furthermore, our finalizing a requirement for an added sugars declaration and any separate consideration of the healthy claim under section 403(r) of the FD&C Act do not violate the APA, as discussed in our response to comment 51.

(Comment 60) One comment stated the proposed added sugars declaration and DRV violate the NLEA because the 2015 DGAC Report and the science on which we rely are not sufficiently reliable or objective. Another comment suggested that the declaration of added sugars violates the FD&C Act and the APA because the DRV for added sugars is not based on a NAS report, which the comment stated ''the House Committee Report urged'' FDA to rely on for nutrients listed on the label, and therefore, presents impermissible and inconsistent Agency reasoning that is arbitrary and capricious (citing *Allentown Mack. Sales & Serv., Inc.* v. *NLRB,* 522 U.S. 359, 374 through 375 (1998)). The comment considered the use of the 2015 DGAC Report as the basis for the DRV to be a departure from past practice that is not sufficiently explained and without ''sufficient scientific consensus.''

(Response) The comment conflates several arguments and statements and is incorrect in its reliance on the NLEA's legislative history to support its position. The reference to the National Academy of Science report in this context also is misplaced. As stated in the comment itself, the House Committee's reference in 1990 was to a specific National Academy of Science report that had been commissioned at the time. The report stated that the ''Committee expects the Secretary to consider the hearing record before the Subcommittee and the NAS study on nutrition labeling, if that study is available in sufficient time to meet the statutory deadline'' (H.R. Rep. No. 101–538, at 17). If the report was not completed, it did not need to be taken into consideration. Furthermore, this statement in the report did not constitute a limiting statement as to future decisions regarding other nutrients and what they should be based on. In addition, the comment only stated that the decision with regard to the DRV for added sugars is based on an impermissible source and did not dispute the entire decision to require the declaration of added sugars.

The reference to the *NLRB* case is similarly misplaced. The case refers to an Agency changing the standard it is applying to a determination of the evidence without describing any reasoned basis for the change. Here, we have provided a reasoned explanation for requiring the declaration and DRV for added sugars, and have done so throughout the rulemaking process. The science on the contributions of dietary patterns has evolved, and the 2015 DGAC Report contains evidence with regard to the effect of a diet that includes lower amounts of added sugars compared to a diet that includes higher amounts of added sugars. This evidence supplements the growing scientific evidence from the 2010 DGA and concern about added sugars and their impact on public health and the ability to maintain healthy dietary practices by consuming a diet sufficient in nutrients within calorie limits, which we included in our rationale for the proposed declaration for added sugars. The ability of a nutrient declaration to assist consumers in maintaining healthy dietary practices remains the determination upon which a new nutrient declaration is based.

(Comment 61) One comment said that we have not adequately explained our departure from what the comment characterized as the 2010 DGA's focus on added sugars labeling, stating further that we relied on the 2015 DGAC Report for a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced risk of

CVD, which the comment stated is contrary to the law (citing *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983) and *Nat'l Ass'n of Home Builders* v. *EPA,* 682 F.3d 1032, 1037 (D.C. Cir. 2012)). The comment suggested that NLEA does not authorize us to rely on this basis for labeling, and, instead, we must rely on the presence or absence of a specific nutrient and disease relationship between added sugars and CVD before requiring such labeling, for which the comment states only moderate evidence is available. The comment cited studies to suggest there is no reliable correlation between added sugar content in food and healthy dietary choices or patterns.

(Response) First, this comment misrepresents the 2010 DGA, citing and quoting a line from Appendix 4 that lists the current nutrients that are displayed on the Nutrition Facts label and saying that this statement is the focus of the 2010 DGA recommendation with regard to added sugars, rather than the key recommendation and substantive chapter of the 2010 DGA. The comment also mistakenly states that the proposed rule and the supplemental proposed rule rely on the findings in the 2015 DGAC Report. As we stated in the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44308), the science underlying the 2015 DGAC Report provides further support for the declaration of added sugars, which was supported in the proposed rule in part by the scientific evidence in the 2010 DGA related to reducing calories from added sugar. Thus, contrary to what the comment seemed to suggest, we are not departing from the science set forth in the 2010 DGA that is included in the evidence on which we rely for added sugars, but are also including additional evidence from the 2015 DGAC Report to further support the added sugars declaration, so the cases cited regarding the level of explanation that is necessary to explain a change in policy are not relevant.

The comment suggested that reliance on a rationale other than a specific disease relationship between added sugars and CVD is not permitted by the NLEA. The NLEA and FD&C Act state that nutrient declarations can be added if determined to assist consumers in maintaining healthy dietary practices. There is no further restriction on the evidence that can be used to support a declaration in the statute. Both the preamble to proposed rule and the preamble to the supplemental proposed rule thoroughly explain the rationale for the required declaration for added sugars.

Furthermore, a healthy dietary pattern, characterized in part by a reduced amount of sugar sweetened foods and beverages, is strongly associated with a reduced risk of CVD compared to less healthy dietary patterns. Thus, we disagree with the comment's statement that there is no reliable correlation between added sugar content in food and healthy dietary choices or patterns. The studies cited by the comment that looked at nutrient content claims and the data underlying a 2002 IOM suggested maximum intake level of 25 percent or less of added sugars are not relevant to the basis for our declaration of added sugars. One study cited by the comment described how small amounts of added sugars may increase the palatability of nutrient-dense foods. We acknowledged this finding in the preamble to the proposed rule (79 FR 11879 at 11905), and it is consistent with the requirement to declare added sugars and the percent DV so that consumers can understand how to incorporate such amounts of added sugars into their daily diets.

4. Recordkeeping Authority

The preamble to the proposed rule (79 FR 11879 at 11884 and 11956 through 11957) discussed our legal authority for the proposed recordkeeping requirements. We stated that we were relying on our authority under sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act, to propose record requirements to support nutrient declarations in labeling for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid, under certain circumstances, so that we can determine compliance with labeling requirements and take enforcement action, as needed. We described how the records requirements would apply only to the narrow circumstances where there are not any appropriate reliable analytical methods that can be used to verify the compliance of a nutrient declaration.

We noted that failing to accurately state the amounts of nutrients on the label under § 101.9(g) would result in a product being misbranded. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains and, moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, we stated that the proposed recordkeeping requirements are designed to ensure that the nutrient declarations are accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Furthermore, the records would allow us to verify the declared amount of each of these nutrients and that such amount is truthful and not misleading. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act. We also noted that our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary, and cited *National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693 through 694 (D.C. Cir. 1978)) (79 FR 11879 at 11884 and 11957). In addition to having the authority to require the maintenance of such records, we further stated that our authority also provided for FDA to have access to such records because in order to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Without such authority to access the records supporting the declarations, these nutrient declarations that have been determined to be necessary to assist consumers to maintain healthy dietary practices would be unenforceable.

(Comment 62) While several comments supported our proposed requirement, many comments broadly asserted that we do not have the authority to require recordkeeping.

(Response) The FD&C Act requires foods to bear truthful and not misleading information about the amount of nutrients in the food to assist consumers in maintaining health dietary practices (sections 403(q), 403(a)(1), and 201(n) of the FD&C Act). As we stated in the preamble to the proposed rule (79 FR 11879 at 11956), under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act in order to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Supp. 1179, 1183 (D. Del. 1980))). The recordkeeping requirements are intended to ensure that the nutrient declarations, which would be based on information known only to the manufacturer, are truthful and not misleading, and to facilitate efficient enforcement of the requirements for nutrient declaration when necessary. The recordkeeping requirements are only for foods for which official AOAC or other reliable and appropriate

analytical methods are not available. FDA access to information, in the form of a record, required to support an added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and/or folate/folic acid declaration, where the information is known only to the manufacturer, is a practical alternative means by which we can verify that the nutrient declarations comply with section 403(q) of the FD&C Act and thus, assist in the efficient enforcement of the FD&C Act. Moreover, such information would also be necessary for the manufacturer to maintain in order to ensure the accuracy of the label.

(Comment 63) Several comments stated that the FD&C Act does not give us express authority to require recordkeeping for nutrition labeling. Other comments specifically argued that sections 403(q), 403(a) and 201(n) of the FD&C Act do not provide for recordkeeping authority and that Congress had exercised care in defining the scope of our recordkeeping authority in the statute. Additionally, some comments said that Congress has not given FDA general records authority and Congress must grant specific authority to FDA to access manufacturing records but declined to do so for nutrition labeling. Several comments pointed out instances in the FD&C Act that provide express recordkeeping authority, arguing that the fact that Congress provided it in certain contexts means that it was not intended here.

(Response) Courts have not found that a specific grant of authority from Congress is necessary in order to promulgate every portion of every regulation (see, *e.g., American Trucking Ass'ns, Inc.* v. *United States,* 344 U.S. 298, 308–313 (1953) (''the promulgation of these rules . . . falls within the Commission's power, despite the absence of specific reference to leasing practices in the Act [citation omitted]. The grant of general rulemaking power necessary for enforcement compels this result.'') and *Permian Basin Area Rate Cases,* 390 U.S. 747, 780 (1968) (''We are, in the absence of compelling evidence that such was Congress' intention, unwilling to prohibit administrative action imperative for the achievement of an Agency's ultimate purposes.'')). This was also held to be true in *Califano,* where the court found that Congress had not intended to immunize the manufacturers from requirements, including recordkeeping, by not having an express recordkeeping provision in the statute (*Califano,* 569 F.2d at 693; see also *Morrow* v. *Clayton,* 326 F.2d 36, 44 (10th Cir. 1963) (Powers of an Agency are not limited to those expressly granted by statutes—where the end is required, appropriate means are given and every grant of power carries with it the use of necessary and lawful means for its effective execution) and *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 653 (1973) (Some Agency authority is ''implicit in the regulatory scheme, not spelled out in haec verba'' in the statute)).

Furthermore, we disagree that the express grant of records authority in other contexts means that it was expressly contemplated and rejected under the circumstances proposed here. The provision for efficient enforcement of the FD&C Act in section 701(a) of the FD&C Act, along with the authority to require or voluntary permit these nutrient declarations under section 403(q) of the FD&C Act to prevent misleading labeling, provides the ability to require such records to effectuate the goal of enforcing nutrition labeling for those limited products covered by the recordkeeping requirements.

(Comment 64) Several comments stated that courts have repeatedly explained that FDA cannot create records access using section 701(a) of the FD&C Act, citing *Association of American Physicians & Surgeons* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) and *National Confectioners Association* v. *Califano,* 569 F.2d 690, 695 (D.C. Cir. 1978).

(Response) The comments' reading of these cases is not correct. First, while the cited cases state that section 701(a) of the FD&C Act is not an unlimited or stand-alone provision, neither case found that maintenance of records was not a proper exercise of authority related to section 701(a) of the FD&C Act, when combined with authority provided in other substantive sections of the FD&C Act. In fact, maintenance of records was one requirement that the court in *Califano* upheld, stating, ''In our opinion however the coding and record-keeping requirements here at issue clearly do not distend the scope of regulation authorized by the Act'' (*Califano,* 569 F.2d at 695). One section in *Assn. Amer. Physicians & Surgeons* that the comment quoted is ''Section 371 [701(a)] does not constitute an independent grant of authority that permits FDA to issue any regulation the Agency determines would advance the public health. Rather, 371 permits FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress.'' Unlike the separate requirement to do testing and include labeling that were discussed in *Assn. Amer. Physicians & Surgeons,* the limited records requirement discussed here is for the express purpose of administering the delegated authority in section 403(q) of the FD&C Act to require truthful and not misleading labeling and accurate nutrition labeling for the purpose of assisting consumers to maintain healthy dietary practices. In essence, it is a requirement simply to document how the manufacturer complied with the substantive requirements in certain circumstances.

The cited cases support the requirement of records to simply document how the manufacturer complies with the rule in this context. The court in *Califano* even cites case law that specifically addresses the relevance of remedying enforcement problems, which is the basis for the recordkeeping requirement here, stating that ''. . . whether statutory scheme as a whole justified promulgation of the regulation . . . will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets'' (*Califano,* 569 F.2d at 693 (citing *Toilet Goods Association, Inc.* v. *Gardner,* 387 U.S. 158, 163 (1967))). As we have discussed, in the case of the Nutrition Facts rule, the purpose of the statute is to ensure truthful and not misleading labeling as well as to assist consumers to maintain healthy dietary practices by providing nutrition information on the labels of food. The requirement to maintain these records would effectuate that purpose by allowing enforcement of the declarations of certain required nutrients.

(Comment 65) One comment argued that section 701(a) of the FD&C Act cannot be reasonably construed to authorize records access because it does not constitute a separate grant of authority and cannot be read to authorize recordkeeping authority if that authority is not already included in the other sections being used for authority, such as sections 403(q), 403(a), and 201(n) of the FD&C Act, in this case.

(Response) We agree that section 701(a) of the FD&C Act does not constitute a completely separate grant of authority to promulgate any regulation to protect the public health, but we disagree that it cannot be used to authorize records access for the nutrient declarations identified when there is no express authority in section 403(q) of the FD&C Act to require and access these specific records, as the comment argues. If there had to be an express provision in every relevant substantive provisions of the statute, such as section

403(q) of the FD&C Act, reference to section 701(a) of the FD&C Act and its use to effectuate the efficient enforcement of the FD&C Act would never be necessary, and it would be rendered superfluous.

Furthermore, as discussed in greater detail in our response to comment 64, this notion was explicitly rejected in *Califano,* where the court stated that it was rejecting the idea that the regulation must stand or fall on the substantive section alone and found that Congress had not intended to immunize the manufacturers from requirements, including recordkeeping, by not having an express provision in the statute (*Califano,* 569 F.2d at 693; see also *Morrow* v. *Clayton,* 326 F.2d 36, 44 (10th Cir. 1963) and *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 653 (1973)). In the current context, records access is necessary to efficiently enforce the statutory requirements in certain limited circumstances.

(Comment 66) One comment argued that the case law we cited did not support our records access authority because the cases were not specific to nutrition labeling and were related to drug labeling. The comment said that the cases have no bearing on the issues here. Another comment argued that we should not have relied on *National Confectioners Association* v. *Califano* because it was decided before the NLEA was enacted.

(Response) We first note that many cases cited by these and other comments are not specific to nutrition labeling and were decided well before the NLEA was enacted. We disagree with these comments and find the cases, which many comments also cited, to be both applicable and the best indication of the proper reading of the FD&C Act. While it is rare to find case law that directly mirrors the situation at issue, *Califano* is striking in that it specifically affirms our authority to promulgate a recordkeeping requirement for certain food products when needed to be able to effectuate the statutory purpose. Congress has not acted to overturn that decision, which was the applicable existing legal framework when Congress was enacting the NLEA.

(Comment 67) Several comments referenced section 301(e) of the FD&C Act, regarding what recordkeeping violations constitute a prohibited act, as an exclusive list of what recordkeeping provisions are authorized and as evidence that sections 403(q), 403(a), 201(n), and 701(a) of the FD&C Act do not authorize recordkeeping provisions.

(Response) We disagree that the absence of the specified provisions in the list of prohibited acts regarding records bears on whether we have the authority to require records under the statute. Section 301(e) of the FD&C Act, regarding prohibited acts, refers to the express recordkeeping requirements in the FD&C Act. Moreover, a prohibited act violation in section 301(e) of the FD&C Act is separate and distinct from a misbranding violation in section 403(q) of the FD&C Act. It is a prohibited act under section 301(a) of the FD&C Act to introduce, or deliver for introduction, a misbranded food into interstate commerce. Thus, the fact that there is not a prohibited act violation for access to, and copying of, records related to the nutrient declarations for these select nutrients under section 403(q) of the FD&C Act does not mean that we do not have authority under sections 403(q) and 701(a) of the FD&C Act to require these records under these circumstances. As we explained earlier, express authority in section 403(q) of the FD&C Act is not needed for these records (see *Califano,* 569 F.2d at 693). Maintenance of and access to records for certain nutrition labeling declarations only under certain circumstances is necessary for the efficient enforcement of the Nutrition Facts labeling requirements, whether or not compliance with the those requirements are included as prohibited act under the statute.

(Comment 68) Several comments referenced a statement in the preamble to the 1993 nutrition labeling final rule stating that, to support a misbranding charge for inaccurate nutrient content information, we must have accurate, reliable, and objective data to present in a court of law and that, to obtain that information, we rely upon the work performed by our trained employees because we do not have legal authority in most instances to inspect a food manufacturing firm's records (58 FR 2079 at 2110, January 6, 1993). The comments asserted that this statement was evidence that we recognized that we do not have the authority to access manufacturing records as part of our enforcement of the nutrition labeling requirements.

(Response) We do not agree with this characterization of the statement in the 1993 final rule. The cited statement was part of a discussion of why we perform our own laboratory analyses and use those results for enforcement, rather than looking at or verifying laboratory analysis results kept in the records of a manufacturer. When there are available reliable laboratory analyses in order to test for a specific nutrient, we still rely on those analyses for compliance purposes. As we have described, the records requirements in this final rule apply only to the narrow circumstances where there are not any appropriate reliable analytical methods that can be used to verify the compliance of a nutrient declaration.

Where there are appropriate reliable analytical methods, we would not need to access manufacturing records in order to enforce the FD&C Act. However, the narrow circumstances where we do have the authority and are exercising the authority here are those circumstances where we do not have access to appropriate reliable analytical methods.

(Comment 69) While one comment pointed out that § 101.9(g)(9) already contemplates and provides a mechanism for the use of an alternative means of compliance for nutrition labeling, supporting our use of an alternative means to enforce compliance here, a few comments took exception to the preamble to the proposed rule's reference to situations where our regulations already provided for maintenance of records in the nutrition context. The comments stated that those instances regarding aeration to reduce fat and caloric content of foods (58 FR 2229 at 2271, January 6, 1993) and caloric content of new products with reduced digestibility (58 FR 2079 at 2111) were optional recordkeeping in instances where a manufacturer chooses to depart from the established regulations or to support a voluntary claim, rather than the broad regulations we proposed here for all manufacturers.

(Response) These examples were provided as illustrations of the use of records in a compliance context, not to demonstrate our authority. Any discussion of these other regulatory examples does not affect our authority with regard to this particular records requirement. We do not agree that these are broad regulations; rather, they are for a quite limited purpose and scope—only required when the manufacturer is including a mixture of products that cannot be distinguished by the analytical methods detailed in the regulations. The requirements also are quite flexible, not requiring any particular records and allowing the manufacturer to determine the best records to establish and maintain in order to comply. Furthermore, we disagree with the comment that the cited existing regulations with reliance on records for compliance purposes are all optional or voluntary. In the context of calculating appropriate caloric content of new products with reduced digestibility, the caloric declaration is a required declaration, and products wishing to adjust the declared amount because they are using certain novel

ingredients would need to submit documentation of their calculations to FDA.

(Comment 70) Several comments stated that, because they believed we did not have a scientific basis for requiring the declaration of added sugars, our authority to require records to verify the added sugars declaration was questionable.

(Response) Please see part II.H.3 for a more detailed discussion of our scientific basis for requiring the declaration of added sugars. Because the added sugar declaration is necessary to assist consumers in maintaining healthy dietary practices, which is the statutory mandate, the recordkeeping requirements are necessary and authorized for the efficient enforcement of the FD&C Act.

(Comment 71) Multiple comments argued that our authority excludes access to ''recipes for food,'' among other proprietary information. Some comments stated that we may not access or that we lack authority to access recipes for food, or that recipes were protected by Congress. Another comment stated that it is ''beyond the scope of the Agency to inspect records related to product formulation.'' Other comments noted that the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) (BT Act), as well as section 414 of the FD&C Act, expressly carve out recipes as a record that we cannot access even in food safety emergency situations.

(Response) The exclusion of recipes that several comments referred to is found in the BT Act, and there is no more general protection of recipes by Congress. We further disagree that the parameters of the recordkeeping authority in the BT Act affect our ability to require records here. The purpose of the review of records under the BT Act is distinct from the purpose of the record review for nutrition labeling, and section 306 of the BT Act says that it shall not be construed to limit the ability of the Secretary to require records under other provisions of the FD&C Act.

Furthermore, the final rule's recordkeeping requirement is flexible and does not require any specific document to support the declarations. While the preamble to the proposed rule provided some examples of records that manufacturers may choose to maintain (see, *e.g.,* 79 FR 11879 at 11956), they are not required to maintain any particular record and would also be permitted to maintain redacted documents if they established the necessary information. See part II.R.3 for a description of the variety of records that manufacturers can establish or maintain to meet the requirements.

We discuss other comments regarding the proper handling and confidentiality of any proprietary information that is submitted in part II.R.3.

(Comment 72) Some comments said that the recordkeeping authority previously given to FDA, as in the case of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), were unrelated to nutrition labeling.

(Response) We agree that the BT Act authority is unrelated, and we disagree that the scope of recordkeeping authority in the BT Act limits our ability to require records. Section 306 of the BT Act states that it shall not be construed to limit the ability of the Secretary to require records under other provisions of the FD&C Act.

(Comment 73) Some comments stated that we did not need records access to enforce the nutrition declarations because companies are already required to ensure that their labels are not false or misleading under section 403(a)(1) of the FD&C Act and § 101.9(g).

(Response) While we agree with the comment that manufacturers are already required to ensure that their labels are not false or misleading, we are requiring that records be maintained that can specifically support certain declarations required under § 101.9(g) because without access to those records, we are not able to verify the accuracy of the required declared amounts.

(Comment 74) Some comments argued that, even if we had the authority to access records, we did not have the authority to copy records, stating that copying of records is not required for the efficient enforcement of the FD&C Act and that inspectors should be able to inspect and evaluate records onsite at the manufacturing facility without copying them.

(Response) We disagree with this comment. As we stated in the preamble to the proposed rule (79 FR 11879 at 11957), in order to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Without the authority to access the records supporting the declarations, the nutrient declarations that we have determined to be necessary to assist consumers in maintaining healthy dietary practices would be unenforceable. While we understand the concerns with confidentiality of certain corporate information, and we discuss safeguards for such information in part II.R.3, practically, we need to be able to copy the records and access them at FDA headquarters in order to fully evaluate them to determine compliance or the need for any further regulatory action or enforcement proceedings (see FDA Regulatory Procedure Manual, section 4–1–4, regarding Center concurrence for labeling violations). Such full evaluation by us is not possible onsite at the facility.

(Comment 75) One comment suggested that the inspectional authority in section 704 of the FD&C Act did not provide for access to these records.

(Response) Section 704 of the FD&C Act states that the inspection ''shall'' extend to records when section 414 of the FD&C Act applies. We do not interpret this as an exclusive extension. Section 414 of the FD&C Act specifically states that it does not limit the authority of the secretary to inspect records under other provisions of the FD&C Act. This specific grant of authority applies to a single specific statutory provision regarding food safety, and does not address false and misleading labeling. It does not prevent us from accessing records that we can require by other regulations.

5. Miscellaneous Comments

Several comments raised other legal issues with respect to various parts of the rule.

Dietary Fiber

(Comment 76) One comment stated the definition of dietary fiber, which requires a dietary fiber to have a physiological effect beneficial to health, would ''prohibit the use of accurate, well substantiated dietary fiber determinations in nutrition labeling for many foods.'' The comment said that the restriction is not adequately justified to advance FDA's labeling objectives, nor is adequately tailored, to satisfy the First Amendment.

(Response) We disagree that, by defining ''dietary fiber,'' we are prohibiting the use of ''accurate, well substantiated dietary fiber determinations'' as the comment suggests. As we explain in our response to comment 252, the definition includes dietary fibers that have been shown to have a physiological effect beneficial to human health, and therefore, the declared amount of dietary fiber will include information about the amount of fibers in a serving of food that are necessary to maintain healthy dietary practices, consistent with our authority in section 403(q)(2) of the FD&C Act. Manufacturers will be able to petition

FDA to request that we amend the definition to include additional fibers, as appropriate. If a substance is a fiber, but not a ''dietary fiber'' that has a physiological effect beneficial to human health (such that the fiber is not eligible to be, and not listed as, a ''dietary fiber'' in the codified definition of ''dietary fiber''), a manufacturer may still declare the substance as part of total carbohydrate. Furthermore, a manufacturer may make a statement about the amount of these other fiber substances in the food, provided the statement is truthful and not misleading. The comment did not provide further explanation for why our definition for dietary fiber is not adequately justified or adequately tailored under the First Amendment and, based on the reasons we provide, we are not making any changes in response to this comment.

D. Factors for Mandatory or Voluntary Declaration of Non-Statutory Nutrients

The preamble to the proposed rule (79 FR 11879 at 11890 through 11891) discussed the factors that we primarily considered in requiring the declaration of most non-statutory nutrients or providing for the voluntary declaration of such nutrients. Our discussion of these factors in the proposed rule related to the nutrients for which there is an independent relationship between the nutrient and risk of a chronic disease, health-related condition, or physiological endpoint. We did not consider these factors for added sugars because our rationale for the declaration of added sugars differs and is not based on an independent relationship between added sugars and risk of chronic disease, health-related condition, or physiological endpoint. Thus, to help clarify when we refer to a nutrient for which there is such an independent relationship, we refer to the nutrient as ''this type of'' or ''this category of'' or, if plural, ''these types of'' nutrient(s), or similar phrase. We discuss our rationale for requiring added sugars separately because our rationale for added sugars is distinct from the factors that applied more generally to these other types of nutrients. In general, we continue to consider mandatory declaration appropriate for these types of nutrients when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI). However, we also have considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient (*e.g., trans* fat) in chronic disease risk. The preamble to the proposed rule (79 FR 11879 at 11889) explained that, under section 403(q)(1)(C) and (D) of the FD&C Act, nutrition information in food labeling must include the total number of calories, derived from any source and derived from the total fat, and the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein. We referred to the nutrients that are explicitly required by the FD&C Act to be declared on the Nutrition Facts label as ''statutorily required nutrients.'' Section 403(q)(2)(B) of the FD&C Act permits us to remove a statutorily required nutrient from the label or labeling of food, by regulation, if we determine the information related to that nutrient is not necessary to assist consumers in maintaining healthy dietary practices.

Section 403(q)(2)(A) of the FD&C Act also gives us the authority to require, by regulation, other nutrients to be declared if the we determine that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The preamble to the proposed rule explained that we consider such nutrients that are not statutorily required, but subject to our discretion under section 403(q)(2)(A) of the FD&C Act, to be ''non-statutory nutrients'' to distinguish them from the ''statutorily required nutrients'' (79 FR 11879 at 11889). Thus, insofar as ''non-statutory nutrients'' are concerned, previously we have: (1) Required the declaration of certain essential vitamins and minerals (such as vitamins A and C, iron, and calcium) for which an RDI was established and that were determined to have public health significance; and (2) permitted the declaration of the remaining essential vitamins and minerals for which there was an established RDI or DRV (*i.e.,* vitamin E) or that had public health significance, and permitted the declaration of certain subcategories of macronutrients for which a DRV was not established (including monounsaturated fat, polyunsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate) (id.).

The preamble to the proposed rule (id. at 11890) explained that, to help us determine whether a non-statutory nutrient, for which there is an independent relationship between the nutrient and risk of chronic disease, health-related condition, or physiological endpoint, should be a required or permitted declaration, we consider: (1) The existence of quantitative intake recommendations; and (2) public health significance. Quantitative intake recommendations are reference intake levels provided in consensus reports that can be used to set a DRV or RDI. We expect these consensus reports to be published for the purpose of setting quantitative intake recommendations (*e.g.,* the IOM DRI reports), but, if DRIs are not available for nutrients, other than essential vitamins and minerals, then we consider the scientific evidence from other U.S. consensus reports or the DGA. Public health significance refers to two elements. First, we consider whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint. This can be demonstrated either by well-established evidence (in the form of U.S. consensus reports) or, for essential vitamins and minerals, the health consequences of inadequacy of the nutrient. Second, we consider whether there is evidence of a problem related to health in the general U.S. population. This is demonstrated by both evidence of a problem with the intake of the nutrient in the general U.S. population and evidence of the prevalence of the chronic disease, health-related condition, or health-related physiological endpoint that is linked to that nutrient in the general U.S. population.

For mandatory declaration of this type of non-statutory nutrient, in general, we consider mandatory declaration appropriate when there is public health significance and scientific evidence to support a quantitative intake (which, for purposes of convenience, we will refer to as ''a quantitative intake recommendation'') that can be used for setting a DV (DRV or RDI). However, we have also considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient (*e.g., trans* fat) in chronic disease risk.

For voluntary declaration of a non-essential vitamin or mineral (*e.g.,* fluoride, soluble and insoluble fiber, monounsaturated fatty acids and polyunsaturated fatty acids), we consider voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation, but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance. In addition, we permit voluntary declaration for essential vitamins or minerals that we determine do not fit within our considerations for mandatory declaration, but that have an RDI.

The preamble to the proposed rule also noted that we continue to be mindful of factors such as the number

of nutrients that can be listed in nutrition labeling, the possibility that some individuals could interpret a long list of nutrients as implying that a food has greater nutritional significance than is the case, and that there is limited space for nutrition information on the label (id.).

(Comment 77) The preamble to the proposed rule (id. at 11891) invited public comment on our factors for mandatory and voluntary declarations of these types of nutrients. Some comments supported the factors. One comment, however, also suggested that, if the 2015–2020 DGA is released before we publish a final rule, the vitamins and minerals considered to be of public health significance should be based on the most recent version of the DGA.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11890 and 11918), the factors that we consider for determining the essential vitamins and minerals with the greatest public health significance to be those for which the IOM based DRIs on a chronic disease risk, or health related condition, or a nutrient deficiency with clinical significance. Additionally, we consider whether nutrient intake data, and/or, when available, biomarkers of nutrient status, provide evidence of inadequate intakes in the general healthy U.S. population (ages 4 years and older) and whether a substantial prevalence of a disease, or health related condition or a nutrient deficiency with clinical significance exists that was linked to the particular nutrient. Our intake and status biomarker analysis is conducted for the U.S. general population, ages 4 years and older, which is the focus of the label, while the DGA focuses on the U.S. population ages 2 years and older. The 2015 DGAC (Ref. 19) used a three-pronged approach similar to our factors for determining the nutrients of public health concern, including analysis of intake data, available valid biochemical indices from NHANES dietary survey, and data on the prevalence of health condition in the U.S. population. Based on the scientific evidence in the 2015 DGAC approach, vitamin D, calcium, potassium, iron, and fiber were considered as nutrients of public health concern for under consumption.

(Comment 78) Another comment agreed with the factors, but suggested that we use the 2010 DGA or the 2015–2020 DGA (if it became available) when a quantitative intake recommendation by the IOM is not available and can be supported by a ''Nutrition Evidence Library Review system.''

(Response) We agree that it is often appropriate to consider the scientific information in the DGA when the IOM does not provide a quantitative intake recommendation. The preamble to the proposed rule stated that we will consider quantitative intake recommendations from the IOM report, but if DRIs are not available for nutrients (other than essential vitamins and minerals), we will consider science-based recommendations from other U.S. consensus reports or the DGA policy reports (id. at 11890).

E. Calories

Under section 403(q)(1)(C)(i) of the FD&C Act, nutrition information in food labels or labeling must include the total number of calories derived from any source. Our preexisting regulations require the total caloric content of a food to be declared on the Nutrition Facts label (§ 101.9(c)(1)), and the proposed rule would not modify the requirement to declare total calories. However, in the preamble to the proposed rule (79 FR 11879 at 11891), we stated that we were reconsidering a number of other requirements related to the declaration of information about calories. The other requirements related to ''Calories from fat,'' ''Calories from saturated fat,'' the 2,000 reference calorie intake level, a percent DV for calories, and requirements related to prominence of the calorie declaration and the footnote statement and table of DVs for 2,000 and 2,500 calorie diets.

1. Calories From Fat

Our preexisting regulations, at § 101.9(c)(1)(ii), require the declaration of ''Calories from fat'' on the label. This requirement stems from section 403(q)(1)(C)(ii) of the FD&C Act which, in turn, requires total calories from fat to be declared on the label or labeling of food. However, section 403(q)(2)(B) of the FD&C Act gives us the discretion to remove the requirement by regulation if we determine that the requirement is not necessary to assist consumers in maintaining healthy dietary practices. The preamble to the proposed rule (79 FR 11879 at 11891) explained that we reviewed current scientific evidence and consensus reports in determining whether information on calories from fat is necessary to assist consumers in maintaining healthy dietary practices. Current dietary recommendations no longer emphasize total fat. Certain fatty acids are understood to be beneficial, while others are understood to have negative health effects, particularly related to cardiovascular disease. Consequently, the proposed rule would no longer require, nor would it allow voluntarily, the declaration of ''Calories from fat'' on the Nutrition Facts label. In the preamble to the proposed rule (79 FR 11879 at 11891), we acknowledged that eliminating the declaration of ''Calories from fat'' may appear to be a loss of information on the amount of fat being consumed, but noted that the amount of fat being consumed can still be obtained from the total fat declaration elsewhere on the Nutrition Facts label, and consumers can still use the percent DV for total fat to put fat content in the context of a total daily diet, compare products, and plan diets. Thus, the proposed rule would remove § 101.9(c)(1)(ii), which requires declaration of calories from fat, and redesignate § 101.9(c)(1)(iii) as § 101.9(c)(1)(ii).

(Comment 79) Several comments supported removing the declaration of ''Calories from fat'' because current dietary recommendations emphasize that the intake of total calories and the type of fat consumed are more important than information on calories from fat in maintaining healthy dietary practices.

Many comments opposed removing the declaration of ''Calories from fat'' because of the importance of knowing this information for consumers who are diabetic, overweight, have high blood pressure, or are at risk of heart disease. Several comments also noted that, in general, the information was useful to monitor the amount of calories from fat consumed in packaged foods. These comments noted that some people use the ''Calories from fat'' information to make a choice between similar products and that, because of fat's caloric density, consumers need to be informed regarding the amount of calories they were getting from fat. Other comments also suggested that we require the declaration of ''Percent of calories from fat,'' and some comments supported removing the ''Calories from fat'' declaration if a declaration of monounsaturated and polyunsaturated fats was mandatory.

A few comments opposed to removing the ''Calories from fat'' declaration stated that this information remains useful to consumers; the comments, however, did agree that the total number of calories and types of fatty acids consumed are more important than total fat consumption in maintaining healthy dietary practices and reducing cardiovascular risk. One comment stated that it is important for total fat consumption to be within the acceptable range (*i.e.,* 20 to 35 percent of daily caloric intake) established by the IOM, and that ''Calories from fat'' provides valuable information to help consumers put the Dietary Guidelines into action. Another comment disagreed

with our assessment that removing ''Calories from fat'' does not constitute a loss of information to consumers because there is presently no other means for conveying differences in nutrient density between macronutrients on the Nutrition Facts label. One comment indicated that, as long as the ''Calories from fat'' declaration is truthful and not misleading, the information is protected commercial speech under the First Amendment and that there is no legal basis to prohibit it. The comment said that ''Calories from fat'' should continue to be allowed on the Nutrition Facts label on a voluntary basis.

(Response) We disagree that the labeling of ''Calories from fat'' is required for specific health conditions or that it is necessary for consumers to monitor their calories from total fat. The Nutrition Facts label is intended to provide nutrition information to the general U.S. population and not for specific populations with specific diseases. Current dietary recommendations no longer emphasize total fat. Consumers already have information on the quantitative amount of total fat on the label as well as information of its DV on the label. The extra emphasis of calories from fat is not needed based on the new science for total fat. As we stated in the preamble to the proposed rule (79 FR 11879 at 11891), U.S. consensus reports recognized that there are benefits to consuming moderate amounts of fat and that different types of fat have different roles in chronic disease risk, so the additional emphasis of ''Calories from fat'' is not warranted. The results of these reports and dietary recommendations also establish why a declaration of ''Percent of Calories from Fat'' is not necessary to assist consumers in maintaining healthy dietary practices, because the reports emphasize the intake of ''total calories'' and the type of fat consumed. We also note that the information required for fats in the Nutrition Facts label, in the absence of a declaration of ''Calories from Fat,'' provides consumers with the information to compare similar products and make healthy dietary choices.

Information on monounsaturated and polyunsaturated fats is voluntary on the Nutrition Facts label due to their role in health, and information on saturated fat will still be required. Ultimately, we do not think mandatory information on the amounts of monounsaturated and polyunsaturated fats is necessary to help consumers maintain healthy dietary practices because information on the quantitative amount and the percent DV of total fat and saturated fat will still be required on the Nutrition Facts label. We discuss monounsaturated and polyunsaturated fats in greater detail in part II.F.4.

We disagree that the declaration of ''Calories from fat'' should be voluntary on the Nutrition Facts label. Based on current scientific evidence and dietary recommendations, we have concluded that the declaration of ''Calories from fat'' is not necessary to assist consumers in maintain health dietary practices. Information on total calories, the quantitative and percent DVs for total fat and saturated fat, and quantitative amount of *trans* fat provides consumers with information to maintain healthy dietary practices and to put total fat and saturated fat in the context of a total daily diet, to compare products, and to plan diets.

(Comment 80) Some comments supporting the continued declaration of ''Calories from fat'' suggested requiring a declaration only for certain foods that contained above a specified level of total fat or if the food contained more than a certain amount of saturated and *trans* fat.

(Response) We decline to revise the rule as suggested by the comments. To require a declaration for ''Calories from fat'' only on certain products would not be consistent with our conclusion that information on ''Calories from fat'' is not necessary to help consumers in maintaining healthy dietary practices. Furthermore, the quantitative amounts and percent DV for total fat and saturated fat are already provided, as well as the quantitative amount of *trans* fat. Finally, the DGAs and other consensus reports emphasize the importance of total calories rather than the amount of calories from any particular macronutrient.

2. Calories From Saturated Fat

Under our preexisting regulations at § 101.9(c)(1)(iii), the declaration of ''Calories from saturated fat'' is voluntary. The preamble to the proposed rule noted that saturated fat is known to increase the risk of cardiovascular disease and, unlike ''Calories from fat,'' which could include calories attributable to fatty acids that decrease or increase the risk of certain diseases, ''Calories from saturated fat'' would provide information about calories from a source known to increase disease risk (79 FR 11879 at 11892). Although we tentatively concluded that mandatory declaration of ''Calories from saturated fat'' is not necessary because the amount of saturated fat being consumed can be obtained from the total saturated fat declaration elsewhere on the Nutrition Facts label and because consumers can still use the percent DV for saturated fat to put saturated fat content in the context of a total daily diet, compare products, and plan diets, we decided that, due to the strong evidence associating higher intakes of saturated fat with higher low-density lipoprotein (LDL) cholesterol levels, information on ''Calories from saturated fat'' can assist consumers in maintaining healthy dietary practices. Therefore, the proposed rule would not change the current voluntary labeling of ''Calories from saturated fat'' in the Nutrition Facts label as specified in § 101.9(c)(1)(iii). However, considering our proposal to eliminate the declaration of ''Calories from fat'' on the Nutrition Facts label (see part II.E.1.), the proposed rule would revise § 101.9(c)(1)(iii) and (d)(5) to specify that the statement ''Calories from saturated fat,'' when declared, must be indented under the statement of calories. In addition, the proposed rule would redesignate § 101.9(c)(1)(iii) as proposed § 101.9(c)(1)(ii).

We did not receive comments on this topic and have finalized the revisions without change.

3. Two Thousand Calories as the Reference Caloric Intake Level

Our preexisting regulations, at § 101.9(c)(9), establish a reference calorie intake level of 2,000 calories to set DRVs for total fat, saturated fat, total carbohydrate, protein, and dietary fiber. In addition, the preexisting regulation requires a footnote on the Nutrition Facts label that states, ''Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs,'' followed by a table with certain DVs based on 2,000 and 2,500 calorie diets.

The preamble to the proposed rule (79 FR 11879 at 11892) discussed recommendations from the IOM macronutrient report that provided estimated energy requirements (EERs) and the IOM labeling report (Refs. 24–25), as well as comments (Ref. 26) received in response to the 2007 ANPRM, in which we asked whether 2,000 calories should continue to be used as the reference calorie intake level and asked questions related to the use of the EERs. The preamble to the proposed rule explained that an EER is a DRI set by the IOM for energy intake and is defined as the dietary energy intake that is predicted to maintain energy balance in a healthy adult of defined age, gender, weight, height, and level of physical activity consistent with good health. The IOM set EERs for all

life-stage and gender groups and based these EERs on normal weight individuals (*i.e.,* Body Mass Index (BMI) < 25) (Ref. 24). The IOM Labeling Committee considered whether there was a basis to use the EERs for developing a new reference calorie intake level for macronutrients in nutrition labeling. The IOM Labeling Committee found that the data necessary to use the EER concept as the basis for a reference calorie intake level for nutrition labeling were incomplete and that retaining the current 2,000 reference calorie intake level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy (Ref. 25). The proposed rule would not suggest any changes to the current use of 2,000 reference calorie intake level as the basis for setting DRVs for total fat, saturated fat, total carbohydrate, dietary fiber, and protein.

(Comment 81) Many comments supported using 2,000 calories as the reference caloric intake levels based on the same rationale provided by U.S. consensus reports and the IOM labeling report mentioned in the preamble to the proposed rule and agreed that the EER was not an appropriate way to set a reference caloric intake level.

In contrast, many other comments opposed using 2,000 calories as a reference caloric intake level. The comments said that many individuals do not consume 2,000 calories (*i.e.,* individuals may need more or less depending on age, sex, weight, height and physical activity level). Other comments wanted us to use a different reference calorie intake level (*i.e.,* 1,400 calories, 1,800 calories or more than 2,000 calories) or to eliminate the concept of a reference calorie intake level because, according to the comments, it is not useful or accurate because all individuals do not consume 2,000 calories per day.

(Response) We agree that an individual's caloric needs can vary; however, we disagree that the reference caloric intake level should be a value other than 2,000 calories or that there should not be one at all. As we stated in the preamble to the proposed rule, the reference calorie intake level is not used as a target for caloric intake, but rather to set DVs for total fat, saturated fat, total carbohydrate, protein, and dietary fiber (see 79 FR 11879 at 11892). We agree with the IOM labeling report (Ref. 25) that a reference caloric intake level of 2,000 calories provides continuity and would not encourage higher calorie intake and overconsumption of energy (id.).

We also use 2,000 calories because a rounded value is easier for other consumers to use and is less likely suggest an inappropriate level of precision as would 1,500 calories, 1,800 calories, or 2,350 calories. The comments supporting a different reference caloric intake level did not provide evidence to support these values for our consideration; consequently, we do not have sufficient information to determine the advantages or disadvantages associated with a different value or how the values compare against the 2,000 calorie value used now.

4. Percent DV Declaration for Calories

Our preexisting regulations do not provide for a DRV for calories. The preamble to the proposed rule (79 FR 11879 at 11892 through 11893) explained that setting a DRV for calories would necessitate determining a quantitative intake recommendation for calories, but also noted that there is no appropriate quantitative intake recommendation and that we were not aware of any other data or information on which a DRV for calories could be determined. Thus, the proposed rule would not set a DRV for calories and, as a result, neither require nor permit a percent DV declaration for calories.

(Comment 82) Many comments agreed with our rationale for not providing a percent DV for calories. Some comments said that a percent DV for calories would be misleading, not accurate, or not useful because not all individuals consume 2,000 calories a day.

In contrast, other comments supported a declaration for percent DV because, according to the comments, this information would be useful to consumers by allowing them to learn about the relationship between portion size and calorie intake. Another comment noted that an optional declaration of a percent DV for calories would allow consumers to make more informed decisions regarding selection of processed foods. Some comments suggested having different percent DVs for calories (*i.e.,* one for men and woman, or one for growing children and adults, or two DVs of 1,500 and 2,000 calories).

(Response) We do not agree that a DV for calories, for purposes of nutrition labeling, should be set at any caloric level. We continue to believe that, to provide a DV, a DRV based on quantitative intake recommendations for calories would need to be set. Quantitative intake recommendations for calories are called estimated energy requirements (EERs), and they are based on normal weight healthy individuals of defined age, gender, weight, height, and level of physical activity. It would be difficult to combine the EERs into a single reference calorie level applicable to the general population because calorie needs vary based on many factors.

As for the comments suggesting that a DV could help consumers with the relationship between portion size and calorie intake and to make informed food selections, we note that the declaration of ''Calories'' can by itself alert consumers to the amount of calories in a serving of a food and assist consumers to make informed decisions about their food selections based on the calorie content.

As for the comments suggesting different percent DVs for calories, the comments did not indicate what those DVs would be or how we might calculate them. Therefore, for the same reasons we expressed earlier in this response, we do not have sufficient information to set a DV or multiple DVs, and so the final rule does not establish a percent DV for calories. However, we consider that a statement about daily calorie intake (2,000 calories) should be a necessary part of the footnote in the Nutrition Facts label because 2,000 calories is consistent with widely used food plans and will serve as a basis for menu labeling (79 FR 71156, December 1, 2014). Likewise, the second sentence of the footnote will state: ''2,000 calories a day is used for general nutrition advice'' (see part II.Q.11).

F. Fat

The preamble to the proposed rule (79 FR 11879 at 11893 through 11899) discussed considerations related to definitions, declaration, and DRVs for total fat, saturated fat, *trans* fat, monounsaturated fat, and polyunsaturated fat.

1. Total Fat

a. Definition. Our preexisting regulations at § 101.9(c)(2) define ''fat, total'' or ''total fat'' as a statement of the number of grams (g) of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides.

In the preamble to the proposed rule (79 FR 11879 at 11893), we discussed a 1997 citizen petition submitted by Nabisco, Inc. (Docket No. FDA–1997–P–0476) asking us to amend the definitions of ''total fat'' and ''saturated fat'' to clarify that acetic, propionic, and butyric acids may be excluded when calculating the amount of fat in a food product. We tentatively concluded that the petitioner did not provide a scientific basis on which we could rely to propose to exclude acetic, propionic,

and butyric acids from the definition of total fat based on differences in chemical composition. We therefore, did not propose any changes to the definition of ''total fat'' found in § 101.9(c)(2).

To clarify what we consider to be a fatty acid, we proposed to define ''fatty acids'' in § 101.9(c)(2) as ''aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group.'' We explained that this definition is consistent with other similar definitions found in nutrition and chemistry references (79 FR 11879 at 11893).

(Comment 83) Several comments supported our current definition of ''total fat'' and our proposed definition of ''fatty acids.'' The comments also agreed with our tentative conclusion that acetic, propionic, and butyric acids should continue to be included in the definition of total fat because they are short-chain fatty acids and that the basic chemical group (*i.e.,* the terminal carboxyl group attached to a chain of alkyl groups containing carbon atoms) should remain the main defining factor of a fatty acid.

However, one comment suggested that acetic and propionic acids should not be considered fatty acids, but that butyric acid should be considered both a fatty acid and a saturated fatty acid. The comment cited the International Union of Pure Applied Chemistry (IUPAC) definition of fatty acids, which indicates that ''natural fatty acids commonly have a chain of 4 to 28 carbons'' (Ref. 27). The comment noted that acetic and propionic acid have 2 and 3 carbon chains, respectively, so the comment said extending the definition of fatty acids to these two substances is unjustified. Furthermore, the comment said that acetic and proprionic acids are not functionally fatty acids because acetic acid is a primary component of vinegar and propionic acid is most commonly used as a food stabilizer or anti-microbial agent in the form of sodium or ammonium salts, and is also used in its free form as a taste additive.

(Response) We agree that butyric acid should be considered both a fatty acid and a saturated fatty acid. However, we disagree that acetic acid and propionic acid should be excluded from the declaration of total fat based on their carbon chain length. The IUPAC definition provided says that fatty acids ''commonly'' have a chain length of 4 to 28 carbons, but this definition does not exclude the possibility that there may be fatty acids with carbon chain lengths of less than 4 carbons. Furthermore, other definitions of fatty acids include monocarbonic acids with chain lengths between 1 and nearly 30 carbon atoms (79 FR 11879 at 11893). The final rule, therefore, does not change our pre-existing definition of ''total fat.''

The comment noted that acetic acid is most commonly found in the human diet in vinegar, either separately or as an ingredient, and is responsible for its distinctive odor and taste. The comment noted that propionic acid is used in food as a stabilizer, anti-microbial agent, and as a taste additive. The comment used this information to explain why these acids are not functionally fatty acids rather than explaining how the function of acetic and propionic acids differ from those of other fatty acids. Therefore, the comment did not provide sufficient information for us to consider in determining whether acetic and propionic acid should be excluded from the declaration based on their functional attributes, and we have finalized the definition of ''fatty acids'' in § 101.9(c)(2) without change.

(Comment 84) One comment recommended that consumer education is warranted to make consumers aware that the physiological effects of acetic, propionic, and butyric acids are different from the health effects that have been linked to longer-chain fatty acids.

(Response) The health effects of acetic, propionic, and butyric acids have not been well established in the scientific literature. Therefore, it would be premature to provide consumer education on acetic, propionic, and butyric acids until more is known about these acids.

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of total fat on food labels. Consequently, the Nutrition Facts label includes the mandatory declaration of the gram amount for total fat in § 101.9(c)(2).

The preamble to the proposed rule (79 FR 11879 at 11893) stated that the 2010 DGA recognizes that the types of fatty acids consumed are more important in influencing the risk of CVD than the total amount of fat in the diet. It also stated that current dietary recommendations and clinical guidelines encourage replacing saturated and *trans* fatty acids with beneficial fats, such as polyunsaturated and monounsaturated fatty acids, and that a high intake of most types of saturated fatty acids, *trans* fatty acids, and cholesterol can increase LDL cholesterol levels, which in turn may increase the risk of CHD (id.). Although we concurred with the 2010 DGA that consuming a diet low in saturated fatty acids and cholesterol is more important for reducing CVD risk than consuming a diet low in total fat, we tentatively concluded in the preamble to the proposed rule that mandatory declaration of total fat on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices (id.) for the following reasons:

- Total fat is a calorie-yielding macronutrient and an important piece of the macronutrient profile of a food;
- Consumption of a low fat, high carbohydrate diet can increase the risk of chronic diseases such as CHD and type 2 diabetes; and

Increased fat intake, as a result of increased saturated fat intake, has been shown to increase LDL cholesterol concentrations, and therefore risk of CHD.

(Comment 85) Several comments supported the mandatory declaration of total fat on the Nutrition Facts label. The comments suggested that retaining the declaration of total fat also would help consumers who are trying to consume foods with a lower calorie density because foods higher in fat have a higher caloric density. (Caloric density is the amount of calories per unit of food weight.) Some comments provided evidence to show that consumption of a lower-fat, lower-calorie diet promotes weight loss, weight maintenance, and the reduction in risk of diabetes. Other comments stated that consumers can use a food's total and saturated fat content to estimate its unsaturated fat content. As discussed in part II.F.4, replacing saturated fats with unsaturated fats can lower LDL cholesterol levels and the risk of CVD.

Other comments disagreed with our conclusion and suggested that, rather than listing total fat on the label, we should require the declaration of the amount of each type of fat (*i.e.,* saturated fat, *trans* fat, polyunsaturated fat, and monounsaturated fat). The comments noted that total fat consumption is no longer emphasized in the DGA. Instead consumers are advised to limit their consumption of saturated and *trans* fats, and replace them with monounsaturated and polyunsaturated fats. One comment questioned whether including total fat on the label may inadvertently discourage consumers from selecting foods that appear to be high in fat without regard to the source of fat.

(Response) We agree, in part, and disagree, in part, with the comments. As we stated in the preamble to the proposed rule (79 FR 11879 at 11893), we agree with the recommendations of the 2010 DGA that the types of fatty acids consumed are more important in influencing the risk of CVD than the total amount of fat in the diet. However,

we decline to remove the declaration of total fat from the label as some comments suggested. Total fat continues to be associated with the risk of chronic disease and so a declaration of total fat provides important information about the nutrient profile of a food (79 FR 11879 at 11893). Increased fat intake, as a result of increased saturated fat intake, has been shown to increase LDL cholesterol concentrations, and therefore risk of CHD.

As for the comment asserting that including total fat on the label may inadvertently discourage consumers from selecting healthful foods because of the amount of total fat declared on the label, the comment did not provide any data or other information to support the assertion. We recognize that how a total fat declaration may be understood and used by consumers could have important implications for how we focus our consumer education.

c. DRV. The DRV for total fat is 30 percent of calories (65 grams/day) (§ 101.9(c)(9)). The proposed rule would not change the DRV. The preamble to the proposed rule (79 FR 11879 at 11894) discussed the absence of an AI and RDA for total fat and how the IOM established an AMDR for total fat intake of 20 to 35 percent of energy for adults and an AMDR of 25 to 35 percent of energy for children age 4 to 18 years. (The AMDRs are associated with reduced risk of chronic diseases, such as CHD, while providing for adequate intake of essential nutrients.) We noted that the 2010 DGA acknowledged the IOM's AMDR and indicated that total fat intake should fall within the AMDRs set by the IOM. We explained that the IOM Labeling Committee recommended a population-weighted midpoint of the AMDR because AMDRs vary with age; thus, a population-weighted mid-point of the AMDR for adults, *i.e.,* 20 to 35 percent, yields a DRV of 28 percent or 62 grams of total fat. However, we declined to adjust the DRV because we concluded, in the preamble to the proposed rule (79 FR 11879 at 11894), that the upper level of the AMDR of 35 percent of 2,000 calories as the basis for a DRV would provide no meaningful health benefit and that a population-weighted mid-point of 28 percent of the AMDR (28 percent of calories) as the basis for the DRV is not significantly different from a public health outcome standpoint than the current value of 30 percent of calories.

(Comment 86) One comment agreed that we should not change the DRV for total fat. The comment noted that there is little or no advantage to making a change on this basis because the actual change in the DRV amount is minimal compared to the cost and effort required to educate consumers about the rationale for the change and its significance related to dietary choices.

One comment said we should reduce the DRV for total fat to 40 grams/day (18 percent of calories based on a 2,000 calorie diet), but the comment did not provide a rationale or other information to support the recommended change.

Another comment suggested that we eliminate the DRV for total fat to allow consumers to focus on replacing saturated fats with unsaturated fats. The comment stated that the types of fat consumed are more important in influencing the risk of heart disease than is the total amount of fat. The comment noted that current dietary recommendations and clinical guidelines recommend replacing saturated and *trans* fats with polyunsaturated and monounsaturated fats to reduce the risk of heart disease.

(Response) Since we published the proposed rule in the **Federal Register**, new information and evidence has become available that corroborates the position that the types of fats consumed are more important in influencing the risk of heart disease than is the total amount of fat. The 2015 DGAC concluded that strong and consistent evidence from randomized controlled trials shows that replacing saturated fatty acids with unsaturated fats, especially polyunsaturated fatty acids, significantly reduces total and LDL cholesterol. The 2015 DGAC also concluded that there is strong evidence that dietary patterns that are lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are beneficial for reducing CVD risk. The 2015 DGAC noted that, in low-fat diets, fats are often replaced with refined carbohydrates and this is of particular concern because such diets are generally associated with changes in blood cholesterol levels associated with an increased risk of disease. The 2015 DGAC suggested that dietary advice should put the emphasis on optimizing types of dietary fat consumed and not on reducing total fat intake. The 2015–2020 DGA did not include a recommendation that Americans should reduce their intake of total fat, but did recommend that sources of saturated fat should be replaced with unsaturated fat, particularly polyunsaturated fatty acids (Ref. 28). These recommendations and conclusions are supported by the Lifestyle Management Report and the evidence reviewed for the NHLBI Lifestyle Evidence Review (Refs. 17–18).

We disagree with the comment recommending the elimination of the declaration of the percent DV for total fat because we have concluded that the declaration of the amount of total fat is necessary to assist consumers in maintaining healthy dietary practices and the percent DV declaration can help consumers put the gram amount of total fat declared on the label into the context of their total daily diet. Furthermore, the comment did not explain how removing the declaration of the percent DV for total fat from the label will help consumers focus on replacing saturated fats with monounsaturated fats, especially if the total gram amount of total fat in a serving of a product is still declared on the label. Therefore, we decline to remove the declaration of the percent DV for total fat from the label.

We also disagree that the DRV for total fat should be decreased from 65 grams/day to 40 grams/day. The comment did not provide a basis for the change, so, absent data or evidence to support decreasing the DRV, we do not have sufficient information to support the change and also are unable to determine if the change would be appropriate.

Although we disagree with the comment suggesting that we eliminate the percent DV declaration for total fat, we are reconsidering our position that increasing the DRV for total fat to 35 percent, which is the upper end of the AMDR range, would provide no meaningful health benefit. The scientific community continues to focus on the types of fats consumed and less on the total amount of fat consumed. Current clinical guidelines and dietary recommendations do not include guidance or recommendations to limit total fat. We do not place limitations on the total amount of fat. We are concerned that keeping the DRV for total fat of 30 percent of calories may be misinterpreted as advising consumers to limit their intake of total fat to 30 percent or less. It is also conceivable that consumers could view foods which are good sources of mono and polyunsaturated fats negatively because their percent DV declaration for total fat is high. Given that current dietary recommendations and clinical guidelines corroborate our action to not place limitations on the total amount of fat which should be consumed and acknowledge that replacing total fat in the diet with carbohydrates can have negative health effects, we have reconsidered our statement that the upper level of the AMDR of 35 percent would provide no meaningful health benefit compared to the current value of 30 percent calories. Thus, we are increasing the DRV for total fat from 30 percent of calories to 35 percent of

calories, which results in a DRV of 78 grams.

d. *Declaration of total fat.* The proposed rule would not change the preexisting requirement for mandatory declaration of total fat on the Nutrition Facts label.

(Comment 87) Several comments recommended decreasing the prominence of total fat on the label while increasing the prominence of saturated and *trans* fatty acids because the scientific evidence shows that the type of fat consumed is more important than the total amount consumed. The comments stated that more emphasis on saturated and *trans* fatty acids could help consumers reduce their intake of these types of fats. One comment recommended that the total fat declaration should be listed right after protein and carbohydrate on the label to reduce its prominence. The comment suggested that this change is necessary because high fat diets have been proven to reduce body weight, normalize blood sugars for diabetics, improve cardiac risk profiles, and reduce the risk for other comorbidities, such as the risk of stroke.

(Response) We decline to change the order of nutrients on the label to decrease the prominence of total fat. Fat is one of three major macronutrients in the diet. The listing of the amount of total fat in a product provides valuable information to the consumer about the nutrient profile of a food. While we agree that it is important for consumers to consider the amount of saturated and *trans* fat in a product, these fatty acids are components of total fat. They are indented and listed below total fat on the Nutrition Facts label so that consumers can see that they are part of the total fat declaration. If the declaration of the amount of total fat in a product is separated from the declaration of its components, as suggested in the comment recommending its placement below carbohydrate and protein, it could appear as though saturated and *trans* fat are not part of the total fat declaration.

As for the comment suggesting that high fat diets have been proven to be beneficial for weight loss and to have other beneficial health effects, the comment did not provide evidence related to how the order of nutrients on the label may impact consumers wishing to follow a high fat diet. Without such evidence, we are unable to evaluate the impact of the suggested change in the order of nutrients declared on the label.

(Comment 88) Some comments recommended declaring total fat as a percentage of the total weight of a product or as a percentage of calories in a serving of the product. One comment expressed concern that some manufacturers are making false claims about the percentage of fat in a product, and the comment suggested that knowing the percentage attributed to the total weight of the food by the fat in the product would be beneficial for consumers. The comment also stated that most calculations of body fat and daily intakes are expressed as percentages.

(Response) We decline to require the declaration of total fat as a percentage of the weight of the food or as a percentage of calories in a serving of the product.

We disagree that declaration of the amount of fat as a percentage of weight or as a percentage of calories would be helpful to consumers in maintaining healthy dietary practices. Information found on the label can be used to determine the amount of a nutrient in a food so that it can be used for product comparison or to determine how the food contributes towards recommended amounts of nutrients (see part I.B). The declaration of a percentage of weight that is attributable to the total fat content of a food product would not allow for easy product comparison and would not allow a consumer to determine how the product compares to dietary recommendations for total fat. Dietary recommendations for total fat are provided in grams rather than in percentages (Ref. 29).

Additionally, as discussed in part II.E.1, we are removing calories from fat from the label because the type of fat consumed is more relevant in reducing the risk of CHD than overall total fat intake. Therefore, the declaration of a percentage of calories from fat also is unwarranted.

2. Saturated Fat

a. Definition. Our preexisting regulations define ''Saturated fat'' in § 101.9(c)(2)(i) as the sum of all fatty acids containing no double bonds. We did not propose to change the definition.

(Comment 89) Most comments supported our decision not to revise the definition of saturated fat. However, one comment argued that we should exclude the short-chain fatty acids, acetic acid and proprionic acid, from the definition of both total fat and saturated fat, but another short-chain fatty acid, butyric acid, could remain in the definitions. The comment argued that both acetic acid and proprionic acid have carbon chains shorter than four carbons and that the International Union of Pure Applied Chemistry (IUPAC) has a definition of fatty acids which indicates that ''natural fatty acids commonly have a chain of 4 to 28 carbons'' (Ref. 27).

(Response) We decline to exclude acetic and propionic acid from the declaration of saturated fat based on the length of the carbon chains for reasons already discussed in part II.F.1.

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of saturated fat on food labels. Accordingly, our preexisting regulations require mandatory declaration of the gram amount for saturated fat (§ 101.9(c)(2)). We did not propose any changes to the mandatory declaration of the gram amount for saturated fat.

(Comment 90) Most comments supported our decision not to change the mandatory declaration of saturated fat.

Other comments opposed listing saturated fats because, the comments said, saturated fats are not detrimental to health. One comment that suggested we should break down saturated fat further into medium chain and long chain saturated fatty acids because medium chain saturated fatty acids are beneficial to health, while long chain saturated fatty acids are not.

(Response) We disagree that the Nutrition Facts label no longer needs to list saturated fats and also decline to break down saturated fat further into medium chain and long chain saturated fatty acids. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of saturated fat on food labels, and, in the preamble to the proposed rule (79 FR 11879 at 11895), we described how dietary recommendations continue to recognize the well-established relationship between consumption of saturated fat, which include all saturated fatty acids chain lengths, and its effect on blood cholesterol levels. In addition, the 2010 DGA provided scientific evidence supporting a quantitative intake recommendation for saturated fat which likewise, include all saturated fatty acid chain lengths.

The comments suggesting that saturated fat did not need to be declared or should be further broken down by chain length did not provide any information that could be used to contradict the dietary recommendations, nor did they provide information that would enable us to determine that the nutrient information is no longer necessary to assist consumers in maintaining healthy dietary practices (as section 403(q)(2)(B) of the FD&C Act requires when removing nutrient information). Thus, based on the science and dietary recommendations and the absence of evidence indicating that the

information is no longer necessary to assist consumers in maintaining healthy dietary practices, we are retaining the declaration of saturated fat in the Nutrition Facts label.

c. DRV. Under our preexisting regulations at § 101.9(c)(9), the DRV for saturated fat is 20 grams, which is 10 percent of calories based on a 2,000 reference calorie intake level. In the preamble to the proposed rule (79 FR 11879 at 11895), we discussed how current consensus reports, such as the IOM DRIs, the 2010 DGA, and a 2002 report from the National Cholesterol Education Program of the NIH National Heart, Lung, and Blood Institute, continue to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. Additionally, the scientific evidence in the 2015–2020 DGA supports limiting calories from saturated fat which corroborates the consensus reports. Consequently, we did not propose to change the DRV for saturated fat in § 101.9(c)(9).

(Comment 91) Many comments supported our decision to keep the existing saturated fat DRV of 20 grams, but some comments would have us lower the DRV to 6 or 7 percent of calories. The comments indicated that this range would calculate to a DRV of approximately 13 to 15 grams of saturated fat. Other comments noted that recent guidelines published by the American Heart Association and American College of Cardiology, in collaboration with the National Heart, Lung, and Blood Institute, concluded that no more than 5 to 6 percent of calories should come from saturated fat. One comment also argued that the saturated fat DRV was too low and that human diets, both historical and among different cultures, are consistent with diets higher in saturated fat and that current science supports higher levels of intake.

Two comments suggested that we remove stearic acid from any calculation of the percent DV. The comments argued that the DRV is based on adverse physiological effect and that each saturated fatty acid should be considered individually regarding these effects. The comments suggested that a percent DV for saturated fat of an individual food could be calculated using different weighting factors for saturated fatty acids dependent on the level of adverse effect of each individual fatty acid. The comments also argued that, because stearic acid is neutral in regard to effects on levels of serum total and LDL-cholesterol compared to other saturated fatty acids, stearic acid would end up being left out of the calculation for the percent DV.

(Response) We decline to revise the DRV for saturated fat. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11895), current consensus reports reviewing the scientific evidence related to saturated fatty acid intake continue to support saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. For example, the scientific evidence in the 2010 DGA (Ref. 30) supports reducing saturated fatty acid intake to less than 10 percent of calories, and the scientific evidence in the 2015 DGAC supports retaining the 10 percent upper limit for saturated fat intake. These guidelines apply to intake levels for the general population. Other guidelines that support lower than 10 percent of calories do exist for therapeutic uses, which would apply to specific populations in need of, for example, lowering of LDL cholesterol levels in the blood (Ref. 31). These are specific populations such as those with diagnosed heart disease or type 2 diabetes, those with family histories of high blood cholesterol, and others with high risk for CVD (Ref. 32).

As for the comment claiming that the DRV for saturated fat is too low, the comment did not provide evidence for increasing the DRV, and we are unaware of current scientific information that would support an increase. The current dietary recommendations for intake of saturated fatty acids, of less than 10 percent of calories, are still applicable to the general U.S. population. Thus, the existing DRV of 20 grams is consistent with the scientific evidence supporting a maximum intake level that covers the general U.S. population.

We also disagree with comments that would exclude stearic acid from the calculation of an individual food's percent DV for saturated fat. The scientific evidence supporting the current dietary recommendations for saturated fat, does not differentiate among the individual saturated fatty acids. The scientific evidence relates to the intake of all saturated fatty acids combined, and this would include stearic acid. We note that the 2015–2020 DGA recommendation to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid and, instead, relates to the intake of total saturated fatty acids (Ref. 28). Because the DRV is based on the intake of all saturated fatty acids, determination of percent DV is also based on content of all saturated fatty acids in the individual food.

3. *Trans* Fat

a. Definition. Our preexisting regulations, at § 101.9(c)(2)(ii), define ''*Trans* fat'' or ''*Trans*'' as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.,* non-conjugated) double bonds in a *trans* configuration. The proposed rule would not change the definition.

(Comment 92) Most comments supported our decision to retain the definition of *trans* fat.

One comment, however, said that the physiological effects of *trans* fat from ruminant sources differs from the effects of *trans* fat from industrial sources (*i.e.,* partially hydrogenated oils). The comment said we should exclude *trans* fat from ruminant sources from the definition of *trans* fat.

(Response) We decline to exclude *trans* fat from ruminant sources from the definition of *trans* fat. *Trans* fat is generally understood to be any unsaturated fatty acid that contains a double bond, regardless of source (Ref. 29). Additionally, as we stated in the preamble to the proposed rule (79 FR 11879 at 11896), the chemical definition is consistent with how we define polyunsaturated fat as cis, cis-methylene-interrupted (§ 101.9(c)(2)(ii)).

We also note that, in the **Federal Register** of June 17, 2015 (80 FR 34650), we issued a declaratory order making a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially produced *trans* fatty acids (IPTFA) are generally recognized as safe (GRAS) for any use in human food. The major provisions of our declaratory order were that:

- PHOs are not GRAS for any use in human food;
- Any interested party may seek food additive approval for one or more specific uses of PHOs with data demonstrating a reasonable certainty of no harm of the proposed use(s); and
- For the purposes of the declaratory order, FDA defined PHOs as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4.

We established a compliance date of June 18, 2018 for the declaratory order.

b. Mandatory declaration. Our preexisting regulations, at § 101.9(c)(2)(ii), require the declaration of *trans* fat on the Nutrition Facts label (§ 101.9(c)(2)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11896), we tentatively concluded that information on the amount of *trans* fat in food products allows consumers to

reduce their intake of *trans* fat, and thus, reduce the risk of CHD, so we did not propose to change this requirement. However, we also stated that, in the **Federal Register** of November 8, 2013 (78 FR 67169), we had published a tentative determination that partially hydrogenated oils (PHOs), the source of industrially produced *trans* fat, may not be generally recognized as safe (GRAS), and we invited comment on whether mandatory labeling of *trans* fat would still be necessary if we finalized our determination (79 FR 11879 at 11896).

(Comment 93) Regarding the mandatory declaration of *trans* fat, all comments supported our decision to continue requiring the declaration of *trans* fats.

With respect to the GRAS determination of PHOs, the comments were divided. Some comments supported requiring the declaration of *trans* fats on the label regardless of the final GRAS determination; other comments supported removing the declaration of *trans* fat from label if PHOs are no longer GRAS.

The comments supporting the declaration of *trans* fat on the label, even if PHOs are no longer declared GRAS, discussed the continued presence of *trans* fat in products even after PHOs are removed from foods. The comments explained that *trans* fat could come from both natural sources, such as the *trans* fat in dairy products, and from uses of oils that are either currently allowed as food additives or could potentially be permitted in the future. The comments said that *trans* fat content is still information that consumers need even if total overall presence in the food supply is reduced.

Other comments supporting removal of the *trans* fat declaration if PHOs are no longer GRAS said that, if PHOs are no longer GRAS, most foods would not have any *trans* fat, except for the *trans* fat that comes from animal sources. Thus, to these comments, few foods would have declarable levels of *trans* fat, and most foods would indicate a *trans* fat content of zero. Because so few foods would contain *trans* fat, the comments stated, a *trans* fat declaration would no longer be needed on the label. Some comments also noted that animal products, such as dairy, are considered part of normal, healthful diets, and *trans* fat information on those products is not necessary. Some comments, however, did suggest that if *trans* fat from animal sources exceeded a certain level, such as 1.0 g per serving, then we should require its disclosure on the label.

(Response) Based on the available scientific evidence and the findings of expert scientific panels, in the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order stating that PHOs are not GRAS for any use in human food. Although we have made this determination regarding PHOs, some *trans* fats will continue to be present in foods. For example, the declaratory order provided a compliance date of June 18, 2018; this gives manufacturers up to 3 years to remove PHOs, and the accompanying *trans* fats in PHOs, from foods. The 3 years also provides time for manufacturers to petition us for approval of PHOs as food additives, which could allow PHOs to be included in food in certain circumstances. Moreover, *trans* fat will always be naturally present in foods from ruminant sources (*e.g.,* beef products and dairy foods). Using the latest data from the Gladson database (data current as of March 2015), we calculate that, based on the Gladson values, there could potentially be more than 5,000 foods remaining with declarable levels of *trans* fat, after removal of PHOs. Thus, it is premature to consider removing *trans* fat from the Nutrition Facts label at this time. We expect there to be a great deal of reformulation of products over the next 3 years, and we will need to evaluate the remaining *trans* fat content in foods, both from approved or potentially approved food additive uses of PHOs and from naturally occurring *trans* fat, after the expected reformulations have occurred. We will then be able to consider whether, in light of any remaining *trans* fat content in foods, declaring *trans* fat on the label continues to assist consumers in maintaining healthy dietary practices. Until such time, however, the scientific evidence continues to support the need to inform consumers about the continued presence of *trans* fat in foods.

c. DRV. Our preexisting regulations do not provide a DRV for *trans* fat. In the preamble to the proposed rule (79 FR 11879 at 11896 through 11897), we described various efforts (such as the use of ANPRMs) to consider determining a DRV for *trans* fat, including the use of food composition data, menu modeling and data from dietary surveys, and a potential joint percent DV for *trans* fat and saturated fat. We described how a number of evaluations of the existing scientific evidence were not able to set a definitive quantitative intake recommendation for *trans* fat. We tentatively concluded that there was not a basis for setting a DRV for *trans* fat, and so we did not propose a DRV for *trans* fat.

(Comment 93a) Most comments agreed that the scientific evidence is insufficient to set a DRV. In contrast, two comments said we should set a DV for *trans* fat, but did not provide information that would enable us to establish a DRV.

(Response) We decline to revise the rule to establish a DV for *trans* fat. The comments did not provide information that would enable us to establish a DV, and, as we discussed in the preamble to the proposed rule (id.), consensus reports were unable to determine a specific level of *trans* fat intake that would likely pose no risk of adverse health effects. The IOM, for example, said that a DV for *trans* fat could not be established because ''any increase in *trans* fat intake increases CHD risk but because *trans* fats are unavoidable in ordinary diets, consuming zero percent of calories would require significant changes in dietary intake patterns that may introduce undesirable effects and unknown and unquantifiable health risks'' (Ref. 29). We continue to adhere to the recommendation from the IOM that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.

d. Declaring the amount of trans fat. Our preexisting regulations, at § 101.9(c)(2)(ii), state that, if the serving contains less than 0.5 grams, the content declared on the Nutrition Facts label must be expressed as zero. For most nutrients, the maximum amount permitted for a zero declaration is governed by the limitations associated with analytical methods available, and, in the preamble to the proposed rule (79 FR 11879 at 11896), we said that validated analytical methodologies that provide sensitive and reliable estimates of *trans* fatty acids in all foods at levels below 0.5 grams per serving are currently not available. Thus, we did not propose to change the requirements for a zero declaration of *trans* fat.

(Comment 94) Several comments asked us to lower the maximum amount permitted for a zero declaration. The comments provided several different values, such as 0.0 grams, 0.05 grams, 0.1 grams, and 0.2 grams, as alternatives to the preexisting value of 0.5 grams. The comments argued that even very small amounts of *trans* fat in a food (*i.e.,* less than 0.5 grams) could be harmful to consumers' health, and consumers should know if foods contained any *trans* fat at all. Most comments did not address the issue of a lack of validated analytical methodologies. One comment did, however, state that a validated analytical methodology did exist to detect *trans* fat below 0.5 grams per

serving and cited AOAC 996.06 (Ref. 33).

(Response) We agree that consumers should be informed of *trans* fat content in foods. With the current analytical methodologies, however, quantification of *trans* fat content in foods is limited. When determining the maximum amount permitted for a zero declaration, we need to consider, for compliance purposes, whether the *trans* fat content at those low levels can be reliably and accurately measured in all foods by an analytical method(s) that has been validated to do so. Currently, there are no validated analytical methods to determine *trans* fat content at levels less than 0.5 grams for all foods.

With respect to the comment that cited AOAC 996.06 as a methodology to detect *trans* fat, AOAC 996.06 does not provide validation data for *trans* fatty acids. AOAC 996.06 does provide validation data for total fat, saturated fat, and monounsaturated fat (Ref. 33). We are aware of ongoing efforts for validation of improved analytical methods for *trans* fat (Ref. 34), and if new validated methods become available, we may reevaluate the threshold for a zero declaration of *trans* fat.

4. Monounsaturated Fat and Polyunsaturated Fat

a. Voluntary declaration. Our preexisting regulations, at § 101.9(c)(2)(iii) and (iv), permit, but do not require, the declaration of monounsaturated fat (defined as cis-monounsaturated fatty acids (*e.g.,* oleic acid)) and the declaration of polyunsaturated fat (defined as cis, cis-methylene-interrupted polyunsaturated fatty acids) on the Nutrition Facts label.

The preamble to the proposed rule (79 FR 11879 at 11897 through 11899) described how we considered recommendations in current consensus reports, as well as comments received in response to the 2007 ANPRM in which we requested comment on whether declaration of monounsaturated fat and polyunsaturated fat should remain voluntary or be made mandatory. We noted that we have been unable to set a DRV for monounsaturated fat and polyunsaturated fat due to the absence of DRIs for both (id.)

Consistent with the 2010 DGA, the 2015–2020 DGA recommends that foods high in saturated fats should be replaced with foods high in unsaturated fats (Ref. 28).

(Comment 95) One comment supported voluntary declaration of monounsaturated and polyunsaturated fats and said that omitting unsaturated fats would reduce label clutter.

(Response) While it is possible that omitting unsaturated fats would reduce label clutter, our reason for not requiring the declaration of monounsaturated or polyunsaturated fats is due to the lack of a DRV and our consideration of the factors for mandatory and voluntary declaration for these types of nutrients. We consider voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation, but does not have public health significance or does not have a quantitative intake recommendation available for setting a DRV, but has public health significance.

(Comment 96) Some comments supported voluntary declaration of monounsaturated and polyunsaturated fats because, according to the comments, they were a key recommendation in the 2010 DGA, ''Consume less than 10 percent of calories from saturated fatty acids by replacing them with monounsaturated and polyunsaturated fatty acids.''

Other comments supporting mandatory declaration of monounsaturated and polyunsaturated fats also referred to the 2010 DGA recommendation. Some comments asserted that being a key recommendation was sufficient for mandatory listing of added sugars and claimed that we were being inconsistent with the use of dietary guidance recommendations, especially because the scientific evidence is stronger for monounsaturated and polyunsaturated fats than for added sugars.

(Response) We proposed to retain the voluntary declaration of monounsaturated and polyunsaturated fats based on the factors identified for the mandatory and voluntary listing of these types of non-statutory nutrients. While added sugars is not a statutory nutrient, we are requiring the declaration of added sugars based on the need for consumers to have this information, which relates to a dietary pattern, to assist consumers to maintain healthy dietary practices and not based on a specific relationship of added sugars to chronic disease risk. Thus, the basis for requiring the declaration of added sugars differs from that for monounsaturated and polyunsaturated fats. We acknowledge that the 2010 DGA provided a key recommendation for monounsaturated and polyunsaturated fats because of the strong evidence (79 FR 11879 at 11898); however, some evidence supporting this is replacing saturated fat with monounsaturated and polyunsaturated fats. Because saturated fat is on the label, we believe consumers can use that information in addition with total fat DV to maintain healthy dietary practices. The scientific evidence for added sugars (and solid fats) is based on the modeling of dietary patterns to ensure adequate consumption of nutrient dense foods and avoidance of excess empty calories that can lead to weight management issues and obesity.

(Comment 97) One comment supporting mandatory declaration noted that the 2010 DGA stated that there is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fat lowers LDL cholesterol and has health benefits.

(Response) We agree that there is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fats lowers LDL cholesterol and therefore reduces the risk of heart disease, and the preamble to the proposed rule (79 FR 11879 at 11897 through 11898) discussed how replacing saturated fatty acids with monounsaturated or polyunsaturated fats reduced blood LDL cholesterol levels. A quantitative intake recommendation, however, is not available for either monounsaturated or polyunsaturated fat. Therefore, in considering the factors for mandatory or voluntary declaration, we determined that monounsaturated and polyunsaturated fat warrants voluntary declaration.

An FDA health claim is available for the labeling of foods: ''Replacing saturated fat with similar amounts of unsaturated fats may reduce the risk of heart disease. To achieve this benefit, total daily calories should not increase'' (see ''Health Claim Notification for the Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease'') (Ref. 35).

(Comment 98) One comment supported mandatory declaration of polyunsaturated fat because, according to the comment, polyunsaturated fat includes essential nutrients.

(Response) We agree that polyunsaturated fat includes essential fatty acids (*i.e.,* linoleic and alpha linolenic acid). We disagree, however, that the listing of polyunsaturated fat should be mandatory for this reason. Essentiality of a nutrient is not factor considered for the mandatory or voluntary labeling of these types of non-statutory nutrients, other than essential vitamins and minerals. The basis for proposing voluntary declaration of polyunsaturated fat was because of its role in reducing the risk of CVD when replacing saturated fat, which has public health significance.

(Comment 99) One comment supporting mandatory declaration noted that the 2002 IOM report (Ref. 29) concluded that the type of fat, rather than total fat, was relevant to health and the 2010 DGA shifted the focus from total fat to the type of fat. Another comment noted that we were no longer requiring ''Calories from fat'' because the focus is more on the type of fat. Several comments supporting mandatory declaration of monounsaturated and polyunsaturated fats noted that it is not possible to identify these types of fats which have health benefits, and, therefore, it is not possible to differentiate from unhealthy fats. One comment said that listing these fats can help people distinguish between fatty foods that can be eaten more often compared to those with higher saturated fat content to be eaten less often.

Other comments supporting mandatory declaration claimed that consumers need to be able to compare products and select foods that are not only lower in saturated fat but contain monounsaturated and polyunsaturated fats.

(Response) We agree that the four chemically defined categories of type of fat (*i.e.,* saturated, *trans,* monounsaturated fat, and polyunsaturated fat), rather than total fat, are relevant to health, specifically CVD risk. Current dietary recommendations no longer emphasize total fat. Certain categories of fatty acids are beneficial, while others categories have negative health effects, particularly related to CVD (see 79 FR 11879 at 11891). We recognize that monounsaturated and polyunsaturated fat have public health relevance when they replace saturated fat (id. at 11898). There is not a quantitative intake recommendation available, however, that identifies how much monounsaturated and polyunsaturated fat must replace saturated fat, and there is no dose-response relationship between mono- and polyunsaturated fats to risk of CHD, independent of saturated fat, similar to the relationship between *trans* fat and risk of CHD. Therefore, we decline to require the declaration of monounsaturated and polyunsaturated fat. A quantitative intake recommendation is a factor we considered for mandatory declaration of these types of non-statutory nutrients (79 FR 11879 at 11890).

b. DRV. The proposed rule would not establish DRVs for either monounsaturated or polyunsaturated fat because quantitative intake recommendations are not available for setting DRVs (79 FR 11879 at 11897, 11899).

(Comment 100) One comment agreed with not setting a DRV for monounsaturated or polyunsaturated fat because there is no agreed upon scientific basis for establishing a DV due to diverse nature of these fatty acids.

(Response) We maintain that there is an insufficient basis to set a DRV for either monounsaturated or polyunsaturated fat, so the final rule does not establish a DRV for either monounsaturated or polyunsaturated fat.

c. Declaration of individual polyunsaturated fatty acids. Polyunsaturated fats represent two general categories: n-6 and n-3 polyunsaturated fatty acids. The most common n-6 and n-3 polyunsaturated fatty acid in food is linoleic acid and α-linolenic acid, respectively. Other n-3 fatty acids found in foods, particularly in fish, are the long chain fatty acids, eicosapentaeneoic acid (EPA) and docosahexaenoic acid (DHA).

The preamble to the proposed rule (79 FR 11879 at 11898) discussed the possibility of establishing separate DRVs for linoleic acid and α-linolenic acid, and, if so, whether the declaration of these nutrients should be voluntary or made mandatory. We decided that, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Thus, the proposed rule would not provide for the individual declaration of either n-3 or n-6 polyunsaturated fatty acids on the Nutrition Facts label. Similarly, because of the lack of well-established evidence for a role of EPA and DHA in chronic disease risk and the lack of a quantitative intake recommendation, the proposed rule would not provide for the declarations of EPA and DHA.

(Comment 101) Although some comments agreed with our decision not to require the declaration of n-3 or n-6 polyunsaturated fatty acids, other comments would revise the rule to allow for the voluntary declaration of the n-3 polyunsaturated fatty acids, eicosapentaeneoic acid (EPA), and docosahexaenoic acid (DHA). One comment supported the voluntary declaration of EPA and DHA because humans have a limited capability to synthesize, elongate, and desaturate α-linolenic acid (ALA) to EPA and DHA.

(Response) While humans may have a limited capability to elongate and desaturate ALA to EPA and DHA, we do not have evidence to demonstrate that biosynthesis of EPA and DHA is insufficient in the general population such that EPA and DHA are essential in the diet. Therefore, there is no basis on which we can rely to support a voluntary declaration.

(Comment 102) Other comments supporting the voluntary declaration of n-3 and n-6 polyunsaturated fatty acids noted that monounsaturated fat, polyunsaturated fat, sugars, soluble fiber, insoluble fiber, sugar alcohols, and added sugars are being allowed or required on the label but do not have a DV. Therefore, the comments argued, we should treat n-3 and n-6 polyunsaturated fatty acids in the same manner.

(Response) There is well-established evidence for the role of sugars, monounsaturated fat, polyunsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols in reducing the risk of chronic disease or providing a beneficial physiological effect. Therefore, these nutrients have public health relevance, which is the basis for voluntary labeling. Specifically, there is strong evidence for sugars increasing the risk of dental caries (see 79 FR 11879 at 11902), as well as reducing the risk of dental caries when sugar alcohols replace sugar in the diet (id. at 11908). There also is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fat reduces the risk of CVD (Ref. 35). There is strong evidence that soluble fibers reduce the risk of CHD (see 79 FR 11879 at 11911). There is well established evidence that insoluble fibers can improve laxation, a beneficial physiological effect (Ref. 36). Moreover, the scientific evidence for added sugars differs from that for n-3 and n-6 polyunsaturated fatty acids. There is a strong association between a healthy dietary pattern characterized by a lower intake of sugar sweetened foods and beverages, as compared to less healthy dietary patterns, and a reduced risk of CVD. A DV is being provided for added sugars (see part II.H.3).

In contrast, there is supportive, but not conclusive, evidence to suggest that n-3 polyunsaturated fatty acids reduce the risk of CHD (Ref. 37). Furthermore, there is no conclusive evidence for an independent role of n-6 polyunsaturated fatty acids in reducing blood cholesterol levels, and consequently, risk of CHD (see 79 FR 11879 at 11898). Therefore, we disagree that there is a sufficient basis to treat n-3 and n-6 polyunsaturated fatty acids the same as

the other nutrients discussed in the comment, so the final rule does not provide for voluntary declaration of n-3 and n-6 polyunsaturated fatty acids.

(Comment 103) One comment supporting the voluntary declaration of n-3 polyunsaturated fatty acids said that we could have reached the same conclusion for n-3 polyunsaturated fatty acid in the same way that we did for vitamin D. The 2010 DGA recommendation to increase the amount and variety of seafood in place of some meat and poultry was made to increase EPA and DHA in the American diet, as well as the total package of benefits seafood provides, including vitamin D.

(Response) We disagree that n-3 polyunsaturated fatty acids were handled differently than vitamin D. There is strong evidence for a relationship between vitamin D intake and risk of osteoporosis (see 79 FR 11879 at 11921). Furthermore, the IOM provided a quantitative intake recommendation (*i.e.,* RDA) for vitamin D (Ref. 38). We considered the scientific evidence for this recommendation when setting an RDI (see our response to comment 372). In contrast, the evidence for n-3 polyunsaturated fatty acids is not well-established, and a quantitative intake recommendation is not available (see 79 FR 11879 at 11897 through 11899).

(Comment 104) Several comments supporting the voluntary declaration of n-3 polyunsaturated fatty acids stated that not providing information on n-3 polyunsaturated fatty acids affords the consumer little opportunity to apply important dietary guidance as in the 2010 DGA. The comments said that, while the IOM did not set a DRI for EPA and/or DHA, this is an insufficient reason for disallowing the voluntary declaration of these essential fatty acids on the Nutrition Facts label. The comments said that the DGA concluded that moderate evidence indicates that 250 mg EPA and DHA daily is associated with reduced cardiac deaths among individuals with and without preexisting CVD and this recommendation contributes to prevention of heart disease. The comments also noted that, while we have not authorized a health claim regarding EPA and DHA and CVD risk, we have allowed the use of qualified health claims for 10 years.

(Response) The 2010 DGA concluded that moderate evidence shows that the consumption of 8 ounces per week of a variety of seafood, which provides an average consumption of 250 mg per day of EPA and DHA, is associated with reduced cardiac deaths among individuals with and without preexisting CVD. A DGA key recommendation was not provided for EPA and DHA, but rather for seafood. It is not clear whether EPA and DHA per se, or other substances in fish contribute to cardiac deaths. The qualified health claim on EPA and DHA and CVD risk is supportive, but not conclusive, evidence to suggest that n-3 polyunsaturated fatty acids reduce the risk of CHD (Ref. 37). The factors for mandatory and voluntary labeling of these types of non-statutory nutrients on the Nutrition Facts label depend on strong (rather than moderate or inconclusive) evidence. Therefore, we disagree that the information provided in the 2010 DGA report is sufficient to warrant the voluntary declaration of EPA and DHA.

(Comment 105) One comment supporting the voluntary declaration of n-3 polyunsaturated fatty acids noted that an article on a summary of a workshop stated that, ''National public health initiatives to increase n-3 fatty acid consumption are needed: The working group believes that data are currently sufficient to indicate that intake of n-3 fatty acids is suboptimal and a national and international initiative should be launched to shift n-3 fatty acid intake upward'' (Ref. 39). Another comment cited a paper which concluded that a large percentage of the U.S. adult population is not meeting recommendations for omega-3 fatty acid consumption set forth by the 2010 DGA (Ref. 40). One comment cited an article that evaluated intakes of ALA, EPA, and DHA intake in children 4 to 8 years of age (Madden *et al.*, 2009).

(Response) We disagree with the comments' interpretation of the cited articles. With respect to the cited articles, we note that the Akabas and Decklebaum article did not provide information to explain the basis for concluding that the intake of n-3 polyunsaturated fatty acids is suboptimal. The Papanikolaou article used 250 mg/day to assess adequacy of intake, however, the value was not a recommendation put forth by the 2010 DGA. The article by Madden *et al.* (2009) used the AI of 900 mg/day to assess adequacy of ALA, and 10 percent of this value (90 mg/day) was used to assess intake adequacy for EPA and DHA. We disagree with how Madden (Ref. 41) assessed nutrient intake for EPA and DHA because the IOM did not set an AI or EAR for EPA and DHA. The IOM only noted that EPA and DHA contribute approximately 10 percent of the total n-3 polyunsaturated fat intake (Ref. 29). There is no quantitative intake recommendation (*i.e.,* EAR) available for assessing inadequate intake in populations. Furthermore, there are a number of nutrients for which there is suboptimal intake which was considered as part of the factors for mandatory or voluntary declaration. However, we did not rely on suboptimal intake alone for such voluntary declarations in the Nutrition Facts label.

(Comment 106) Other comments supporting the voluntary declaration of n-3 polyunsaturated fats cited published articles or gave Web site addresses to discuss the health benefits of these fatty acids.

(Response) We have reviewed the articles and Web sites and, based on our review, decline to revise the rule to provide for the voluntary declaration of n-3 polyunsaturated fats.

- Many articles were review articles or meta-analyses that included studies that tested individuals who had a previous coronary event; therefore, the studies were evaluating the effect of the n-3 polyunsaturated fatty acids on secondary prevention of CVD (Refs. 42–47). Furthermore, some articles included observational studies on the association between the intake of polyunsaturated fatty acids and CVD risk. Scientific conclusions from such studies are not sufficient to support conclusions about the causal role of these n-3 polyunsaturated fatty acids on CHD risk in the general population.
- One article (Ref. 48) was a one-page abstract from a meeting. The Web site address that was cited (*http://www.goedomega3.com/healthcare*) is a general resource for health care professionals. Another Web site provided a list of organizations that have intake recommendations for EPA and DHA (*http://www.goedomega3.com/index.php/files/download/304*). None of the citations provided information that we would consider for voluntary declaration of EPA and DHA related to a relationship between these nutrients and risk of CHD.
- One article (Ref. 49) evaluated the relationship between plasma phospholipid EPA and DHA as a biomarker of intake and mortality. Figure 2 of this article showed that the dose-response relationship between EPA and DHA intake and plasma phospholipid EPA and DHA was not linear and plateaued at around 0.5 grams/day. Therefore, plasma phospholipid EPA and DHA is not a reliable indicator of EPA and DHA consumption, and scientific conclusions could not be drawn from such as study.
- One article (Ref. 50) was on an animal study that tested the effect of DHA on melanoma. The article did not present the totality of the evidence on DHA and risk of melanoma.

Furthermore, we would not rely on animal data for evaluating the efficacy of DHA to reduction of risk to melanoma in humans to establish a nutrient declaration.

• One article (Ref. 51) was a meta-analysis on EPA and DHA intake and blood pressure. There are several limitations of this meta-analysis including: (1) Not providing all of the relevant studies on EPA and DHA and blood pressure; (2) including studies that lacked an appropriate control group; and (3) including studies that conducted inappropriate statistical analyses.

• One article (Ref. 52) was an European Food Safety Association (EFSA) scientific opinion on a labeling reference value for n-3 and n-6 polyunsaturated fatty acids in which EFSA provided a recommended intake level of 250 mg/day of EPA and DHA. The article did not discuss the scientific evidence in detail to show how this quantitative intake recommendation was determined. Furthermore, while the scientific opinion cited several references to support 250 mg/day, a number of these included observational data in which information was obtained on fish consumption. The IOM did not set a DRI for EPA or DHA because much of the observational evidence measured fish or fish oil intake as a proxy for n-3 polyunsaturated fat intake, and other components in fish may have effects that are similar to n-3 fatty acids and therefore may confound the results of the observational studies (Ref. 29).

(Comment 107) Some comments supporting the voluntary declaration of individual polyunsaturated fatty acids discussed consumer use or consumer understanding as reasons for allowing voluntary declaration.

One comment cited the 2014 IFIC Food and Health survey data to assert that the data suggests that voluntary declaration of individual polyunsaturated fatty acids is necessary for the consumer to make the purchase decisions that they intend. The comment indicated that 21 percent of consumers are looking to increase their omega-3 intake.

Some comments stated that a distinction between the different n-3 polyunsaturated fatty acids is necessary so that consumers seeking specifically EPA or DHA are not misled by voluntary declaration of polyunsaturated fat, because the levels are inflated by the presence of n-6 polyunsaturated fatty acids and ALA. The comments said that, while 85 percent of Americans are aware the n-3 polyunsaturated fatty acids reduce the risk CHD, not all n-3 polyunsaturated fatty acids are equal.

Other comments said that, while manufacturers may express the content of EPA and DHA in a product bearing a claim, doing so outside the Nutrition Facts label denies the consumer an opportunity to recognize if a meaningful amount of these fatty acids are provided relative to the other fats in the product.

(Response) We recognize that the 2014 IFIC survey concluded that 21 percent of consumers are trying to increase their consumption of omega-3 fats. We also recognize that the majority of polyunsaturated fats in foods are in the form of n-6 polyunsaturated fatty acids and that not all n-3 polyunsaturated fatty acids have the same effect on CHD risk. However, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Because neither of these factors for voluntary declaration for these types of nutrients has been met, and the comments provided no scientific basis on which we could rely to support the declaration, we disagree that meaningful amounts of EPA and DHA should be voluntarily listed to provide its amount relative to the other fats in the product.

(Comment 108) Some comments supporting the voluntary declaration of n-3 polyunsaturated fatty acids stated that the recognition of only polyunsaturated fat may have unintended consequences of consumers failing to understand differences in biopotency of n-3 long-chain polyunsaturated fatty acids compared to other polyunsaturated fatty acids. According to the comments, not declaring n-3 polyunsaturated fatty acids may confuse consumers who are not aware of differences among individual polyunsaturated fatty acids with respect to their ability to reduce heart disease risk.

(Response) We disagree that potential differences in biopotency of n-3 polyunsaturated fatty acids is a basis for voluntary declaration. While there may be differences in biopotency with respect to CHD risk, there is insufficient scientific evidence and information to warrant voluntary declaration.

With respect to possible consumer confusion and unintended consequences, the comments did not describe the extent to which consumers might be confused or what the unintended consequences might be, so we do not have sufficient information to evaluate those aspects of the comments.

G. Cholesterol

1. Mandatory Declaration

Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of cholesterol on food labels, and cholesterol content must be declared on the Nutrition Facts label in accordance with § 101.9(c)(3). In the preamble to the proposed rule (79 FR 11879 at 11899), we explained that current dietary recommendations continue to recognize the well-established relationship between consumption of cholesterol and its effect on blood cholesterol levels, which are a surrogate endpoint for CHD risk and that we were unaware of evidence that would support a change to the requirement for mandatory declaration of cholesterol on the Nutrition Facts label in § 101.9(c)(3). Consequently, we did not propose any changes to the requirement for mandatory declaration of cholesterol.

Relying on information provided in the NHLBI Lifestyle Evidence Review (Ref. 17), the 2015 DGAC Report concluded that cholesterol is not a nutrient of public health concern (Ref. 19). The 2015–2020 DGA noted that, while adequate evidence is not available for a quantitative limit for dietary cholesterol specific to the Dietary Guidelines, individuals should eat as little dietary cholesterol as possible while consuming a healthy dietary pattern that includes eggs and shellfish (Ref. 28).

Much of the published evidence, as was analyzed and reported by the IOM (Ref. 53), has demonstrated a positive association between cholesterol intake and total cholesterol in the blood. The IOM conducted a dose-response analysis of clinical trials to evaluate the relationship between dietary cholesterol and blood total cholesterol because most of the available evidence was on total cholesterol (Ref. 53). From this IOM analysis, it was concluded that, on average, an increase of 100 mg/day of dietary cholesterol is predicted to result in a 0.05 to 0.1 mmol/L increase in total serum cholesterol, of which approximately 80 percent is in the LDL fraction. The IOM cited evidence showing that the majority of the increase in serum total cholesterol with increased dietary cholesterol was due to an increase in LDL cholesterol (rather than HDL) concentration, therefore adversely affecting the cholesterol profile. The IOM analysis was the basis for the IOM concluding that cholesterol consumption should be as low as

possible while consuming a nutritionally adequate diet.

Data from NHANES (2007–2010) show that, for all individuals over 1 year of age, 32 percent consume cholesterol in excess of the DRV of 300 mg. For men and women 19 years of age and older, 59 percent and 17 percent consume in excess of 300 mg/day of cholesterol, respectively. These findings are indicative that a significant portion of the U.S. population consumes amounts of cholesterol in excess of the DRV of 300 mg.

We do not consider there to be new information that alters the conclusions of the 2002 IOM report. Therefore, we conclude that the declaration of cholesterol on the Nutrition Facts label can assist consumers in maintaining healthy dietary practices and therefore should remain mandatory.

(Comment 109) One comment supporting mandatory declaration of cholesterol noted that the 2002 IOM report (Ref. 53) showed a strong positive relationship between cholesterol intake and increased LDL cholesterol levels. The comment cited a meta-analysis of clinical studies in which people consumed eggs or a cholesterol-free egg substitute found that LDL cholesterol rose by 2 mg/dL for every 100 mg of cholesterol consumed (Ref. 54).

(Response) While the 2002 IOM report provided its own analysis that evaluated the relationship between dietary cholesterol and cholesterol levels, it specifically evaluated total cholesterol levels, rather than LDL cholesterol levels. The IOM reported a positive association between change in cholesterol intake and change in total cholesterol levels which supports our position for mandatory listing. We recognize that the meta-analysis cited in the comment (Weggemans et al. 2001 (Ref. 54)) estimated that each additional 100 mg of dietary cholesterol would increase serum LDL cholesterol by 0.036 (1.4 mg/dL) in the studies with a background diet low in saturated fat and by 0.061 (2.4 mg/dL) in the studies with a background high in saturated fat (P = 0.03). However, this study only evaluated the effect of cholesterol from eggs rather than total dietary cholesterol. Thus, this meta-analysis, by itself, is insufficient to evaluate the effect of total cholesterol intake on blood cholesterol levels, and therefore CVD risk.

(Comment 110) Some comments opposed mandatory declaration of cholesterol because, the comments said, saturated fat has the biggest negative impact on blood cholesterol. The comments said that the EFSA concluded that, ''Although there is a positive-dose-dependent relationship between the intake of dietary cholesterol with blood LDL cholesterol concentrations, the main dietary determinant of blood LDL cholesterol concentrations is saturated fat.'' Other comments said there is not enough evidence on the effect of dietary cholesterol on blood cholesterol, the relationship between cholesterol consumption and blood cholesterol levels is weak and has been overestimated, and cholesterol intake does not raise blood cholesterol levels. Some comments cited several meta-analyses that concluded that there were small, modest reductions in serum cholesterol with reductions (*e.g.,* 100 mg/day) in dietary cholesterol (Refs. 55–57).

(Response) We agree that saturated fat has a larger impact on raising blood cholesterol levels. We disagree that there is not enough evidence or that the evidence for the cholesterol-raising effects of dietary cholesterol is weak or does not exist. Numerous clinical studies have reported a cholesterol-raising effect of dietary cholesterol (Ref. 53). Using such studies, the IOM illustrated a curvilinear relationship between change in dietary cholesterol and change in serum total cholesterol levels ranging from 0 to 4,500 mg/day, with the greatest change (increase) in serum cholesterol occurring with an increased cholesterol intake of up to 50 mg/day.

The comments about EFSA support mandatory listing of both cholesterol and saturated fat because EFSA recognizes that intake of both nutrients have a positive association with blood cholesterol levels.

The final rule, therefore, does not change the pre-existing requirement for mandatory declaration of cholesterol.

(Comment 111) Some comments opposed to mandatory declaration of cholesterol noted that the NHLBI Lifestyle Evidence Review (Ref. 17) states that there is insufficient evidence to determine whether lowering dietary cholesterol reduced LDL cholesterol in the blood.

(Response) While we recognize the conclusion of the NHLBI Lifestyle Evidence Review in addition to blood LDL cholesterol being a surrogate endpoint for CHD risk, blood total cholesterol is also considered a valid predictor of CHD risk as approximately 80 percent of total cholesterol is LDL cholesterol (Ref. 29). The NHLBI Lifestyle Evidence Review did not review the findings for blood total cholesterol. Much of the evidence, as was analyzed and reported by the IOM (2002), demonstrated a positive association between cholesterol intake and total cholesterol in the blood. While the 2015 DGAC concluded that there was no appreciable relationship between the consumption of dietary cholesterol and serum cholesterol, the only information the DGAC considered was that in the NHLBI Lifestyle Evidence Review, which was specific to studies that measured LDL cholesterol.

(Comment 112) One comment opposed to mandatory declaration of cholesterol stated that clinical trials have identified individuals across all ages who have very limited or no increase in plasma cholesterol as a result of additional dietary cholesterol. The comments said that, even among hyper-responders (high response in blood cholesterol to dietary cholesterol), the response is an increase in both LDL and HDL cholesterol levels, such that the LDL/HDL ratio, a key marker of CHD risk, does not change (Refs. 58–61). Furthermore, the comments said, the amounts of cholesterol provided in clinical trials are well in excess of normal consumption.

(Response) We agree that individual's blood cholesterol levels respond differently to dietary cholesterol; this difference in individual response is true for most nutrients when they are associated with chronic disease risk. We disagree that differences in individual response is a basis for not considering the numerous studies showing that cholesterol intake raises average blood cholesterol levels. The reported findings on blood cholesterol levels from clinical trials usually represent the averages of these blood levels of the study subjects, including those who respond and those who do not respond. Assessment of the average findings from clinical studies is more relevant because the Nutrition Facts label is intended for the general U.S. population.

We also disagree that the ratio of LDL cholesterol to HDL cholesterol is a key marker of CHD risk. We do not consider HDL cholesterol, and therefore the LDL:HDL cholesterol ratio, to be a key marker (*i.e.,* surrogate endpoint) of CHD risk. Blood HDL cholesterol has not been qualified as being a strong predictor of CHD risk. Therefore, the evidence on LDL cholesterol outweighs any evidence on the LDL:HDL cholesterol ratio with respect to evaluating the role of cholesterol in CHD risk.

(Comment 113) Some comments opposed to the mandatory declaration of cholesterol said that the 2010 DGA stated that an egg a day does not increase blood cholesterol levels, that eggs are not associated with greater risk of CVD, and that eggs are nutrient-dense. Other comments cited a number

of studies and meta-analyses (Refs. 62–66) concluding that there was not an association between egg consumption and CVD or CHD risk.

(Response) We recognize that the 2010 DGA noted that evidence suggests that one egg (*i.e.,* egg yolk) per day does not result in increased blood cholesterol levels, nor does it increase the risk of cardiovascular disease in healthy people. The 2010 DGAC, however, noted that, while eggs are a major source of cholesterol in the American diet, eggs and egg mixed dishes provide 25 percent of total cholesterol intake. Therefore, we do not consider studies involving only eggs to be sufficient to understand the role of total cholesterol intake on CVD risk.

As for the comments stating that eggs are nutrient-dense, the mandatory declaration of cholesterol relates to the relationship between cholesterol intake from consumption of all food sources, as part of the total daily dietary intake, and risk of CHD. Therefore, the comment does not change our conclusion about the scientific basis for the mandatory declaration of cholesterol. As we stated in the preamble to the proposed rule (79 FR 11879 at 11899), current dietary recommendations continue to recognize the well-established relationship between consumption of cholesterol and its effect on blood cholesterol levels, which are a surrogate endpoint for CHD risk. We continue to believe that information regarding cholesterol is necessary to assist consumers in maintaining healthy dietary practices.

As for the studies cited in the comments, the studies do not imply that total cholesterol intake (from all dietary sources) does not contribute to CHD risk. Consequently, rather than view eggs and cholesterol content in eggs in isolation, our Nutrition Facts label provides information to help the consumer understand the ''relative significance'' of eggs and their cholesterol content in the context of a ''total daily diet'' (see section 2(b)(1)(A) of the NLEA).

(Comment 114) Some comments opposed to mandatory declaration of cholesterol stated that dietary cholesterol has been proven to be unrelated to CVD and CVD mortality. The comments cited review articles (Refs. 67–68) to assert such studies do not support a connection between dietary cholesterol and CHD events. The review articles summarized observational studies, as well as some clinical trials, that questioned an association between cholesterol intake and risk of CHD.

(Response) We agree that some observational studies have failed to support an association between dietary cholesterol and CHD events. However, we put greater reliance on clinical trials when substantiating nutrient and disease relationships. Observational studies measure associations between foods/nutrients and diseases without demonstrating that the food or nutrient caused, in part, the change in risk of a chronic disease. The IOM (2002) (Ref. 29) noted that the lack of consistency in observational studies on dietary cholesterol may be due to many factors, including inaccuracies of dietary intake data, and to the limited ability to distinguish the effects of dietary cholesterol, independent of energy intake and other dietary variables that may be positively (*e.g.,* saturated fat) or negatively (*e.g.,* dietary fiber intake) associated with dietary cholesterol and heart disease risk. Individual studies, as well as an analysis of a number of these studies (Ref. 29), have demonstrated a positive association between cholesterol intake and total cholesterol, which is a risk factor of CHD. Therefore, we rely on the best available data and use clinical trial data more heavily than observational data when they are available for evaluating the role of dietary cholesterol in CHD risk. These two review articles (Refs. 67–68) also cited clinical trial data and noted that, while dietary cholesterol raises LDL cholesterol, it also raises HDL cholesterol and therefore does not change the LDL:HDL ratio. While LDL cholesterol is considered a surrogate endpoint for CHD risk, HDL is not. Therefore, the LDL:HDL ratio is not relied on for evaluating CHD risk.

(Comment 115) One comment opposed to the mandatory declaration of cholesterol stated that the evidence is questionable for an association between cholesterol intake and risk of type 2 diabetes.

(Response) Whether or not the evidence supporting cholesterol's role in type 2 diabetes risk may be questionable, the basis for mandatory declaration of cholesterol on the label is because of its role in CHD risk.

(Comment 116) One comment opposed to the mandatory declaration of cholesterol said that overconsumption of cholesterol is not a concern in the United States. The comment said that the average dietary cholesterol intake reported by CDC is 307 mg/day for men and 225 mg/day for women and that, among men, the average consumption exceeds 300 mg/day by only 2 percent while, among women, the average consumption is 25 percent below 300 mg/day (NHANES 1999–2000).

(Response) We disagree with the comment. Data from NHANES (2007–2010) show that, for all individuals over 1 year of age, 32 percent consume cholesterol in excess of 300 mg/day. For men and women 19 years of age and older, 59 percent and 17 percent consume in excess of 300 mg/day of cholesterol, respectively. These findings are indicative that a significant portion of the U.S. population consumes amounts of cholesterol in excess of the DRV of 300 mg. Therefore, we decline to make changes in response to this comment.

(Comment 117) Other comments opposed the mandatory declaration of cholesterol for several reasons. The comments said that:

- Consumers who want to take care of their blood cholesterol levels may orient their food choices only towards foods that contain low amounts of cholesterol, regardless of their saturated fat content. A focus on saturated fat may lead to better results in terms of public health.
- Listing cholesterol could have a negative impact on protein intake. According to the comments, because most meat and other protein rich foods also contain cholesterol, cholesterol declaration will likely dissuade consumers from eating protein-rich foods. The result will be an increase in the consumption of carbohydrate-rich foods, causing delayed satiety and contributing to increased caloric consumption.

(Response) We require declaration of cholesterol on the Nutrition Facts label pursuant to section 403(q) of the FD&C Act. Cholesterol intake is related to the risk of CHD. The comments did not provide information on the impact of the mandatory declaration of cholesterol on the consumer's intake of saturated fat, protein or carbohydrate-rich foods. We are not aware of information indicating that mandatory listing of cholesterol over the past 20 years has resulted in more focus on cholesterol, less focus on saturated fat, and reduced intake of protein-rich foods. We consider the declaration of cholesterol is necessary to assist consumers maintain healthy dietary practices and are making no changes in response to this comment.

(Comment 118) One comment said that mandatory declaration of cholesterol was not necessary because cholesterol consumption has not been a concern for a long time in treating patients with high cholesterol levels.

(Response) The Nutrition Facts label is intended for the general U.S. population, and nutrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and there is a strong relationship between dietary cholesterol intake and total serum

cholesterol which is a marker of CVD risk (see 79 FR 11879 at 11887 and part II.C.).

(Comment 119) One comment opposed to the mandatory declaration of cholesterol said that the U.S. government's advice to reduce cholesterol intake is unusual compared to other countries in focusing on dietary cholesterol. The comment said that dietary recommendations in other countries, such as Canada, do not have an upper limit for cholesterol intake and, instead, focus on saturated and *trans* fat.

(Response) There is a strong relationship between dietary cholesterol intake and total serum cholesterol which is a marker of CVD risk. Section 403(q)(2)(B) of the FD&C Act authorizes us to remove, by regulation and under certain circumstances, nutrient information. We would need a scientific basis about the relationship between total cholesterol intake and CVD risk to no longer require the mandatory declaration of cholesterol. While other countries may not require the listing of cholesterol on their food labels, section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of cholesterol on the food label. The fact that other countries lack cholesterol recommendations is, alone, an insufficient reason for us to no longer require the mandatory listing of cholesterol.

2. DRV

Our preexisting regulations, at § 101.9(c)(9), provide a DRV for cholesterol of 300 mg. In the preamble to the proposed rule (79 FR 11879 at 11899), we discussed how the IOM Labeling Committee had recommended that the DV for cholesterol (along with saturated fat and *trans* fat) be set at a level that is as low as possible in keeping with an achievable health-promoting diet and how, in the 2007 ANPRM, we asked for public comment on whether the current DRV for cholesterol of 300 mg should be retained. We also noted that, although the 2010 DGA recommended that cholesterol intake levels should be less than 200 mg/day for individuals at high risk of CVD, we considered the DGA recommendation of 300 mg/day for maintaining normal blood cholesterol levels as an appropriate basis for setting a DRV because it represents the maximum intake level that covers the general U.S. population 4 years of age and older (id.). Consequently, we did not propose changes to the DRV for cholesterol of 300 mg specified in § 101.9(c)(9).

(Comment 120) One comment did not support a DRV for cholesterol because cholesterol is made in the body.

(Response) We agree that cholesterol is made in the body and is therefore not essential in the diet. However, the basis for the DRV is an intake level not to exceed to reduce the risk of CHD, rather than an intake level to achieve (*e.g.,* a DV for essential vitamins and minerals). Therefore, we decline to revise § 101.9(c)(9) insofar as a DRV for cholesterol is concerned.

H. Carbohydrate

1. Total Carbohydrate

a. Calculation of total carbohydrate. Under our preexisting regulations, at § 101.9(c)(6), total carbohydrate content is calculated by subtracting the sum of protein, total fat, moisture, and ash from the total weight of the food. This calculation method is called ''carbohydrate by difference'' and is described in A.L. Merrill and B.K. Watt, ''Energy Value of Foods—Basis and Derivation,'' in the USDA Handbook No. 74 (Ref. 69). Total carbohydrate includes starch, sugars, sugar alcohols, and dietary fiber.

We did not propose to change the method for calculating carbohydrate content.

(Comment 121) While some comments agreed with our decision to retain the calculation method for total carbohydrate content, other comments suggested that dietary fiber should not be included in the declaration of total carbohydrate. The comments stated that a significant number of consumers, especially individuals who have diabetes, want to know the amount of carbohydrates excluding dietary fiber (also known as ''net carbs'') because it is helpful to know when trying to control blood glucose. One comment recommended that carbohydrate should be calculated by difference, but that moisture, fat, protein, dietary fiber, and ash should be excluded from the declaration of carbohydrate. The comment suggested that the benefits of such an approach include easy comparison of carbohydrates between food choices that do or do not contain dietary fiber, easy calculation of calories from carbohydrates with a value of 4 calories per gram, and easy calculation of calories from dietary fiber with a value of approximately 2 calories per gram. In addition, the comment stated that such an approach would encourage manufacturers to increase the dietary fiber content of their product without increasing the carbohydrate content of their product and that it would simplify consumer education and understanding. The comment further stated that nutrient databases can easily exclude dietary fiber from the calculation of carbohydrate because analytical laboratories are easily able to determine total carbohydrate by excluding protein, total fat, moisture, dietary fiber, and ash from the total weight of the food and nutrient composition tables will continue to change on a regular basis to provide new and updated data.

(Response) We decline to change the current method of calculating carbohydrate by difference. Total carbohydrate is one of the macronutrients and includes starch, sugars, sugar alcohols, and fiber. As discussed in the preamble to the proposed rule (79 FR 11879 at 11900), dietary fibers, with the exception of lignin, are considered carbohydrates and are listed as a subset of total carbohydrate on the label. Individuals who are interested in knowing the amount of carbohydrate in a serving of a product less the amount of dietary fiber may determine this information based on what is currently declared on the label. Because dietary fibers are a type of carbohydrate, to maintain consistency with how components of macronutrients are declared on the label, we decline to remove dietary fiber from the calculation of total carbohydrate, as suggested by the comments.

With respect to comments suggesting that dietary fiber should be excluded from the calculation of total carbohydrate because such a change would be helpful to diabetics when managing their blood sugar levels, we disagree that this should be a reason to remove dietary fiber from the declaration of carbohydrate. The information found in the Nutrition Facts and Supplement Facts labels is not targeted to individuals with acute or chronic diseases, such as diabetics (see part II.B.2; 79 FR 11879 at 11887).

We also disagree that removal of dietary fiber from the declaration of total carbohydrate would allow consumers to compare products that do and do not contain dietary fiber more easily. It is not clear how the comparison would be made easier by removal of dietary fiber from the total carbohydrate declaration because, if the consumer is interested in knowing how much dietary fiber is in a product, the consumer can take that information into consideration by looking for the declaration of the amount of dietary fiber on the label.

Calories from total carbohydrate may be declared voluntarily on the label. We discuss calculation of calories from total carbohydrate in greater detail later in

this part. We agree that additional steps are necessary to calculate calories from total carbohydrates when dietary fiber is included in the declaration. However, we did not receive any comments that the calculation of total carbohydrate when dietary fiber is included in the declaration would be unnecessarily burdensome or difficult for manufacturers to perform. The calculation would not require additional laboratory analysis or expense.

We disagree that exclusion of dietary fiber from the declaration of total carbohydrate would encourage manufacturers to raise dietary fiber values independent from raising carbohydrate values. So long as the dietary fiber added to a product meets our definition of dietary fiber, the additional fiber added by the manufacturer would be reflected in the dietary fiber declaration. Consumers who are interested in consuming more dietary fiber may use the dietary fiber declaration to determine which products they purchase. Therefore, it is not clear how removing dietary fiber from the declaration of carbohydrate on the label would encourage manufacturers to add dietary fiber to their products.

With respect to the assertion that exclusion of dietary fiber from the calculation of total carbohydrate simplifies the education process and understanding for consumers, absent additional information, we are unable to judge whether such a change would lead to better understanding of the total carbohydrate and/or dietary fiber declaration on the label, and thus, whether consumers would benefit from such a change in how carbohydrate is calculated.

With respect to the comment asserting that nutrient databases can easily exclude dietary fiber from the calculation of carbohydrate, we disagree that this is a reason to exclude dietary fiber from the calculation of total carbohydrate. Although nutrient databases may be updated, we decline to exclude dietary fiber from the calculation of total carbohydrate because dietary fiber is a carbohydrate and should be declared as such to maintain consistency with how other macronutrients are determined and declared on the label.

(Comment 122) One comment encouraged us to conduct consumer studies to examine if the separation of dietary fiber from total carbohydrate on the label would benefit the overall use of the Nutrition Facts label as a tool for nutrition literacy and education.

(Response) We are always interested in understanding how consumers interpret and use information on the label. However, we are not aware of a specific need, and the comment did not specify how this information could aid consumers. Therefore, we decline to conduct these studies. We will consider conducting such studies if we have information showing that there is a need for these studies and we have the resources available to conduct such studies.

b. Classification of carbohydrates based on a chemical definition or physiological effect. The preamble to the proposed rule (79 FR 11879 at 11900 through 11901) discussed how the 2007 ANPRM invited comment on whether carbohydrates should be classified and declared in nutrition labeling based on their chemical definition (which is the current method) or on their physiological effect (*e.g.,* attenuation of blood sugar or laxation), and whether additional types of carbohydrates (*e.g.,* starch) should be listed separately on the Nutrition Facts label. We explained that carbohydrates include starch, sugars, sugar alcohols, and dietary fibers and that different carbohydrates have different physiological effects (id. at 11901). Within the different types of carbohydrate (*i.e.,* starch, sugars, sugar alcohols, and dietary fibers), too, specific carbohydrates may have different physiological effects (*e.g.,* different types of dietary fibers) making it difficult to apply a definition that is based on physiological effects across a category of carbohydrates. Furthermore, analytical methods for measuring different types of carbohydrates are based on chemical structure rather than physiological effect. Given the various components of total carbohydrate and different types of physiological effects of each, we decided not to change our provisions for the classification or declaration of carbohydrates specified in § 101.9(c)(6).

(Comment 123) One comment recommended that complex carbohydrates should be listed separately under total carbohydrate on the label. The comment stated that people do not understand that they have to subtract in order to get an idea of how much good carbohydrates are in a food product.

(Response) We decline to list complex carbohydrates separately on the label. The comment did not provide any information to explain what is considered to be a ''complex'' or ''good carbohydrate,'' and it did not explain what subtraction method can be used to calculate ''good'' or ''complex'' carbohydrates from information found on the label.

We have allowed for voluntary declaration of ''other carbohydrate'' on the Nutrition Facts label (§ 101.9(c)(6)(iv)). Our regulations define ''other carbohydrate'' as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared, ''other carbohydrate'' is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars (§ 101.9(c)(6)(iv)). Thus, the category of ''other carbohydrate'' includes what are typically considered to be complex carbohydrates. As discussed in part II.H.6, the final rule does not permit the category of ''other carbohydrate'' to be declared on the label.

c. Separate declaration of additional individual types of carbohydrates. In the preamble to the proposed rule (79 FR 11879 at 11901), we discussed how the 2007 ANPRM asked whether additional types of carbohydrates (*e.g.,* starch) should be listed separately on the Nutrition Facts label. We stated that the comments we received in response to the 2007 ANPRM did not support the declaration of additional types of carbohydrates (*e.g.,* starch). Thus, the proposed rule would not require the separate declaration of additional types of individual carbohydrates, such as starch, on the Nutrition Facts label.

(Comment 124) Several comments discussed Allulose. Allulose (also known as psicose) is a monosaccharide that is derived from fructose. According to the comments, Allulose is approximately 70 percent as sweet as sucrose, but contributes less than 0.2 calories/gram to the diet. The comments said that Allulose is added to foods and beverages as a partial replacement for sugars and/or high-fructose corn syrup because of its low, near zero, calorie content and other organoleptic properties (*e.g.* mouthfeel, texture, etc.).

One comment said we should not include Allulose in the declaration for total carbohydrate and added sugar. In contrast, another comment said Allulose should be included in the declaration of ''total carbohydrate'' for nutrition labeling purposes, but should not be included in the declaration of ''sugars'' or ''added sugars.'' The comments suggested that Allulose does not have the metabolic properties of fructose or other sugars and does not contribute calories or raise blood sugar levels like other sugars do. The comments said that, upon ingestion, approximately 70 percent of Allulose is unabsorbed in the small intestine, passes into the bloodstream and is then excreted in the urine, without significant metabolism; the other 30 percent that is not absorbed

is transported to the large intestine where it is not fermented. Allulose is then excreted without being absorbed (Refs. 70–71).

One comment stated that, when Allulose is used in food, there should be a reduction in the amount of calories declared of 4 calories/gram.

(Response) On April 10, 2015, we received a citizen petition from Tate & Lyle Ingredients Americas LLC (Docket Number FDA–2015–P–1201) requesting that Allulose be exempt from being included as a carbohydrate, sugars, or added sugar in the Nutrition Facts label on foods and beverages. The petition provided data and other information suggesting that Allulose is different from other sugars in that it is not metabolized by the human body, has negligible calories (0.2 calories per gram or less), does not contribute to increases in blood glucose or insulin levels, and, if included as carbohydrates and sugars (added sugars) on the Nutrition Facts label, would lead to consumer confusion, particularly consumers with diabetes or consumers otherwise concerned with accurately monitoring blood glucose. The petition, which was submitted after the comment period for the proposed rule had ended, provided new evidence that was not previously submitted in comments to the proposed rule. We need additional time to fully consider the information provided in the comments and the citizen petition. Therefore, the final rule does not reach a decision as to whether Allulose should be excluded from the labeling of carbohydrate, sugars and/or added sugars, and Allulose, as a monosaccharide, must be included in the declaration of each pending any future rulemaking that would otherwise exclude this substance from the declaration.

d. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of total carbohydrate, and our preexisting regulations, at § 101.9(c)(6), require the declaration of the amount of total carbohydrate on the Nutrition Facts label. In the preamble to the proposed rule (79 FR 11879 at 11901), we said that carbohydrates are an essential part of the diet because they provide energy to the cells in the body, especially the brain, which is dependent on carbohydrate for proper functioning, and we tentatively concluded that the declaration of carbohydrates on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices.

(Comment 125) Many comments supported the continued mandatory declaration of total carbohydrates; some comments stated that the reason that total carbohydrates should continue to be declared on the label is because the information is used by individuals who have diabetes to ''count carbs.''

(Response) While we agree that total carbohydrates should continue to be declared on the label, we disagree with the comments' rationale for the continued mandatory labeling of total carbohydrates. As discussed in part II.B.2, the information on the label is intended for the general healthy population rather than individuals with chronic diseases such as diabetes. In the preamble to the proposed rule (79 FR 11879 at 11901), we explained that carbohydrates are an essential part of the diet because they provide energy to the cells in the body, especially the brain, which is dependent on carbohydrate for proper functioning. Thus, the declaration of carbohydrates on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices, and so the final rule does not change the requirement in § 101.9(c)(7) for mandatory labeling of total carbohydrate.

e. DRV. The DRV for total carbohydrate is 300 grams (§ 101.9(c)(9)). Consistent with calculating total carbohydrate ''by difference,'' the proposed rule would not change the approach to calculate the percent DV for carbohydrate ''by difference'' as well. In addition, the proposed rule would not change the DRVs for fat or protein (see parts II.F.1.c, II.F.2.c, II.F.3.c, II.F.4.b, and II.I.3), which are used to derive the DRV for total carbohydrate. The DRV for total carbohydrate would remain at 300 grams/day. We note that the RDA for carbohydrate for men and women 19 years of age and older is 130 grams/day. Therefore, the DRV should not be viewed as an intake requirement, but as a reference amount.

(Comment 126) One comment said we should no longer require a percent DV declaration for total carbohydrate because consumption of some carbohydrates, such as naturally occurring sugars from fruit and milk, are not a public health concern.

(Response) We disagree with the comment that the percent DV declaration for total carbohydrate should no longer be required. Total carbohydrate is one of the three major macronutrients in the diet. It provides basic information about a food's nutrient profile. The percent DV declaration for total carbohydrate helps consumers put the amount of total carbohydrate in a serving of a food into the context of their total daily diet.

(Comment 127) One comment supported maintaining the current DRV for total carbohydrate of 300 grams. The comment stated that it falls within the AMDR range. In addition, the comment said, although there is an EAR and RDA for total carbohydrate, neither is appropriate or needed to serve as the basis for the DRV because relevant public health concerns are the ratio of carbohydrate to total fat and the source and type of carbohydrate in the diet.

Other comments suggested that the DRV of 300 grams is too high and that we should take a different approach to setting the DRV for total carbohydrate. One comment stated that, even though the DRV should not be viewed as an intake requirement, but rather as a reference amount, consumers often perceive it as recommended amount. The comment recommended using the population-weighted mid-point of the AMDR for adults and children of 275 grams to encourage reduction in carbohydrate consumption. The comment suggested that the current DRV of 300 grams is excessive given that the RDA for carbohydrate for adults 19 years of age and older is 130 grams/day, and that excessive carbohydrate intake is a central cause of the American obesity epidemic.

Another comment recommended reducing the DRV for total carbohydrate because the American population is sedentary and prone to metabolic syndrome. The comment also referred to the current DRV of 300 grams as a recommended intake level for a daily energy intake of 2,000 calories.

(Response) We agree with the comments recommending a reduction in the DRV for total carbohydrate, but for different reasons. We disagree with the comment that recommended decreasing the DRV for total carbohydrate because the American population is sedentary and prone to metabolic syndrome. It is unclear, based on the comment, what the comment is suggesting regarding the relationship between consumption of carbohydrates and a sedentary lifestyle or risk of metabolic syndrome. Furthermore, we disagree with the comment that the current DRV is a recommended intake level. As stated in the preamble to the proposed rule (79 FR 11879 at 11901), the DRV should not be viewed as an intake requirement, but as a reference amount.

We agree that neither the EAR or RDA values for total carbohydrate are appropriate to serve as the basis for a DRV, but we agree for different reasons than those stated in the comment. As discussed in the preamble to the proposed rule (79 FR 11879 at 11901), the EAR and RDA values set by the IOM

do not include sugar alcohols or dietary fiber. Our calculation of total carbohydrate, for the purposes of nutrition labeling, accounts for all types of carbohydrates, including sugar alcohols and dietary fiber. Therefore, using the EAR and RDA to set a DRV for total carbohydrate would result in a reference value that is based on recommendations specifically for sugars and starches. As we stated in the preamble to the proposed rule (id.), if the midpoint of the AMDR range is used as the basis for the DRV, there would be a discrepancy in what carbohydrates are encompassed in the information provided on the label for the absolute gram amount versus the percent DV.

The current DRV for total carbohydrate of 300 grams is calculated based on 60 percent of a 2,000 calorie diet ((0.60 × 2,000 calories)/4 calories per gram of carbohydrate = 300 grams). The percentage of calories contributed by total fat, total carbohydrate, and protein add up to 100 percent on the label. The DRV for carbohydrate of 60 percent of a 2,000 calorie diet is determined by the difference of what is left over by the DRVs for total fat and protein and 100 percent. As discussed in part II.F.1, we are increasing the DRV for total fat from 30 to 35 percent. Therefore, in order for the percentages of calories contributed by total fat, total carbohydrate, and protein to add up to 100 percent, either the percentage of calories contributed by the DRV for total carbohydrate or protein needs to decrease. Some comments suggested that the DRV for total carbohydrates be decreased, and the DRV for total carbohydrate is significantly greater than the RDA for carbohydrate for adults 19 years of age and older of 130 grams/day. Reducing the DRV for protein to 5 percent of calories to account for the 5 percent increase in the DRV for fat would result in a DRV value of 25 grams of protein, which is below the RDA for protein for children and adults 9 years and older. Therefore, we conclude that the DRV for total carbohydrate should be decreased from 60 percent of calories to 55 percent of calories for a DRV of 275 grams.

f. How total carbohydrates appears on the label.

(Comment 128) Several comments discussed the placement of carbohydrates on the label itself. One comment said that consumers need to be made aware of the fact that carbohydrates are sugars chemically because, according to the comment, most consumers believe that carbohydrates and sugars are two distinct nutrients. The comment would place the word ''sugars'' in parentheses next to ''Total Carbs'' or place ''Total Carbs'' in parentheses next to ''Total Sugars.''

(Response) We disagree that carbohydrates are chemically sugars. Although the body converts carbohydrates to sugars, the chemical structure of some carbohydrates (*e.g.,* starches) differs from the chemical structure of sugars. Sugars are a subset of carbohydrates and are declared as such on the label. Some examples of carbohydrates include sugars, such as sucrose and lactose, and polysaccharides, such as cellulose, glycogen, and starch. Therefore, we decline to change the label's format as suggested by the comment.

(Comment 129) Some comments would move ''Total Carbohydrates'' to the top of the list of declared nutrients on the label. The comments cited the significant rise in diabetes and the need to make the declared amount of total carbohydrates more prominent on the label.

(Response) We disagree that the increase in diabetes in the United States is a reason to move total carbohydrates to the top of list of declared nutrients on the label. As stated in part II.B.2, the intended purpose of information on the Nutrition Facts label is to assist the general healthy population in maintaining healthy dietary practices.

(Comment 130) One comment recommended listing the amount of total carbohydrate in a product in teaspoons rather than grams. The comment said that people do not understand what gram of carbohydrate would look like and providing the information in teaspoons would be more helpful for consumers.

(Response) We decline to revise the rule as suggested by the comment. We address arguments regarding the use of household measures, rather than in gram amounts on the label, in part II.B.3.

g. Calculation of calories from carbohydrate. Our preexisting regulations, at § 101.9(c)(1)(i)(C), require that the calories from total carbohydrate be calculated by using the general factor of 4 calories/gram of carbohydrate less the amount of insoluble dietary fiber. The proposed rule also would revise the definition of dietary fiber so that only those dietary fibers that we have determined to have a physiological effect that is beneficial to human health would be considered to be ''dietary fiber'' on the Nutrition Facts label. For the purposes of calculating calories from carbohydrate, when it is voluntarily declared, all soluble and insoluble non-digestible carbohydrates should be excluded from the calculation, not just those known to meet the definition of dietary fiber. To ensure that all soluble and insoluble non-digestible carbohydrates are excluded from the calculation of calories from carbohydrate, we proposed to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 calories/g of total carbohydrate less the amount of non-digestible carbohydrates and sugar alcohols, and the caloric value of each (the non-digestible carbohydrates and sugar alcohols) is then added to the sum of the carbohydrates.

We did not receive any comments on this proposed amendment, and so we have finalized the rule without change.

2. Sugars

a. Definition. Our preexisting regulations, at § 101.9(c)(6)(ii), define sugars as a statement of the number of grams of sugars in a serving. They are the sum of all free mono and disaccharides (*e.g.,* glucose, fructose, lactose, and sucrose). We considered whether we should continue to require mandatory declaration of sugars on the label in the proposed rule, but tentatively concluded that the declaration of sugars continues to be necessary to assist consumers in maintaining healthy dietary practices, and thus did not propose to change the current requirement for mandatory declaration of sugars (79 FR 11879 at 11902).

As discussed in the total carbohydrates section at part II.H.1, some comments and a citizen petition said we should exclude Allulose from the declaration of sugars. We discuss those comments in part II.H.1 (see comment 124).

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of sugars, and our preexisting regulations, at § 101.9(c)(6)(ii), require the declaration of sugars on the Nutrition Facts label. We did not propose to change this requirement.

(Comment 131) Several comments supported the continued mandatory declaration of sugars. One comment stated that sugars should continue to be labeled as part of total carbohydrate because they are a type of carbohydrate. The comment added that the amount of declared sugar is possible to quantify, easy to verify using analytical methods, and is information that is easily understood by consumers, nutritionists, and health professionals.

In contrast, other comments asked us to remove sugars from the label or replace it with a declaration of added sugars or ''fruit & milk sugars.'' The

comments recommending replacement of sugars with added sugars said that consumers, including individuals who have diabetes, focus on the sugars instead of the total carbohydrate amount declared on the label. One comment suggested that, when registered dietitians provide Medical Nutrition Therapy for diabetics, the sugars line is not valuable and contributes to information overload. The comment also stated that the sugars declaration makes consumers reluctant to eat foods, such as fruit and milk, which contain sugars as their source of carbohydrates.

One comment would replace sugars with fruit and milk sugars and place the new heading directly under dietary fiber; the comment said this change would clearly distinguish added sugars from naturally occurring sugars in whole fruit and from sugars from dairy ingredients and also eliminate the need for a double indentation (for declaration of added sugars) under the ''Total Carbs'' heading. The comment cited data from an online survey of 500 participants showing that, when ''Sugars'' is replaced with ''Fruit & Milk Sugars'' on the Nutrition Facts label, significantly more individuals were able to correctly identify the amount of naturally occurring sugars in one serving of the food (Ref. 72).

(Response) We decline to remove the declaration of sugars from the label because consumption of sugars continues to be associated with an increased risk of dental caries; thus, the information continues to be necessary to assist consumers in maintaining healthy dietary practices. We agree that sugars should continue to be labeled as part of total carbohydrate and that the amount of total sugars can be quantified using existing analytical methods.

Similarly, we disagree with the comments suggesting that the total sugars declaration should be removed from the label because consumers, especially individuals with diabetes, focus on the sugars declaration rather than the total carbohydrate declaration and may be overwhelmed by the information. The comments did not provide data or other evidence, nor are we aware of such data or evidence, to support this assertion. The total carbohydrate and sugars declaration has been on the label for over 20 years. Furthermore, as noted in part II.B.2, the information on the label is intended for the general healthy population and not for individuals with chronic diseases, such as diabetes.

Likewise, we are unable to evaluate whether the sugars declaration results in a reluctance to consume foods, such as fruit or milk, which are natural sources of sugars because the comment did not provide data or information, and we are not aware of such data or information, to support this assertion.

We disagree with the comment which would replace ''Sugars'' with ''Fruit & Milk Sugars'' on the Nutrition Facts label. Total sugars continue to be associated with risk of dental caries. Furthermore, our definition of added sugars includes (see part II.H.3.n) some fruit and milk sugars, such as sugars found in concentrated fruit juice that is not reconstituted to 100 percent fruit juice.

c. Changing ''Sugars'' to ''Total Sugars''. In the preamble to the proposed rule (79 FR 11879 at 11902), we said that we were considering whether to use the term ''Total Sugars'' instead of ''Sugars'' on the label if we finalize a declaration of added sugars. We also said that we planned to conduct consumer research that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help or enhance our understanding of how consumers would comprehend and use this new information, and to inform education efforts (id.). In the supplemental proposed rule (80 FR 44303 at 44306, 44308), we discussed the results of our consumer research which showed that when an ''Added Sugars'' declaration was indented below a ''Total Sugars'' declaration on the label, participants appeared to be better able to comprehend the total amount of sugars in a food than if an ''Added Sugars'' declaration was indented below a ''Sugars'' declaration. In the supplemental proposed rule (id. at 44304), we asked for comment on whether the term ''Total Sugars'' should be declared on the label instead of ''Sugars.''

The final rule uses the term ''Total Sugars'' to replace the declaration of ''Sugars.'' We explain our rationale and respond to comments on this change in part II.H.3.

d. DRV. Our preexisting regulations do not specify a DRV for sugars. In the preamble to the proposed rule (79 FR 11879 at 11902), we explained that consensus reports did not set dietary reference values based on which we could derive an appropriate DRV for total sugars. Therefore, we did not propose to establish a DRV for total sugars.

(Comment 132) Some comments submitted in response to the proposed rule agreed that there is insufficient information to establish a DRV for sugars. However, others comments recommended establishing a DRV and requiring mandatory declaration of a percent DV for sugars. One comment stated that such information would help consumers choose food and beverages that are low in sugar. Another comment said that, with ''skyrocketing'' overweight, obesity, and their co-morbidities, a percent DV for sugar would be a useful tool for informing consumers of sugar content and would help consumers make better choices. The comment said that the declaration could help consumers to visually understand approximately how much sugar they should be getting each day and how much sugar they are actually consuming. One comment suggested that a declaration of a percent DV for sugars would allow consumers to compare products more easily.

Other comments said that a DRV for sugars could be based on recommendations from the World Health Organization or the American Heart Association. One comment said that the National Institutes of Health should ask the IOM to set a suggested limit on how much sugar one should consume on a daily basis.

(Response) We decline to set a DRV for sugars or to require the declaration of a percent DV for sugars. We are not aware of data or information related to a quantitative intake recommendation for sugars that we could use as the basis for a DRV for total sugars.

With respect to the comments suggesting that the World Health Organization (WHO) or the American Heart Association (AHA) could give us a basis to establish a DRV, we acknowledge that the WHO recently released guidelines for sugars intake for adults and children (Ref. 73). The WHO recommends reducing the intake of free sugars to less than 10 percent of total energy intake in both children and adults. It also provided a conditional recommendation which suggested further reduction of the intake of free sugars to below 5 percent of total energy intake. The WHO defines ''free sugars'' as monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook, or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates (Ref. 73). The WHO definition of ''free sugars'' is not consistent with our definition of ''sugars'' because the WHO definition does not include all free mono and disaccharides. It excludes some naturally occurring sugars, such as lactose. Therefore, we disagree that the WHO's recommendations could be used to establish a DRV for sugars. The AHA recommended limits for intake of added sugars and not total sugars (Ref. 74). Therefore, it would not be appropriate

to use the AHA recommendations to establish a DRV for total sugars.

As for the comment suggesting that the IOM could set a maximum intake recommendation, the IOM reviewed the evidence on this topic in the Macronutrient report (Ref. 75). As discussed in the preamble to the proposed rule (79 FR 11879 at 11902), the IOM found an association between sugar consumption and risk of dental caries, but, due to the various factors that contribute to dental caries, the IOM could not determine an intake level of sugars that is associated with increased risk of dental caries and, therefore, did not have sufficient evidence to set a UL for sugars.

e. Seasonal variation in sugars content.

(Comment 133) One comment noted that, depending on the time of year, the sugar content of fruit changes, which could impact the sugar content of products to which fruit is added. The comment questioned whether the product labels have to change throughout the year to reflect the seasonal variation in sugar content of the fruit or fruit juice in a product. The comment also questioned if the seasonal variation in the sweetness of fruit is compensated for by adjusting the amount of sugar alcohols in the product and whether a label change would be required. Another comment suggested that sugars may be added to fruits and vegetables to achieve a standard flavor profile and said that the amount of sugars added to the food may change throughout the year.

(Response) Our compliance requirements in § 101.9(g)(5) state that a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. However, no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved. This approach takes into account seasonal variability as well as variability due to the analytical method used. Therefore, so long as the variability in the sugars content of the fruit does not cause the total sugars comment to be greater than 20 percent in excess of the declared value, the manufacturer of a product containing fruit would not be in violation of the regulation. The manufacturer is in the best position to determine if and when a label change is needed based on the total sugar content and the amount of sugars or sugar alcohols added to standardize the flavor profile of the food.

The declaration of the amount of sugar alcohols on the Nutrition Facts label is voluntary, so if a manufacturer uses sugar alcohols to account for the variation in the sugar content of the product, the label would only need to change if the amount of sugar alcohol is voluntarily declared on the label. However, if a food product does not typically contain a certain sugar alcohol which is added to adjust for the sugars content of fruit, that sugar alcohol would need to be declared in the ingredient list.

3. Added Sugars

In the preamble to the proposed rule, we explained that current regulations neither define the term ''added sugars'' nor require or permit the declaration of added sugars on the label. We considered requiring the declaration of added sugars taking into account new information. We tentatively concluded that the declaration of added sugars on the label is necessary to assist consumers to maintain healthy dietary practices, and we proposed to require the declaration of the amount of added sugars in a serving of a product (79 FR 11879 at 11905). We are finalizing the requirement for mandatory labeling of added sugars in § 101.9(c)(6)(iii), and our rationale for doing so is discussed in this section below.

We have requirements for label statements that must be made if a product contains an insignificant amount of many nutrients on the label such as carbohydrate, sugars, and dietary fiber. We also have requirements for when the nutrient content can be expressed as zero. We proposed that a statement of added sugars content would not be required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content and we are finalizing this requirement, as proposed, in § 101.9(c)(6)(iii). We proposed to require that the phrase ''Not a significant source of added sugars'' be placed at the bottom of the table of nutrient values if a statement of the added sugars content is not required, and as a result, is not declared. Alternatively, we proposed to permit the use of the alternative statements ''Contains less than 1 g'' and ''less than 1 g'' to be declared. We also proposed to permit the added sugars content to be expressed as zero if a serving of food contains less than 0.5 grams of added sugars. We are finalizing the requirements for when label statements if a product contains an insignificant amount of added sugars and for when the added sugars content may be expressed as zero, as proposed, in § 101.9(c)(6).

Because our preexisting regulations do not define ''added sugars,'' the proposed rule would define ''added sugars'' as sugars that are added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.* fruit juice concentrates), and other caloric sweeteners. A summary of the comments regarding our proposed definition of added sugars, and our responses to those comments, can be found in part II.H.3.a.

In February 2015, the 2015 DGAC submitted the 2015 DGAC Report to the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. The 2015 DGAC reaffirmed recommendations in the 2010 DGA, which included recommending the reduction of added sugars intake. For the first time, the 2015 DGAC conducted a systematic review of the evidence related to dietary patterns and health outcomes, including cardiovascular disease (CVD), body weight and type 2 diabetes, cancer, congenital abnormalities, neurological and psychological illness, and bone health. The 2015 DGAC concluded that there is strong and consistent evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy patterns, are associated with a reduced risk of CVD. We considered the evidence that the 2015 DGAC relied upon in making its determinations, and tentatively concluded, in the preamble to the supplemental proposed rule (80 FR 44303), that this information provides further support for our proposal to require the mandatory declaration of the amount of added sugars in a serving of a product on the label.

The proposed rule would not establish a DRV for added sugars. We explained, in the preamble to the proposed rule (79 FR 11879 at 11906), that the USDA Food Patterns specify the maximum amount of calories from solid fats and added sugars that can be consumed at each calorie level, while staying within calorie limits. A 2,000 calorie diet could contain approximately 260 calories from solid fats and added sugars (id.). The limit of 260 calories served as a reference to ensure the selection of a nutrient dense

diet without excess discretionary calories from added sugars and solid fats. These limits established for calories from solid fats and added sugars in the USDA Food Patterns are based on food pattern modeling. Because the limits are not based on any biomarker of risk of disease from an independent relationship between a nutrient and chronic disease risk we stated that we did not have a quantitative intake recommendation upon which a DRV for added sugars could be derived. The statement was not intended to suggest a limitation for when we can mandate a nutrient declaration in the nutrition label, as some comments seem to suggest. The 2015 DGAC further evaluated limits for added sugars in the diet based, in part, on food pattern modeling and recommended that Americans limit their intake of added sugars to a maximum of 10 percent of total daily caloric intake. The 2015 DGAC said that its recommendation was supported by a food pattern modeling analysis conducted by the 2015 DGAC and the scientific evidence review on added sugars and chronic disease risk. In the preamble to the supplemental proposed rule (80 FR 44303 at 44308), we reconsidered our tentative conclusion that a DRV for added sugars could not be established and proposed to establish a DRV for added sugars of 10 percent of total energy intake from added sugars and to require the declaration of the percent DV for added sugars on the label.

Thus, we have scientific evidence to support a limit for added sugars that can serve as the basis for a DRV for added sugars. The limit for calories from added sugars to less than 10 percent of calories is a reference value that is appropriate for use as a DRV for added sugars. The DRV is used to calculate the percent DV, and a percent DV provides information that Americans can use to determine how the amount of added sugars in a serving of food contributes to his or her individual total daily diet. The food pattern modeling used to support a limit in the intake of added sugars to less than 10 percent of calories was used to create the USDA Food Patterns. The USDA Food Patterns provide suggested amounts of food to consume from the basic food groups, subgroups, and oils to meet recommended nutrient intakes at 12 different calorie levels. They can be used by Americans to construct a healthful dietary pattern that is consistent with current recommendations. We have concluded that evidence on dietary patterns and health outcomes showing that healthy dietary patterns characterized, in part, by lower amounts of sugar-sweetened foods and beverages are associated with a reduced risk of CVD supports a mandatory declaration of added sugars. Both the USDA Food Patterns and the dietary patterns and health outcomes analysis that were discussed in the 2015 DGAC Report provide information about healthy dietary patterns. Therefore, the DRV of 10 percent of calories and the mandatory declaration of the amount of added sugars in a serving of food are related to providing information that will assist consumers in constructing a healthy dietary pattern.

On January 7, 2016, the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture released the 2015–2020 DGA (Ref. 28). The 2015–2020 DGA focuses on eating patterns in addition to nutrients and foods because healthy dietary patterns may be more predictive of overall health status and disease risk than individual foods or nutrients. A key recommendation of the 2015–2020 DGA is to limit calories from added sugars and saturated fats and reduce sodium intake. In order to achieve this recommendation, the 2015–2020 DGA says that Americans should consume an eating pattern that is low in added sugars. Another key recommendation of the 2015–2020 DGA is to consume less than 10 percent of calories per day from added sugars. The 2015–2020 DGA is consistent with the recommendations and the science presented in the 2015 DGAC Report. We considered the scientific evidence in the 2015 DGAC Report related to dietary patterns, as well as evidence related to limiting calories from added sugars that served as our basis for proposing a DRV for added sugars of 10 percent of total calories.

Throughout this part, we refer to the underlying scientific evidence that we have reviewed and considered which supports our basis for the mandatory declaration of the amount of added sugars in a serving of a product, the DRV, and the declaration of the percent DV for added sugars. The need for a mandatory declaration of added sugar is supported by strong and consistent evidence that dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy dietary patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are associated with a decreased risk of CVD. The scientific evidence from the 2010 DGA supporting that consumption of excess calories from added sugars can lead to a less nutrient-dense diet, current consumption data showing that Americans are consuming too many calories from added sugars, and the strong evidence that greater intake of sugar-sweetened beverages is associated with increased adiposity in children also support mandatory declaration of added sugars.

We reviewed and considered the evidence that the 2015 DGAC relied upon for its conclusion that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD relative to less healthy dietary patterns, which included an existing review from the NEL Dietary Patterns Systematic Review Project as well as the NHLBI Lifestyle Evidence Review and the associated Lifestyle Management Report (Refs. 17–18). We have concluded that it is appropriate to rely on evidence that considered not only added sugars but also sugar-sweetened foods and beverages to support the mandatory declaration of added sugars on the label because sugars are added to sugar-sweetened foods and beverages and provide extra calories in those foods. When those foods are consumed in excess, they are not consistent with healthy dietary patterns. We also note that the strong and consistent association with CVD risk was seen when healthy dietary patterns were compared with less healthy dietary patterns. As discussed in the 2015 DGAC Report, dietary patterns of the American public are suboptimal and are causally related to poor individual and population health and higher chronic disease rates. On average, the U.S. diet is low in vegetables, fruits, and whole grains, and high in sodium, calories, saturated fat, refined grains, and added sugars. Underconsumption of the essential nutrients vitamin D, calcium, potassium, and fiber are public health concerns for the majority of the U.S. population, and iron intake is of concern among adolescents and premenopausal females (Ref. 19).

There were many statements made in the 2010 DGA related to consuming a dietary pattern that is nutrient dense. Those statements included the concepts that added sugars displace other nutrient-dense foods in the diet and that as the amount of solid fats and added sugars increase in the diet, it becomes more difficult to also eat foods with sufficient dietary fiber and essential vitamins and minerals, and still stay

within calorie limits. The 2010 DGA relied on food pattern modeling done for the USDA Food Patterns to support statements in the 2010 DGA related to nutrient density. We considered these statements and evidence from the IOM macronutrient report (Ref. 75) showing that decreased intake of some micronutrients occurs when individuals consume in excess of 25 percent of calories from added sugars.

The 2015 DGAC said that current intake of added sugars remains high at 268 calories, or 13.4 percent of total calories per day among the total population ages 1 year and older (Ref. 19). Intake data from the What We Eat In America, 2007–2010 (Ref. 76), the dietary component of NHANES was used by the 2015 DGAC to answer questions related to current intake of added sugars. We also considered how this current intake data relates to recommendations from the 2015 DGAC when concluding that Americans are consuming too many calories from added sugars.

We considered the scientific evidence in the 2010 DGAC Report supporting the conclusion related to consumption of sugar-sweetened beverages and adiposity in children when determining that the evidence supports the mandatory declaration of added sugars. The 2010 DGAC conducted a full NEL search to evaluate the association between sugar-sweetened beverages and adiposity in children. Results of this review, covering 2004–2009 were supplemented by the findings of prospective studies included in an earlier evidence review conducted by the American Dietetic Association (ADA) (1982–2004). Although we have concluded that this body of evidence provides further support for a mandatory declaration of added sugars on the label, it is limited to children. Therefore, we refer to the general population, which includes both children and adults, when we discuss the evidence on dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages and decreased risk of CVD because the healthy dietary pattern components described in the literature for adults are reaffirmed with the USDA Food Patterns, which aim to meet nutrient needs across the lifespan, including children 2 years of age and older.

a. Declaration

(i) Comments on the Rationale for Requiring Mandatory Declaration of Added Sugars

In the preamble to the proposed rule, we identified the factors that we considered when determining which non-statutory (those that are not explicitly required by the FD&C Act) nutrients should be declared on a mandatory and voluntary basis on the label (79 FR 11879 at 11889). We considered whether a quantitative intake recommendation existed and whether there is public health significance when determining which nutrients should be declared on the label. We considered mandatory declaration to be appropriate when there is public health significance and a quantitative intake recommendation that can be used for setting a DV for a nutrient (79 FR 11879 at 11890). For nutrients that are not essential vitamins and minerals, we considered voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance (79 FR 11879 at 11891). We also considered the scientific evidence from the 2010 DGA related to the intake of added sugars in the diet and the role of such information in assisting consumers to maintain healthy dietary practices. We noted that our review for added sugars was not based on the factors we have traditionally considered for mandatory declaration that are related to an independent relationship between the particular nutrient and a risk of chronic disease, health-related condition, or health-related physiological endpoint.

(Comment 134) Many comments addressed our rationale for requiring the declaration of added sugars on the label in relation to the risk of chronic disease. One comment recognized that our rationale for proposing to require the mandatory declaration of added sugars is atypical and is not based on a traditional nutrient health-outcome linkage. In contrast, other comments suggested that we not require the declaration of added sugars on the label because they do not meet the factors outlined in our criteria for mandatory labeling. One comment also objected to voluntary declaration of added sugars because, according to the comment, it does not meet either of our proposed factors. Another comment said that we have not shown that a public health significance exists for added sugars labeling through well-established scientific evidence. The comments also noted that our rationale for requiring the declaration of added sugars differs from our rationale for declaring other nutrients on the label.

(Response) Our determination under section 403(a)(2)(A) of the FD&C Act of whether a nutrient is necessary to assist consumers in maintaining healthy dietary practices is not limited to the factors we have used when assessing nutrients for which there is an independent relationship between the nutrient and risk of disease, a health-related condition, or a physiological endpoint (see our response to comment 45). Our rationale for requiring the mandatory declaration of added sugars is different from that of nutrients for which such an independent relationship exists. Rather than basing a declaration of added sugars on an association with risk of chronic disease, a health-related condition, or a physiological endpoint, for the purposes of the general population (see part II.H.3), we are considering a declaration of added sugars in the context of how it can assist consumers in maintaining healthy dietary practices by providing information to help them limit consumption of added sugars, and to consume a healthy dietary pattern. Instead of considering an association with risk of chronic disease, for the purposes of the general population, our review for the proposed rule was based on information which supported the need for further information about added sugars on the label to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (79 FR 11879 at 11891). We relied on multi-faceted evidence showing that added sugars consumption in the United States is a public health concern. We cited information from the 2010 DGA indicating that a high intake of calories from excess solid fats and added sugars can decrease the intake of nutrient-dense foods in the diet and can increase the overall caloric intake, which could lead to weight management issues (79 FR 11879 at 11904). We considered evidence related to excess consumption of calories from added sugars. For many years, added sugars have contributed a significant amount of calories to the American diet. The 2010 DGA cited intake data showing that Americans consumed approximately 16 percent of calories from added sugars (Ref. 77). More recent data shows that consumption of added sugars has decreased to approximately 13.4 percent of calories in recent years; however, the intake still remains high and exceeds 10 percent of total calorie intake. In the preamble to the proposed rule, we also

cited to the strong evidence reviewed by the 2010 DGAC that shows that children who consume sugar-sweetened beverages have increased adiposity (increased body fat) (79 FR 11879 at 11904).

The evidence we considered when determining that the amount of added sugars in a serving of a product must be declared on the label includes the scientific evidence from the 2010 DGA and the 2015 DGAC Report related to limiting calories from added sugars. The 2015–2020 DGA also includes this scientific evidence.

A recommendation to limit the intake of added sugars has been long-standing in the various editions of the DGA, although the terminology and specificity of the guidance has evolved over time. In fact, we considered requiring the declaration of added sugars on the label in the January 6, 1993 final rule for the Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (58 FR 2079 at 2098). The comments that we received to a 1990 proposed rule recommended mandating the declaration of added sugars only, rather than total sugars, because dietary recommendations urged the use of sugar in moderation, while at the same time recommending increased consumption of fruits, which are sources of naturally occurring sugars. Though the terminology ''added sugars'' was not introduced into the DGA until 2005, when Americans were advised to ''choose and prepare foods and beverages with little added sugars or caloric sweeteners, such as amounts suggested by the USDA Food Guide and the DASH eating plan,'' the DGA has included key recommendations advising Americans to limit their intake of ''sugar'' since the first report in 1980 (Refs. 30, 78–83). Even in the 1980 DGA, Americans were advised to ''avoid excessive sugars'' by using less of all sugars, including white sugar, brown sugar, raw sugar, honey, and syrups. Consumers were also advised to reduce their consumption of foods containing these sugars such as candy, soft drinks, ice cream, cakes, and cookies. All of the ingredients that consumers were advised to limit in their diet in the 1980 DGA would meet our current definition of an added sugars, and the foods that Americans were advised to limit are some of the largest contributors to added sugars intake today.

Over the past century the health profile of Americans has changed. Deficiencies of essential nutrients have dramatically decreased, and chronic diseases that are related to poor quality dietary patterns and physical inactivity, such as obesity, CVD, type 2 diabetes, and diet-related cancers, have become much more prevalent in the population (Ref. 19). Dietary patterns and their food and nutrient characteristics were at the core of the conceptual model that guided the 2015 DGAC's work and resulted in scientific evidence supporting the recommendations from both the 2015 DGAC Report and the 2015–2020 DGA related to healthy dietary patterns (Refs. 19, 28). For the first time, the 2015 DGAC completed a systematic review to examine the relationship between dietary patterns and health outcomes. The data related to dietary patterns and health outcomes, which was reviewed by the 2015 DGAC, focused on specific health outcomes including: CVD, measures of body weight or obesity, type 2 diabetes, cancer, congenital anomalies, neurological and psychological illnesses, and bone health. The 2015 DGAC concluded that the overall body of evidence examined by the 2015 DGAC identifies that a healthy dietary pattern is higher in vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; and moderate in alcohol (Ref. 19). The 2015 DGAC also concluded that dietary patterns characterized, in part, by lower consumption of sugar-sweetened foods and beverages relative to less healthy dietary patterns were strongly and consistently associated with a reduced risk of CVD (Ref. 19). Evidence for dietary patterns and the other health outcomes that were included in the analysis was moderate or limited. The new evidence from the systematic review examining the relationship between dietary patterns and health outcomes provide further support for a mandatory declaration of added sugars because consumers need to know how much added sugars are in their foods in order for them to construct an overall healthy dietary pattern and to limit consumption of added sugars. The scientific evidence also was included in the 2015–2020 DGA. Furthermore, consumers need to know how much added sugars are in a serving of a product so that they can avoid consuming excess calories from added sugars, at the expense of calories from other components as part of a healthy dietary pattern within calorie limits, such as fruits, vegetables, fat-free and low-fat dairy, grains, protein foods, and oils.

We disagree with the comment that added sugars should not be required on the label because we have not shown that a public health significance exists for added sugars labeling through well-established scientific evidence. The comment is considering the guidance we have given related to determining public health significance in our proposed factors for mandatory and voluntary labeling, which are focused on nutrients for which there is a relationship with a risk of a chronic disease, a health-related condition, or a physiological endpoint. However, we are using a different paradigm for the labeling of added sugars for the general population (see part II.H.3) than has been used traditionally. We have established that there is public health significance of added sugars through other evidence and recommendations related to a healthy dietary pattern low in sugar-sweetened foods and beverages that is associated with reduced risk of CVD, through consumption data showing that Americans are consuming too many calories from added sugars, through evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and through evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children.

We disagree with the comments that suggested that added sugars should not be required to be declared on the label because they do not meet the factors we consider for mandatory labeling of nutrients for which there is an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint. We must evaluate the current nutrition science and determine whether a nutrient will assist consumers in maintaining healthy dietary practices. We are not bound by certain factors when determining if any and all nutrients should be declared on the label now or in the future (see part II.C.3).

The final rule, therefore, at § 101.9(c)(6)(iii), requires the mandatory declaration of added sugars.

(Comment 135) Many comments said we should not require the declaration of added sugars on the label because they do not have a unique role in causing weight gain or increasing the risk of chronic disease when compared to other macronutrients. Many comments cited the 2010 DGA's conclusion that added sugars are no more likely to contribute to weight gain or obesity than any other source of calories (Ref. 30). Some comments also cited the conclusion in the IOM DRI report for macronutrients that there is no clear and consistent association between increased intake of added sugars and BMI (Ref. 75). The comments noted that studies have shown that with respect to weight loss, reducing total caloric intake is more

important than the source of calories. The comments asserted that excess energy in any form will promote body fat accumulation.

(Response) We agree that excess calories from any source can contribute to weight gain. However, Americans are consuming too many calories from added sugars, and those calories typically are not accompanied by other beneficial nutrients. The comments are considering the evidence that we have used to support a declaration of added sugars against our proposed factors for mandatory and voluntary declaration of non-statutory nutrients for which there is an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint. Rather than considering a direct relationship between consumption of added sugars and risk of a chronic disease, health-related condition, or physiological endpoint, for the purposes of the general population (see part II.H.3), we have focused on how added sugars found in sugar-sweetened foods and beverages contribute to a dietary pattern, and how the contribution of added sugars to the total diet impacts health. The evidence points to the need for consumers to know how much added sugars are in a serving of a product to assist them in achieving a healthy dietary pattern and maintaining healthy dietary practices.

(ii) Evidence on Added Sugars and Risk of Chronic Disease

(Comment 136) Many comments suggested that, if we are using the traditional relationship between a nutrient and risk of chronic disease, a health-related condition, or a physiological endpoint when determining if added sugars should be declared on the label, there is specific scientific evidence on added sugars and risk of disease that we should consider. Many comments suggested that a declaration of added sugars is necessary because consumption of added sugars is associated with an increased risk of chronic disease or markers for chronic disease. Some comments provided evidence that increased consumption of sugar-sweetened beverages, which are the primary source of added sugars in the American diet, is associated with increased body weight, an increase in body mass index (BMI), adiposity (body fat), increased blood pressure leading to increased incidence of hypertension, and in increased risk of metabolic syndrome, type 2 diabetes, and gout. Other comments provided evidence that high intakes of fructose-containing sugars can raise levels of triglycerides, visceral fat, liver fat, blood glucose, insulin, and LDL cholesterol. The comments suggested that the findings indicate that diets high in fructose increase markers or risk factors for heart disease, diabetes, non-alcoholic fatty liver disease, and metabolic syndrome. The comments noted that randomized, controlled clinical trials to test the hypothesis that added sugars increase disease risk would violate ethical standards, and therefore, are impossible to conduct.

In contrast, many comments argued that there is no association between consumption of added sugars and risk of chronic disease, and therefore, there is a lack of a scientific basis to require the mandatory declaration of added sugars on the label. One comment stated that evidence available since the 2010 DGA is conflicting and inconclusive. In reference to the evidence showing that all sugars contribute to dental caries, one comment suggested that there are many factors that can contribute to dental caries, including oral bacteria, salivary flow, oral hygiene behavior, and susceptibility of the tooth. The comment stated that it was not aware of any evidence showing that added sugars presents a unique risk for causing dental caries.

Some comments criticized studies on added sugars and risk of disease. The comments suggested that scientific consensus groups have found difficulty in determining any relationship between added sugars intake and health outcomes due to a variety of complex reasons. The reasons cited included lack of harmonization within the scientific literature of the definition and inclusion of ingredients considered to be added sugars, difficulty comparing studies where the primary health outcomes measured are not consistent across studies, systematic reviews draw conclusions across multiple studies with various inclusion criteria and designs, excess energy intake may not be controlled for in the analysis, much of the information about added sugar content of products is proprietary, and methodological problems with observational studies which have suggested detrimental associations of added sugars intake with health outcomes. The comments also noted that sugar-sweetened beverages are often inappropriately used as a proxy or surrogate for total added sugars intake.

(Response) Added sugar in the diet is an area that is of particular interest in the nutrition community. A substantial amount of research has been conducted on the association between consumption of sugar-sweetened beverages and risk of chronic disease, as noted in the comments. The 2010 DGAC concluded that an increased intake of sugar-sweetened beverages is associated with greater adiposity in children. Since 2010, additional evidence on sugar-sweetened beverages and their association with risk of disease has emerged. The 2015 DGAC concluded that there is strong and consistent evidence that intake of added sugars from foods and/or beverages is associated with excess body weight in children and adults (Ref. 19). We note that the majority of the evidence that the 2015 DGAC relied on for this conclusion was from studies on the relationship between intake of sugar-sweetened beverages and body weight. Although the evidence on sugar-sweetened beverages and body weight/adiposity is strong and consistent, sugar-sweetened beverages represent only 39 percent of food sources of added sugars. As noted in the comments, sugar-sweetened beverages may not be an appropriate proxy or surrogate for total added sugars intake.

Research on the health effects of total added sugars continues to emerge. One difficulty that researchers face when designing studies on added sugars from all food sources is that there are many ingredients containing added sugars by different names, and no single definition of added sugars has been adopted by the scientific community. In § 101.9(c)(6)(iii) of the final rule, we are establishing a regulatory definition of added sugars. We expect that, by requiring the declaration of the amount of added sugars in a serving of a product on the label, and by establishing a definition of added sugars, additional research on the health effects of added sugars from food and beverages will be conducted in the future that will further clarify the direct relationship of added sugars with risk of chronic diseases, health-related conditions, and physiological endpoints.

Although we are not basing a mandatory declaration of added sugars for the general population on an independent relationship between added sugars and risk of chronic disease, we are, instead, basing an added sugars declaration on the need to provide consumers with information to construct a healthy dietary pattern that is low in added sugars. We intend to monitor the evidence in this area and will consider how any new evidence may impact our regulations in the future.

(Comment 137) In the preamble to the proposed rule (79 FR 11879 at 11904), we suggested that the disclosure of saturated fat and *trans* fat on the label not only provides information to consumers for managing their risk of

CVD, but the declaration of these nutrients also could provide a marker for foods that contain solid fats (fats which are solid at room temperature and contain a mixture of saturated and unsaturated fatty acids but tend to contain a high percentage of saturated and *trans* fats). We suggested that there is not currently information on the label that could serve as a marker for added sugars.

Some comments took issue with comparisons made between fats and sugars in the proposed rule. The comments noted that there are significant health differences between fats in general and solid fats. The comments asserted that those differences provide a defensible basis for delineating the types of fats on the label, and there are no similar functional health differences between sugars and added sugars. Therefore, the comments said we do not have a basis for requiring a separate declaration for added sugars on the label.

(Response) Our basis for requiring the declaration of added sugars for the general population (see part II.H.3) is not related to an independent relationship between added sugars and a risk of chronic disease, but rather on the contribution of added sugars to an overall dietary pattern. Added sugars consumption among the general U.S. population exceeds what can reasonably be consumed within calorie limits and can have a negative impact on health. The declaration of added sugars will assist consumers in maintaining healthy dietary practices. In the preamble to the proposed rule, we were not making a comparison between the level of evidence related to an independent relationship between the intake of fats and sugars and chronic disease risk. Instead, we were describing whether information on the label for certain fats and sugars would allow the consumer to use the label to reduce their consumption of calories from solid fats and added sugars.

(Comment 138) Some comments likened the public interest in added sugars to that in total fat in previous years and suggested that we consider the unintended consequences associated with a single nutrient-type approach.

(Response) We disagree with the comment's suggestion that we are taking a single nutrient-type approach to the labeling of added sugars. We are considering how added sugars interact with other components in the diet and make it difficult for individuals to meet nutrient needs within calorie limits and to construct a healthful dietary pattern. As noted in the 2015 DGAC Report, added sugars are not intended to be reduced in isolation; in fact, sodium and saturated fats are also recommended to be reduced in order to achieve a healthy dietary pattern that is balanced, as appropriate, in calories (Ref. 19). These considerations have led us to conclude that consumers need information on the amount of added sugars in a serving of a product as well as a percent DV declaration to help them maintain healthy practices and determine how a serving of a product fits into the context of their total daily diet. Furthermore, the declaration of added sugars will be included with other nutrient declarations on the label. This is one of many pieces of nutrition information that consumers should use when making food choices.

(iii) New Evidence Presented in the 2015 DGAC Report

After publication of the 2010 DGA, the USDA NEL completed a systematic review project examining the relationships between dietary patterns and several health outcomes, including CVD, body weight, type 2 diabetes, and dental caries. In addition, the DGAC reviewed the NHLBI Lifestyle Evidence Review and the Lifestyle Management Report. Based on the information provided in the NEL report, the 2015 DGAC made conclusions about the association of healthy dietary patterns and the risk of the named health outcomes. In particular, the 2015 DGAC concluded that strong and consistent evidence demonstrates that dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol, and sodium, and richer in fiber, potassium, and unsaturated fats is associated with a decreased risk of CVD. We reviewed and considered the evidence that the DGAC relied on for making this conclusion, and determined that it supports our basis for requiring the mandatory declaration of the gram amount of added sugars on the label. We requested comment on this new information in the supplemental proposed rule.

(Comment 139) Some comments supporting our inclusion of the new information on dietary patterns and CVD risk in our rationale for the declaration of added sugars said that the U.S. population should be encouraged and guided to consume dietary patterns that are rich in vegetables, fruit, whole grains, seafood, legumes, and nuts; moderate in low- and non-fat dairy products and alcohol (among adults); lower in red and processed meat; and low in sugar-sweetened foods and beverages and refined grains. One comment noted that the dietary patterns that are now recommended for CVD reduction by the American Heart Association and the American College of Cardiology and the new part 2 recommendations of the National Lipid Association all refer to a dietary pattern low in sweets and sugar-sweetened beverages.

Many comments supported the 2015 DGAC's recommendation that Americans reduce their intake of added sugars and said that the recommendation is consistent with the American Cancer Society's nutrition and physical activity guidelines, the recent guidelines from the World Health Organization on added sugars intake, and recent lifestyle guidelines from the American Heart Association and the American College of Cardiology.

(Response) We have reviewed and considered the data and information underlying the 2015 DGAC's recommendations and have concluded that the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. The declaration would enable consumers to limit added sugars as part of a healthy dietary pattern.

(Comment 140) Although we did not propose to rely on the analysis conducted by the 2015 DGAC (Ref. 84) on the relationship between the intake of added sugars and CVD, body weight/obesity, type 2 diabetes, and dental caries, some comments addressed the analysis and whether it supports a mandatory declaration of added sugars.

Some comments said that it is appropriate for us to rely on information from the 2015 DGAC Report as well as the robust science upon which that report is based regarding the health risks of added sugars. The comments said that the DGAC comprehensively reviewed the current scientific literature and concluded that added sugars increase the risk of multiple health outcomes, including excess body weight, type 2 diabetes, CVD and dental caries. According to the comments, the evidence, which was graded either as ''strong'' or ''moderate'' by the DGAC, further supports the mandatory declaration of added sugars on the label and supports the addition of a percent DV declaration on the label. The comments cited additional scientific evidence supporting an association between consumption of added sugars and/or sugar-sweetened beverages and

the risk of the health outcomes named in the 2015 DGAC Report or endpoints such as serum triglycerides, LDL cholesterol, and blood pressure.

Other comments suggested that the existing evidence related to consumption of added sugars and the risk of various chronic diseases and health-related conditions is limited and does not demonstrate a clear, causative relationship or direct contribution of added sugars to obesity, heart disease, or other diseases or conditions.

Some comments questioned why we are relying on evidence related to dietary patterns and risk of disease to support a mandatory declaration of added sugars when a review was done by the DGAC that specifically looked at consumption of added sugars and risk of CVD and the DGAC concluded that the evidence was moderate rather than strong. The comments noted that the evidence reviewed by the DGAC in chapter 6 (clinical trials and observational studies on sources of added sugars and CVD risk) provides a more direct and specific evaluation on added sugars and CVD risk than from data on dietary patterns and CVD risk.

(Response) As discussed in part II.H.3.a, we are requiring an added sugars declaration so that consumers can limit calories from added sugars as part of a healthy dietary pattern lower in sugar-sweetened foods and beverages which is associated with a reduced risk of chronic disease and can meet nutrient needs within calorie limits. We do not need to limit our review of the science to the moderate evidence related to an independent relationship between added sugars and risk of chronic disease; instead, we can include in our review the strong and consistent association between the healthy dietary pattern with lower amounts of sugar-sweetened foods and beverages, compared to less healthy dietary patterns, and reduced risk of CVD (see added sugars introduction). Although the 2015 DGAC concluded that strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages are associated with excess body weight in children and adults, the evidence reviewed by the 2015 DGAC was primarily on sugar-sweetened beverages, which only represent 39 percent of food sources of added sugars. The consumption of added sugars and their impact on health continues to be an area of great interest to the scientific community and to consumers. We intend to monitor future research that may impact the labeling of added sugars.

(Comment 141) Some comments suggested that our review is inconsistent and selective. The comments said that the particular dietary pattern related to CVD was singled out from the DGAC Report of dietary patterns and other chronic diseases (*e.g.* cancer, type 2 diabetes) in the supplemental proposed rule because it was the only chronic disease for which the evidence was considered to be strong and, as such, we consider strong evidence to be necessary for requiring added sugars on nutrients in the proposed rule.

(Response) We have strong and consistent evidence that dietary patterns associated with a decreased risk of CVD are characterized by higher consumption of fruits, vegetables, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meats, and lower intakes of refined grains and sugar-sweetened foods and beverages relative to less healthy dietary patterns. The dietary pattern approach focuses on components of the diet and how they contribute to an overall healthy dietary pattern that is associated with a decreased risk of disease. Although this is the first time that the 2015 DGAC has conducted a systematic review of the evidence related to dietary patterns and health outcomes, analysis of diet quality using scoring indices is an accepted scientific method that has been used for years to assess diet quality. The evidence that the 2015 DGAC considered related to dietary patterns and CVD risk adds to information that we provided in the proposed rule to support an added sugars declaration and is not the only evidence that we are relying on to support the declaration. Evidence related to an independent association between consumption of added sugars and risk of chronic disease continues to emerge. Although science related to the independent relationship between total added sugars and risk of chronic disease is not conclusive at this point, it does not mean that we cannot and should not rely on the evidence that we currently have related to healthy dietary patterns characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced risk of CVD, which is strong and consistent.

(Comment 142) Some comments cited reasons why the type of analysis which was conducted to examine the relationship between healthy dietary patterns and health outcomes cannot be used to make conclusions regarding single nutrients, food components, or foods. The comments noted that we have stated that we do not accept this type of extrapolation from an association of a complex mixture with disease risk to determine the association between a single component of the mixture to disease risk in our Guidance on Evidenced Based Review (Ref. 85). The comments said that the extrapolation does not establish a public health endpoint to justify mandatory declaration added sugars. Some comments also said that the evidence on dietary patterns is not nutrient specific and a dietary pattern is defined as the quantities, proportions, variety or combinations of different foods and beverages in diets, and the frequency with which they are habitually consumed.

(Response) This type of analysis that was conducted to examine the relationship between healthy dietary patterns and health outcomes is appropriate to answer questions about how dietary patterns, as a whole, impact disease risk. This type of analysis also takes into account relationships between components of a healthy dietary intake, which cannot be determined when looking at specific associations with a nutrient and risk of disease. Other analyses are more appropriate for answering questions related to a direct cause and effect relationship between a nutrient and the risk of a disease or health-related endpoint.

The evidence considered by the 2015 DGAC related to dietary patterns and CVD risk provides us with information about the components of a healthy dietary pattern and how those components, when taken in combination, make up a dietary pattern that is associated with the reduced risk of CVD. As noted by the 2015 DGAC, it is often not possible to separate the effects of individual nutrients and foods. The 2015 DGAC Report says that the components of the eating pattern can have interactive and potentially cumulative effects on health (Ref. 19). The 2015–2020 DGA also says that people do not eat food groups and nutrients in isolation but rather in combination, and the totality of the diet forms an overall eating pattern.

The dietary pattern analysis as well as information from the USDA food patterns showing how much added sugars individuals can reasonably consume in their diet while meeting nutrient needs, and consumption data showing that consumption of added sugars among Americans remains high supports limiting consumption of added sugars. In order for consumers to limit consumption of added sugars in the diet, it is necessary for information to be provided on the label that allows consumers to determine how much added sugars is in a serving of food, so

they can determine whether and how that food fits into their total daily diet. Therefore, information about what constitutes a healthy dietary pattern that is associated with a decreased risk of disease supports a label declaration of added sugars even though conclusions about a nutrient-specific association with risk of disease cannot be drawn from this type of evidence.

(Comment 143) Some comments noted that the 2010 DGA said that individuals can achieve a healthy diet in multiple ways and preferably with a wide variety of foods and beverages. Optimal nutrition can be attained by many different dietary patterns, and a single dietary pattern approach or prescription is unnecessary. The comments said that dietary patterns other than those evaluated in Chapter 2 of the 2015 DGAC Report might not have necessarily shown that reduced added sugars intake was associated with increased risk of CVD.

(Response) While individuals can follow a number of different healthful dietary patterns, the NEL review on dietary patterns and CVD risk did not specifically look at studies where individuals were placed on a particular diet or were instructed to follow a specific diet. The 2015 DGAC did consider evidence from DASH trials where participants were placed on the DASH diet. With the exception of the DASH trials, the analyses included free-living individuals who were following many dietary patterns. Certain scoring indices were then applied to intake data to look at how closely the diets of study participants matched certain types of healthy dietary patterns. Scores were then given based on adherence to the dietary pattern of interest. The dietary quality analyses included individuals that did not closely adhere to a particular dietary pattern of interest. In looking at all reports, which included an analysis of adherence to multiple types of healthy dietary patterns, the 2015 DGAC concluded that closer adherence to the healthy dietary patterns of interest, which tended to include less sugar-sweetened foods and beverages, resulted in a decreased risk of CVD. Therefore, the analysis included individuals who followed a wide variety of dietary patterns, some of which were determined to be more strongly associated with chronic disease risk than others. Although it is possible that some dietary patterns including substantial amounts of sugar-sweetened foods and beverages are associated with a decreased risk of CVD, research conducted across cohorts using multiple dietary pattern indices show that there is a high degree of correlation (highest quintile of scores) across scoring indices, and that higher diet quality is significantly and consistently associated with a reduced risk of death due to all causes, CVD, and cancer compared to the lowest quintile of scores (Ref. 86). Therefore, it is very unlikely that the majority of the population can consume a high quality diet that incorporates the proper amounts from food groups to meet nutrient needs as well as a significant amount of added sugars and still stay within calorie limits. The research suggests that there is a high level of consistency between different scoring indices in what is considered to be a healthy diet. Furthermore, as shown in the USDA Food Patterns for three patterns of health eating (a Healthy U.S.-Style Eating Pattern, a Healthy Mediterranean-Style Eating Pattern, and a Healthy Vegetarian Eating Pattern (Ref. 19)), in order to eat a dietary pattern that includes the amounts of other healthy dietary components, it is not possible to consume large amounts of empty calories.

b. The 2015 DGAC Analysis of Dietary Patterns and Health Outcomes

(Comment 144) In the analysis of dietary patterns and health outcomes, dietary quality indices were used to evaluate adherence to certain dietary patterns. An individual's score is derived by comparing and quantifying their adherence to the criterion food and/or nutrient component of the index and then summed over all components (Ref. 19). A population's average mean and individual component scores can be similarly determined. Some examples of the dietary quality scores used for the analysis include: The Health Eating Index (HEI)–2005 and 2010, the Alternate HEI (AHEI) and updated AHEI–2010, the Recommended Food Score (RFS), the Mediterranean Diet Score (MDS), and the Alternate Mediterranean Diet Score (aMed).

Some comments took issue with the various scoring algorithms used to evaluate adherence to certain dietary patterns as well as with the studies included in the analysis. One criticism of the scoring algorithms was that the majority of dietary pattern index studies cited by the 2015 DGAC did not include an added sugars criterion. The comments noted that the MDS, the aMed, the AHEI, and the RFS do not include a ''sweets or sugar products'' component. The comments said the HEI–2005 included sugar in a combined category of solid fats, alcoholic beverages and added sugars, the AHEI–2010 included sugar-sweetened beverages and fruit juice, and the Dietary Approaches to Stop Hypertension adherence index included soda, sugar sweetened beverages or a broader ''sweets'' category depending on the scoring method used. The comments said that none of these indices specifically address added sugars independently. One comment stated that not one of the Mediterranean dietary pattern studies cited by the DGAC had a sugars or added sugars criterion.

Other comments singled out studies from the 55 that were included in the NEL review based on whether they included a measure of added sugars in the study. The comments suggested that studies with scoring indices that did not include a measure of added sugars should be excluded from our analysis. Some comments suggested that, when only the studies in which dietary pattern scoring indices were used that included a measure of added sugars are considered, the evidence related to CVD risk is not strong and consistent. The comments noted that the 2015 DGAC Report says that ''certain scores also included added sugars or sugar-sweetened beverages as negative components.''

(Response) While a number of index studies did not include a direct measure of added sugars or sugar-sweetened foods and/or beverages, the scoring systems in the study were measuring adherence to an overall dietary pattern, such as the Mediterranean diet, that is typically low in added sugars. Furthermore, research shows that there is consistency in scoring as well as association with health outcomes across dietary quality indices, including two that do not typically include a sugar-sweetened food and beverages component (*i.e.* aHEI and AMED) (Ref. 86).

The Dietary Patterns Methods Project conducted standardized and parallel analyses of the prospective association of select dietary patterns characterized by dietary quality indices and mortality outcomes in three large cohort studies conducted in the United States. The investigators selected four commonly used dietary quality indices including the HEI–2010, the AHEI–2010, the aMED, and the DASH (Ref. 86). The comments noted that the AHEI and aMED dietary quality indices do not have a specific measure of added sugars. Liese et al. found that the indices were highly correlated, which means that individuals with the highest scores of adherence were likely to be scored similarly across all of the four dietary quality indices. They also found that higher diet quality (highest quintile of scores) was associated with lower all-

cause, CVD, and cancer mortality when compared to lower diet quality (lowest quintile of scores) across the diet quality indices. Similar findings have been seen across dietary quality scoring indices and large prospective cohort studies (Refs. 87–89). These results suggest that dietary quality scoring indices consistently determine diet quality, regardless of whether they include a component for sugar-sweetened foods and/or beverages. The research also suggests that, because the diet quality indices are so comparable in what they measure as a high quality diet, it is very likely that the diets of individuals with higher diet quality scores will have a lower intake of sugar-sweetened foods and/or beverages. Furthermore, it is very unlikely that participants with high diet quality scores across the various scoring indices would be able to consume enough of the other components of a healthy dietary pattern to receive a high score if they were consuming large amounts of sugar-sweetened foods and beverages.

We also note that the dietary pattern scoring indices were modified by study investigators, so it is necessary to review each study to determine whether the diet quality index used in a particular study included a component that measured added sugars. Table 4–B–I–1 from the 2015 DGAC Report shows a comparison of the dietary components across some of the major diet scoring indices (Ref. 19). The comment noting that the MDS, the aMed, the AHEI, and the RFS do not include a ''sweets or sugar products'' component was likely referring to the information in Table 4–B–I–1. However, to determine if the scoring index used in a particular index study included a measure of sugars-sweetened foods or beverages, it is necessary to go to the study report because investigators did include measures of types of sugar-sweetened foods and/or beverages in most of the studies included in the analysis. For example, Trichopoulou et al. evaluated adherence to a Mediterranean diet by using the MDS, but included sweets as a component of the scoring algorithm.

(Comment 145) One comment noted that, if a company wanted to make a voluntary claim that there is a strong association between diets low in added sugars and a decreased risk of CVD, we would not consider the underlying evidence that the DGAC relied upon as sufficient to support such a claim, yet we are relying on this same level of evidence to require that companies include a mandatory claim on their labels that is potentially false and misleading for certain foods which undergo chemical processes that reduce the amount of sugar in a product.

(Response) To the extent that the comments are suggesting that it is not appropriate for us to rely on evidence related to dietary patterns and health outcomes to support a mandatory declaration of added sugars, we disagree. The scientific evidence related to dietary patterns and health outcomes that was presented in the 2015 DGAC Report, and more specifically the evidence related to a healthy dietary pattern that is associated with a decreased risk of CVD relative to less healthy dietary patterns does show that there are certain characteristics of a healthy dietary pattern that consumers need when selecting foods to eat and when determining how much of those foods they should eat. The information that we are relying upon related to healthy dietary patterns characterized, in part, by lower amounts of sugar-sweetened foods and beverages and CVD risk is directly related to the need for consumers to have information on the label, which they do not currently have in the case of added sugars, so that they can construct a healthy dietary pattern that is associated with a decreased risk of disease and maintain healthy dietary practices.

In response to the comment's suggestion that an added sugars declaration is potentially false and misleading for certain foods which undergo chemical processes that reduce the amount of sugar in a product, we have concluded that, generally, manufacturers of foods that undergo non-enzymatic browning and fermentation are able to determine a reasonable approximation of the amount of added sugars in a serving of their finished product (see part II.H.3.k). Therefore, added sugars declarations on foods that undergo non-enzymatic browning and fermentation are not potentially false and misleading.

(Comment 146) Some comments noted that the studies that did include an assessment of sugar sweetened foods and/or beverages did not include an assessment of everything that we would consider to be added sugars. One comment said that some of the studies only assessed sugars-sweetened beverage intake, and some considered fruit juices to be sugar-sweetened beverages. The studies included no assessment of intake of sugar-containing foods.

Other comments noted that the scoring algorithms used to evaluate dietary pattern adherence may differ and may affect the results of studies examining specific health outcomes. The comments said that this factor may hamper cross-study comparisons and limit reproducibility.

(Response) Some studies included only sugar-sweetened beverages, while others included ''sugar'' or ''sweets.'' The scoring algorithms also did vary from study to study. However, research shows that different dietary quality indices are very comparable in what they consider to be a high quality versus a low-quality diet (Ref. 86). The different dietary quality indices also are very consistent in their association with health outcomes (Ref. 86). Although the studies included different types of added sugars as components of their analysis, when taken as a whole, the data generally shows that healthy dietary patterns that are associated with a decreased risk of CVD relative to less healthy dietary patterns are characterized, in part, by lower amounts of sugar-sweetened foods and beverages. Additionally, it would be extremely difficult for individuals consuming large amounts of empty calories from sugar-sweetened foods and beverages to be able to consume enough of the other components of a healthy dietary pattern to be able to receive a high diet quality score.

We also recognize that the scoring algorithms used in the studies included in the analysis differ from study to study. However, despite having different ways to evaluate many different types of healthy diets, a strong and consistent pattern emerged from the evidence. We view the variety of scoring algorithms to be a strength of the review because, despite the differences in scoring algorithms, there was consistency in what constituted a diet that would receive a high dietary quality score and there was consistency in the association between higher dietary quality scores and CVD risk versus lower diet quality scores.

(Comment 147) Some comments noted that none of the definitions of added sugars used in the studies included in the analysis of dietary patterns and CVD risk are consistent with our proposed definition since it was not released until 2014 and the studies were conducted prior to that date. One comment suggested that many more sources of sugar are included in our proposed definition than in the studies cited in the 2015 DGAC Report.

(Response) The studies included in the analysis on dietary patterns and CVD risk assessed the intake of foods that are part of an eating pattern rather than intake of specific nutrients. Therefore, we would not expect, nor would it be necessary for, our proposed definition of added sugars to be consistent with how sugar-sweetened

foods and beverages were defined for the purposes of this type of analysis. Furthermore, we would not anticipate that researchers would have used our proposed definition as a guide when determining what foods include added sugars because, at the time the studies were conducted, we had not finalized the rule.

(Comment 148) One comment cited several epidemiological studies which evaluated the DASH dietary scoring pattern and CVD outcomes. The comment said that, in one study included in the 2015 DGAC analysis (Ref. 90), the range of sweetened beverage intake across the DASH score quintile was narrow (0.3 servings per day in the lowest quintile and 0.2 servings per day in the highest quintile). The comment noted that the authors of the study concluded that a diet that resembles the DASH eating plan was significantly associated with lower risk of CHD and stroke, but they made no mention of reduced consumption of sweetened beverages as part of the diet. The comment also referred to a subsequent study in the Women's Health Study cohort which evaluated the relationship between adherence to a DASH dietary pattern score and risk of CVD. In this study, an apparently strong association of adherence to the DASH diet with incidence of CVD was attenuated upon control for confounding variables. The comment noted that, Folsom et al. found that adherence to the DASH diet, where sweets were evaluated as a broad category, did not have an independent long-term association with hypertension or CVD mortality after adjustment for confounding variables in a cohort of women (Ref. 91).

(Response) Although study authors may not have mentioned sweetened beverages as part of the DASH eating plan, the DASH diet is typically lower in the category of food called ''sweets.'' Therefore, it is appropriate to rely on studies where a DASH scoring index was used because the scoring algorithm is based on a diet that is low in sweets.

We considered all 55 articles reviewed by the NEL, which summarized evidence from 52 prospective cohort studies and 7 randomized-controlled trials (RCTs), and the NHLBI Lifestyle Evidence Review and the associated Lifestyle Management Report, which included primarily RCTs. Although some studies where a DASH dietary quality scoring index was used did not show an association with CVD risk, and some DASH dietary quality scoring indices did not include a direct measure of sugar-sweetened foods and beverages, as noted in the comments, when taken together with other studies included in the analysis, the body of evidence supports the conclusion that there is strong and consistent evidence dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol and sodium and richer in fiber, potassium, and unsaturated fats are associated with decreased CVD risk.

(Comment 149) Some comments cited a number of studies where an association with higher adherence scores and CVD risk, CHD risk, or ischemic stroke was found, but when an analysis of sugar sweetened foods and/or beverages was done in the same data set, an association with the outcome of interest was not found. The comments referred to component analyses that were conducted as part of some of the studies included in the analysis of the evidence related to dietary patterns and CVD risk. In these component analyses, the data for intake of certain dietary components, such as fruits and vegetables, were looked at more closely to see if they were associated with the outcome of interest (CVD risk) when looked at in isolation. The comments said that ''added sugars'' intake was not a factor in the observed differences in CVD risk in some of the studies where component analyses were performed. Additionally, the comments said that sugars are only one of many dietary factors included in the scoring indexes, and interplay between multiple factors in the dietary patterns cannot be excluded. Some comments said that the analysis is limited because not all of the studies included in the NEL review included a component analysis. The comments pointed to the statement in the 2015 DGAC Report which says ''although a large number of the studies assessed food group components and their association with CVD outcomes, many did not, and more precise determination of the benefits and risks of individual components (*e.g.,* alcohol) would be helpful for policy recommendations. One comment noted that the 2015 DGAC Report fails to mention all of the individual components that were tested that had no effect on CVD (*e.g.,* added sugars). Another comment noted that throughout the studies, the impact of dairy on the association between a dietary pattern and a health outcome was inconsistent, which shows that the methodology used is imprecise.

(Response) For the first time, the 2015 DGAC conducted a systematic review of the evidence related to dietary patterns and health outcomes. The analysis was included because people do not eat nutrients or foods in isolation. Rather than focusing on specific nutrients, the 2015 DGAC and the 2015–2020 DGA focused on eating patterns and shifts that Americans need to make in order to move towards a healthier diet that is associated with a decreased risk of chronic disease. The 2015–2020 DGA said that the key recommendations for healthy eating patterns should be applied in their entirety, given the interconnected relationship that each dietary component can have with others (Ref. 28). The 2015 DGAC Report said, and we agree, that it is often not possible to separate the effects of individual nutrients and foods and that the totality of the diet-the combinations and quantities in which foods and nutrients are consumed may have synergistic and cumulative effects on health and disease (Ref. 19). It is with this information in mind that we reviewed the evidence related to dietary patterns and health outcomes presented in the 2015 DGAC Report.

We disagree with the comments stating that studies that included a component analysis for added sugars and CVD risk that did not show a favorable association cannot be used to support an added sugars declaration. Investigators use component analyses as an exploratory measure to see if the result seen is mainly due to one component or another. How these component analyses are conducted varies from study to study because there is not consensus within the scientific community yet on what methods should be used for component analyses. For example, in some studies, the effects of individual components of the diet are looked at separately without controlling for the effects of other components of the diet, while in other studies investigators control for other variables in the diet when looking at the effect of an individual dietary component. Because the methodology related to dietary pattern component analyses is still evolving and there is a great deal of variability between studies in how the component analyses are performed, we believe that it would not be appropriate to conclude that sugar-sweetened beverages have no responsibility for the overall relationship that is seen with CVD risk just because a component analysis indicates that there is no

independent effect of sugar-sweetened beverage consumption on CVD risk in the data set. Instead, we have considered the evidence related to the totality of the dietary pattern. By considering the makeup of the entire healthy dietary pattern, we can take into account connections that foods and dietary components may have with one another.

As noted in the 2015 DGAC Report, the analysis of dietary patterns and health outcomes captures the relationship between the overall diet and its constituent foods, beverages and nutrients in relationship to outcomes of interest and quality, thereby overcoming the collinearity (closely aligned relationship) among single foods and nutrients (Ref. 19). Therefore, we agree with the comment that said that interplay between multiple factors in dietary patterns cannot be excluded. The dietary pattern should be looked at as a whole rather than a sum of its parts because there is interplay between the multiple factors. When certain nutrients or foods are looked at individually without taking into account the relationships that the nutrient or food component has with other pieces of the dietary pattern, the effects of those relationships are lost. Information that would allow consumers to understand how a food fits into their overall dietary pattern is therefore important to be declared on the label.

In addition, investigators often analyze data using different methods, depending on the research question, and not all articles include a report of all of the study findings. Therefore, it is possible that sugar-sweetened foods and beverages could have been measured or that a component analysis was conducted for sugar-sweetened foods and/or beverages, but the findings were not reported in a particular published article.

(Comment 150) Some comments said that the evidence related to healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages is not strong and questioned whether we relied on the DGAC's analysis and conclusion rather than doing our own analysis of the studies.

(Response) We reviewed and considered the evidence that was considered by the 2015 DGAC when making their conclusions in Chapter 2 of the 2015 DGAC Report. We concluded based on that review and consideration of the evidence that strong and consistent evidence demonstrates that healthy dietary patterns are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages.

The comments that said that the data does not support a strong and consistent relationship with CVD risk were looking at the data in more limited way than we have. They focused their review on a specific nutrient-disease relationship whereas we considered the whole of the dietary pattern. Some comments included conclusions from their own review of the evidence. In those comments, studies were excluded based on whether the dietary quality index used in each study included a measure of added sugars, whether the studies were conducted in the United States, whether a component analysis for a measure of added sugars was conducted, and whether that analysis showed an association with CVD risk. As previously discussed in our responses to comments 147 and 148, we do not agree that it is appropriate to discount studies from the body of evidence considered based on these factors and have looked at the data and the dietary pattern as a whole rather than a sum of its parts.

(Comment 151) One comment questioned the scientific validity of using hypothesis-based dietary pattern scores for determining health outcomes. The comment said that the use of adherence scores, cluster or factor analysis as a science-based measure for predicting health outcomes is flawed and not an accepted scientific methodology. The comment provided an example where an analysis based on dietary pattern scores showed that individuals with higher adherence to the dietary pattern of interest compared to individuals with lower adherence actually had an almost 300 percent increased chance of dying from CVD, which is an incorrect conclusion (Ref. 92).

(Response) The use of this type of scientifically valid approach to looking at complex relationships between dietary patterns at health endpoints is being used by well-established scientific bodies. In fact, some of the dietary quality scoring indices were developed by Federal Agencies (*e.g.,* the HEI). Although this is the first time that the DGAC has conducted a systematic review of the evidence related to dietary patterns and health outcomes, the use of diet quality indexes to look at an association between dietary patterns and health outcomes is not new. For example, the USDA's Center for Nutrition Policy and Promotion created the HEI in 1995. Dietary pattern analysis is becoming more widely accepted in the scientific community because there has been a shift in recent years from focusing on nutrients and their association with disease risk to a dietary pattern approach that considers the fact that individuals do not eat nutrients or foods in isolation. The 2015 DGAC based their conclusions and recommendations on the results of this type of analysis to look at dietary patterns as a whole rather than specific nutrient and disease relationships, and the DGAC uses scientifically valid approaches that are widely accepted in the scientific community.

Other comments suggested that the use of dietary pattern indices to assess the relationship between dietary patterns and health outcomes is flawed for specific reasons. We address those issues in our responses to comment 143.

(Comment 152) Several comments cited a number of limitations of how the dietary intake data was collected in studies included in the analysis. The comments cited a number of criticisms of the use of Food Frequency Questionnaires (FFQs), which were used in the observational studies included in the analysis to assess adherence to scoring patterns. The comments suggested that added sugars are poorly measured by FFQs. Another limitation of FFQs mentioned in comments is that they are based on self-report and may introduce levels of report bias that can attenuate diet-health relationships. The comments stated that the extent to which data from FFQs are valid measures of dietary patterns is not well established. One comment said that FFQs are not designed to assess absolute intakes of foods, and when used only at baseline, the assumption is that intake does not change over several years, when health outcome is measured. The comment also said that FFQs provide little information on how the food was prepared.

Other comments said that the dietary patterns do not assess the frequency of meal and snack consumption, specific combinations of foods consumed together, and aspects of food purchase and preparation, all of which may influence an overall dietary pattern.

One comment said that fats and oils are spread across food groups, making them difficult to account for.

(Response) FFQs are a relatively efficient and cost effective way to collect information about usual intakes in a large population study, which is why they are often used to assess intake in large-scale cohort studies. FFQs are often used in studies because they are inexpensive, can be self-administered, take less time for participants to

complete compared to other dietary assessment methods, and can be read by machines rather than being hand-entered and analyzed (Ref. 93). Although there may be more precise ways to assess dietary intake patterns, other intake methods, such as multiple 24-hour recalls are often less practical for use in large population studies. There are many advantages to having a larger sample size when evaluating habitual intake, which can provide robust results (Ref. 94). FFQs have been shown to be reasonably accurate in reporting food use (Ref. 93). FFQs also provide a better estimate of usual intakes that can be used to assess dietary patterns because they assess intake over a longer period of time than other dietary assessment techniques, such as 24-hour recalls, diet histories, and dietary records. FFQs are also almost always used in retrospective reports about diet (Ref. 95). We accept the use of data from FFQs in observational studies used to support an association between a substance and a disease or health-related condition for health claims (Ref. 85).

We recognize that there are some limitations to the use of FFQs, and that one limitation is that in many of the studies FFQs were only administered at baseline. FFQs do not assess the frequency of meal and snack consumption, specific food combinations, and food preparation. Dietary pattern analysis considers combinations of foods and how they relate to health outcomes, but questions about the frequency of meal and snack consumption, specific food combinations, and food preparation would require a more specific analysis. Like other types of dietary assessment, this type of analysis can only be used to draw general conclusions about what components are included in a dietary pattern that is associated with risk of disease and the relative contribution (higher or lower) of that dietary component to the overall dietary pattern. Further analyses would be required to answer questions related to frequency of meal and snack consumption, specific food combinations that may associated with disease risk, and specific aspects of food preparation.

Fats and oils are spread across food groups, which make them more difficult to account for; however, we are most interested in sugar-sweetened food and beverages and how they fit into the dietary pattern. Sugar-sweetened foods and beverages can be isolated from the diet by the dietary assessment tools used in the studies included in the dietary pattern and health outcomes analysis.

(Comment 153) One comment said that the observational data used in these studies, and the way that they are analyzed, make the findings highly subjected to residual confounding (error that can occur when either the categories of the variables related to the outcome of interest (*e.g.* CVD risk), called confounding variables, are too broad or when some confounding variables are not accounted for). The comment said that even with adjustment for confounders, residual confounding cannot be eliminated from observational studies. More specifically, higher/better dietary index scores were associated with a number of factors, such as higher education, increased physical activity, non-smoker, multivitamin use, hormone therapy (women), and being married vs. single.

(Response) Residual confounding is a general limitation of all observational studies and is not specific to just this type of analysis. The comment did not provide specifics about individual studies for which confounders were not appropriately adjusted. Therefore, the comment does not change our consideration of the data.

(Comment 154) Some comments said that the patterns may be population-specific and therefore, are not generalizable. The comments also noted that some studies were not conducted in the United States and suggested that these studies cannot be used to draw conclusions about the general U.S. population.

(Response) We agree that patterns may be population-specific; however, care was taken to include studies conducted in populations that were very similar to the U.S. population (*e.g.* countries in the E.U.) and that data was collected in populations that would be generalizable to the U.S. population (Ref. 19).

(Comment 155) Some comments said that the NEL project based its conclusions only on those studies where score adherence was associated with decreased CVD risk, leaving all of the studies showing no effect out of the analysis.

(Response) We disagree with the comment that the NEL and the 2015 DGAC based their conclusions only on studies where score adherence was associated with decreased CVD risk. As stated in the 2015 DGAC Report, after the exclusion criteria were applied, a total of 55 studies met the inclusion criteria for the systematic review. The NEL found that the majority of the 55 studies that assessed CVD incidence or mortality reported an inverse association between increased adherence to a healthy dietary pattern and decreased risk of CVD. The NEL considered the results of all 55 studies rather just a subset where score adherence was associated with a decreased CVD risk.

c. Authority for Labeling

(i) Statutory Authority

(Comment 156) Many comments addressed our authority to require the mandatory declaration of added sugars on the label. We discuss our authority under the FD&C Act and our recordkeeping authority in parts II.C.3 and C.4.

Many other comments questioned our authority to require added sugars on the label because the purpose of the Nutrition Facts label is to help consumers reduce their risk of diet-related disease and added sugars are not associated with risk of disease. One comment noted that each of the nutrients currently on the label relate to a disease or serious health condition. Other comments said that we lack the authority to require the disclosure of added sugars because our rationale for requiring labeling, which is related to encouraging consumers to eat a more nutrient-dense diet or dietary planning, is by our own admission not related to a disease or health-related condition, such as obesity.

One comment suggested that, because there is no scientifically supported quantitative intake recommendation for added sugars upon which a DRV can be derived and because no authoritative scientific body has found a public health need to set an Upper Level (UL) for added sugars intake, we have not sufficiently shown that there is a public health need to monitor added sugars intake through labeling for consumers to maintain healthy dietary practices. The comment further stated that our admission in the proposed rule that we cannot establish a DV for added sugars further indicates that added sugars is not the type of nutrition disclosure that Congress intended for the Agency to require on the label.

(Response) As discussed in part II.C.3, under section 403(q)(2)(A) of the FD&C Act, the Secretary of the Department of Health and Human Services may require, by regulation, that information related to additional nutrients be included in the label or labeling of food, if the Secretary determines that providing information regarding the nutritional value of such food will assist consumers in maintaining healthy dietary practices. The FD&C Act requires that nutrition information on

the label be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet. There is evidence that excess consumption of added sugars is a public health concern. Healthy dietary patterns characterized, in part, by lower intakes of foods and beverages which contain added sugars are associated with a decreased risk of CVD. Current scientific evidence supports limiting consumption of added sugars. Without a label declaration of added sugars, consumers are unable to determine how much added sugars a serving of a particular food would contribute to their diet and how to fit that food within an overall healthy eating pattern. We have concluded that the declaration of added sugars will assist consumers in maintaining healthy dietary practices, as required under the FD&C Act.

We disagree with the comment that asserted that added sugars is not the type of nutrient disclosure Congress intended for FDA to require because there is no scientifically supported quantitative intake recommendation for added sugars upon which a DRV can be derived. We are not limited to establishing a quantitative intake recommendation to circumstances in which there is a biomarker of risk of disease. Instead, we are relying on other evidence to support a mandatory declaration of added sugars for the general population which is not based on an independent relationship with a chronic disease, health-related condition, or physiological endpoint, but is based, instead, on constructing an overall healthy eating pattern that is low in added sugars.

As discussed in part II.H.3.o.(i), new evidence has become available since publication of the proposed rule in March 2014 related to limiting intake of added sugars to less than 10 percent of calories (Ref. 19). We have considered the underlying scientific evidence in the 2015 DGAC Report and have determined that the evidence supports establishing a DRV of 10 percent of total calories. The DRV for added sugars of 10 percent of calories is based on the amount of added sugars that can be reasonably accommodated within a healthy dietary pattern. As discussed in part II.H.3, the evidence that we are relying on for a mandatory declaration of added sugars for the general population and for the DRV is based on information related to healthy dietary patterns. Therefore, the comment's concern about a lack of a quantitative intake recommendation for added sugars has been addressed.

(Comment 157) Some comments said that a stronger case can be made for including whole grains or stearic acid on the label.

(Response) The FD&C Act gives us the authority to add and remove nutrients from the label based on whether we determine the nutrients are necessary to assist consumers in maintaining healthy dietary practices. We did not consider whether it would be appropriate to consider whole grains as a nutrient, nor propose a declaration of whole grains on the nutrition label, in the context of this rulemaking. Whole grains are made up of a variety of different grains (*e.g.* amaranth, barley, buckwheat, whole kernel corn, millet, oats, quinoa, rice, rye, sorghum, teff, triticale, wheat, and wild rice), and we would need to give further consideration about whether it would be appropriate to consider whole grains as a nutrient for purposes of nutrition labeling.

In the preamble to the proposed rule (79 FR 11879 at 11894), we considered whether the labeling of stearic acid should be mandatory or voluntary on the label and concluded that the evidence for a role of stearic acid in human health (*e.g.* changes in plasma LDL cholesterol levels) is not well-established. We tentatively concluded that the individual declaration of stearic acid is not necessary to assist consumers in maintaining healthy dietary practices. We also have declined to exclude stearic acid from the calculation of an individual food's percent DV for saturated fat elsewhere in this document (see part II.F.2) because current dietary recommendations for saturated fat, such as those of the DGA, do not differentiate among the individual saturated fatty acids in providing the recommended intake levels. In addition, the DGA recommendation to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid, and instead, relates to the intake of total saturated fatty acids. Therefore, we have determined that stearic acid should not be specifically listed on the label and should not be excluded from the calculation of an individual food's percent DV for saturated fat.

(Comment 158) One comment discussed how the declaration of the amount of added sugars in a product ''could compromise legitimate trade secrets'' based on the declared amount being made public.

(Response) To the extent that the comment argued that the declaration of the amount of added sugars could compromise legitimate trade secrets, we disagree. We are not requiring the public disclosure of formulations or recipes. We are requiring, for all products, the declaration of specific nutrients that have been determined to assist consumers to maintain healthy dietary practices (cf. *Philip Morris, Inc.* v. *Reilly,* 312 F.3d 24 (1st Cir. 2002)). It would be unreasonable for manufacturers to expect that the nutrients on the Nutrition Facts label would never change based on updated scientific evidence and the need to provide information that will assist consumers to maintain healthy dietary practices (see, *e.g., Ruckelhaus* v. *Monsanto Co.,* 467 U.S. 986 (1984), *Corn Products Refinery Co.* v. *Eddy,* 249 U.S. 427 (1919)).

(ii) Material Fact

(Comment 159) Some comments said that a declaration of added sugars is not a material fact because a declaration does not appear to be necessary for consumers to make healthy dietary choices and that, absent a declaration of added sugars, the label is not false or misleading to consumers.

(Response) Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act further defines misleading labeling. In determining whether labeling is false or misleading, we take into account representations made or suggested in the labeling and the extent to which the labeling fails to reveal facts material in light of the representations or with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (id.). In the context of nutrition labeling, we have considered the declaration of meaningful sources of calories or nutrients to be a material fact (see 55 FR 29487 at 29491 through 29492, July 19, 1990 and 68 FR 41434 at 41438, July 11, 2003). Nutritive value cannot be determined without a declaration. Thus, the final rule will ensure that information that relates to the added sugars content of a serving of food, which is fundamental to people's food choices, is available on the food label. The added sugars declaration will provide consumers with information that is material with respect to the consequences of consuming a particular food (see 55 FR 29487 at 29491 through 29492).

We have determined that there is adequate evidence to demonstrate that consumption of added sugars is a public health concern because evidence shows that heathy dietary patterns associated

with a decreased risk of chronic disease are lower in sugar-sweetened foods and beverages that have been sweetened with added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened foods and beverages is associated with increased adiposity in children. Furthermore, the scientific evidence supports that consumers limit their intake of added sugars to less than 10 percent of total calories. Without information on the amount of added sugars in a serving of a food, consumers would not have the information they need to construct a healthy dietary pattern that contains less than 10 percent of calories from added sugars. Therefore, we have concluded that this evidence is adequate to compel a label declaration of added sugars on the Nutrition and Supplement Facts labels.

(iii) Regulations Must Bear a Reasonable Relationship to the Requirements and Purposes of the Statute

(A) Consumers Are Eating Too Many Added Sugars

(Comment 160) Some comments suggested that an added sugars declaration would be beneficial for consumers because evidence shows that Americans are consuming too many added sugars. The comments cited survey data showing that from 2003 to 2006, added sugars, on average, provided about 14 percent of total calories in the American diet, and 25 percent or more of total calories for over 36 million Americans. The comments argued that Americans consume an average of 152 pounds of sugar per year, the average 6- to 11-year-old American boy consumes 22 teaspoons of added sugars per day, and the average girl of that age consumes 18 teaspoons of added sugars per day. The comments also cited data on the average per-capita loss-adjusted food availability data from 2012 showing that, on average, Americans consumed between 18 to 23 teaspoons (about 300 to 390 calories worth) of added sugars per day.

Other comments suggested that the declaration of added sugars is not necessary because current evidence shows that consumption of added sugars is declining in the United States. One comment noted that the American public is already reducing its consumption of sugar-sweetened beverages, especially carbonated sweetened beverages, and it is doing so without having an added sugars declaration on the Nutrition Facts label. Some comments provided evidence that the decrease in the intake of added sugars has been pronounced with an approximate decrease of about 25 percent on a per person basis between 1999 and 2010 (Ref. 96). One comment noted that sugar/sucrose consumption has declined by 33 percent in the United States and that per capita added sugars consumption has declined since 1970 when obesity was not a public health concern.

One comment suggested that the contribution from added sugars to the increase in total calories over the past 30 years is relatively minor. The comment cited evidence from USDA that between 1970 and 2009 there was an increase of 425 calories per person per day, and added sugars contributed less than 10 percent (38 calories) of this increased caloric intake.

One comment suggested that the problem of increasing added sugars consumption has mainly been a problem with beverages, not food. The comment said that almost all of the increase in consumption of sugars between the late 1970s and about 2005 has been in beverages. The total amount of added sugars consumed in sweet pastry, dairy and non-dairy desserts, candy, and other sugars-containing foods has remained almost constant, but the added sugars contributed by sweetened beverages has doubled. Total sugars consumption increased from about 59 grams per person per day to about 84 grams per person per day, and added sugars in sweetened beverages increased from about 17.5 to 41.5 grams per person per day. Twenty-four of the twenty-five grams of increase were in sweetened beverages.

(Response) Although added sugars consumption has decreased in recent years, consumption of added sugars still remains high at an average of 13.4 percent of calories among the U.S. population (Ref. 19). The scientific evidence supports Americans limiting their intake of added sugars to no more than 10 percent of calories (Ref. 19). The scientific evidence also is included in the 2015–DGA. Current consumption exceeds the recommended limit for added sugars. Usual intake data shows that added sugars consumption among some populations, especially children and young adults, is even higher. Based on food intakes in the U.S. population from 2007 to 2010, the usual median intake of added sugars exceeded 15 percent of calories and 300 calories for males 4 to 50 years old. For males 14 to 18 years old, the usual median intake was 22.2 teaspoons per day and 492.3 calories per day. The usual median intake of added sugars for males 19 to 30 years was 21.2 teaspoons per day and 454.6 calories per day. Consumption is also high in females. The usual median intake exceeds 15 teaspoons and 300 calories per day in females aged 9 through 30 years (Ref. 97). At the highest calorie level of 3,200 calories per day in the USDA Food Patterns described in the 2015 DGAC Report, the empty calorie limit available for added sugars is 275 calories (Ref. 98). This means that the median usual intake for most age groups based on 2007 to 2010 intake data exceeds the highest empty calorie limits available for added sugars in the USDA Food Intake Patterns. This information shows that added sugars intake in the U.S. population continues to be excessive. Knowing the amount of added sugars in the foods that we eat may help Americans limit their intake of calories from added sugars and reduce their overall consumption of calories.

(B) Comments on Whether an Added Sugars Declaration Is Necessary To Assist Consumers in Limiting Their Added Sugars Consumption

(Comment 161) Many comments supported mandatory declaration of added sugars on the label because the information is necessary to assist consumers in limiting their intake of added sugars. The comments argued that consumers have no way of knowing the quantity of added sugars in a product unless they are listed on the label, and such a declaration would help consumers avoid the consumption of too much added sugars. The comments stated that, in reading ingredient labels, consumers may not know all forms of added sugars that can be in a food, such as concentrated fruit juice, and they may not understand that ingredients are listed in order of predominance. One comment noted that, for many programs across the country in schools and other institutions, the preexisting label makes it difficult for those developing program guidelines to follow the DGA's recommendations and limit the amount of added sugars in provided foods. To date, limiting total sugars has been the only option, which results in complex standards with detailed exemptions for foods with naturally occurring sugars, such as fruit and dairy.

In contrast, many other comments opposed to the mandatory declaration of added sugars on the label argued that a label declaration of the amount of added sugars is not necessary because it does not convey information that consumers cannot already obtain from total sugars and calorie declarations or from the ingredient list. One comment said that we are already addressing how to help consumers maintain appropriate caloric

balance through increasing the prominence of calories on the Nutrition Facts label, and the DGAs are already providing consumers with recommended food choices to increase consumption of nutrient dense foods. Other comments stated that we did not show how an added sugars declaration would provide consumers with any additional information to help consumers maintain healthy dietary practices or enhance the information that the Nutrition Facts label already provides, and therefore, the added sugars declaration fails to assist consumers in maintaining healthy dietary practices. One comment suggested that an added sugars declaration will not help consumers select a nutrient-dense diet because information on total calories and nutrient content already allows for the identification of other nutrient-dense foods. Other comments noted that foods that are major sources of added sugars are products for which all or virtually all sugar is added and the current sugars declaration already reflects the amount of added sugars.

(Response) The calorie declaration, the total sugars declaration, and the ingredient list do not provide the consumer with the amount of added sugars in a serving of a product. An added sugars declaration is necessary to provide consumers with a measure to assess the relative contribution of the added sugars from a serving of food as part of a healthy dietary pattern and enable consumers to avoid a dietary pattern containing excess calories from added sugars. In some foods that are high in added sugars, such as sugar-sweetened beverages, virtually all sugars in the products are added sugars. In these types of foods, it would be possible for the consumer to determine the amount of added sugars in the product by looking at the (total) sugars declaration. However, many other foods contain a mixture of naturally occurring and added sugars. Based on information that is currently declared on the label, the consumer is unable to determine what portion of the total sugars declaration is naturally occurring and what portion of the total sugars declaration is added sugars. Small amounts of added sugars found in many different foods and ingredients can add up throughout the day and can contribute empty calories in the diet at levels that exceed what would otherwise be reasonable within recommended calorie limits. Therefore, an added sugars declaration allows consumers to better compare products and assess whether a particular product fits into a healthy diet. Furthermore, the calorie declaration reflects calories from all macronutrients, and the total sugars declaration would only be a reflection of the amount of added sugars in a product if all of the sugars are added rather than naturally occurring.

Consumers would not be able to determine the relative amount of added sugars in a serving of a product from the ingredient list for several reasons. There are many different types and forms of sugar that may be added to a food during processing and preparation. Consumers also may not recognize the names of some types of sugars to be a sugar (*e.g.* trehelose). Finally, consumers may also not know that the ingredients are listed in order of predominance by weight, and no quantitative information is provided in the ingredient list.

Although the DGA already provides information on recommended food choices to increase consumption of nutrient dense foods, the DGA does not provide the amount of added sugars in a serving of food that nutritional labeling provides. While some added sugars can be part of a healthy dietary pattern, without a label declaration for added sugars, consumers will not have the information they need to limit added sugars to less than 10 percent of calories. Information about the amount of added sugars in a serving of food and how to put that amount of added sugars into the context of the total daily diet can further assist consumers in reducing their intake of calories from added sugars.

With respect to the comments that suggested we did not show how added sugars would provide consumers with any additional information to help them maintain healthy dietary practices or enhance what the Nutrition Facts label already provides, we are not required to show that consumers will use new information on the label to change their behaviors or dietary practices before requiring the declaration of information on the label. Furthermore, our consumer research shows that without an added sugars declaration, consumers are unable to determine the amount of added sugars in a serving of a product (Ref. 14). Further, the current label provides only information on total carbohydrates and total sugars. A declaration of added sugars on the label would provide the needed information about the added sugars content of a food.

A declaration of the amount of added sugars in a serving of a product will provide more specific quantitative information about the amount of all added sugars found in a serving of a product that is not currently available on the label. We anticipate that providing a declaration of the amount of added sugars in a serving of a product would assist government programs, schools, and other institutions in limiting the amount of added sugars in foods they provide.

(Comment 162) Some comments suggested that added sugars should be declared on the label because this is information that consumers have the right to know.

(Response) While we appreciate consumers' interests, the statutory framework for the declaration of a nutrient under section 403(q)(2) of the FD&C Act is whether the declaration will provide information that will assist consumers in maintaining healthy dietary practices, not whether consumers want access to the information. Furthermore, consumer interest or demand alone does not constitute a material fact under section 201(n) of the FD&C Act and is not a sufficient basis upon which we can require additional labeling for foods (see, *e.g., Stauber* v. *Shalala,* 895 F. Supp. 1178, 1193 (W.D. Wisc. 1995) and *Alliance for BioIntegrity* v. *Shalala,* 116 F. Supp. 2d 166, 179 (D.D.C. 2000)).

Although consumer interest alone is not sufficient to require mandatory labeling, we have discussed in part II.C that the amount of added sugars in a serving of food is a declaration that meets the statutory framework in section 403(q)(2) of the FD&C Act and, furthermore, it is a material fact because added sugars is a public health concern and knowing the amount of added sugars in a serving of food will assist consumers in maintaining healthy dietary practices.

(Comment 163) In our Preliminary Regulatory Impact Analysis (PRIA), we extrapolated from the welfare effects estimated in a retrospective study on the impact of the Nutrition Labeling and Education Act of 1990 (Ref. 99) to quantify benefits of the proposed rule. Some comments suggested that it was inappropriate for us to rely on a paper written by a graduate student, which was not peer-reviewed, as the basis for our proposal to require the mandatory declaration of added sugars. Another comment argued that we provided no basis to require the mandatory declaration of added sugars on the label other than the Abaluck paper.

(Response) We note that we did not rely on the information provided in the Abaluck paper as the basis for our proposal to require the mandatory declaration of added sugars on the label. The information in the Abaluck paper was used to estimate economic benefits

of our proposal for the PRIA. We are relying on information related to overconsumption of added sugars, the reduction of the nutrient density of the diet when substantial amounts of added sugars are present, evidence showing the consumption of sugar-sweetened beverages is associated with increased body weight and adiposity, and evidence showing that consumption of health dietary patterns characterized, in part, by lower consumption of sugar-sweetened foods and beverages is associated with a decreased risk of CVD.

(Comment 164) One comment noted that the FD&C Act only gives us the authority to add nutrients to the Nutrition Facts label to help consumers maintain healthy dietary practices, but our definition of ''healthy'' excludes any consideration of sugars content.

(Response) The comment is referring to our regulation for implied nutrient content claims (§ 101.65). Section 101.65(d)(1)(ii)(2) provides requirements for the use of the term ''healthy'' or related terms on the label or in the labeling of foods. The regulation requires that a food must meet requirements for fat, saturated fat, cholesterol, and other nutrients, but does not include limitations on the amount of total or added sugars that a food may have if it bears an implied ''healthy'' nutrient content claim. Our authority in section 403(r) of the FD&C Act to define a term, by regulation, to characterize the level of a nutrient in the label or labeling is distinct from our authority in section 403(q) of the FD&C Act to require the declaration of a nutrient in nutrition labeling. As previously discussed in part II.B.4, we intend to revisit our other regulations for nutrient content claims at a later date to determine if changes are necessary.

(Comment 165) One comment said that sources of sugar contribute the same number of calories per gram weight of food, and calories should be the principal nutrient of concern of a population striving to achieve desired weight and control obesity. The comment suggested that giving consumers a false impression that reducing added sugars without reducing calories may actually delay finding a real solution to the problem.

(Response) We have increased the prominence of calories on the label because of its importance for consumers to consider for the purposes of weight management. We are not suggesting that consumers should ignore or consider information about the amount of calories in a serving of a food to be secondary to the amount of added sugars in a serving of food. Instead, we are requiring the declaration of added sugars on the label to provide one additional piece of information to consumers to assist them in selecting foods that contribute to a healthy dietary pattern. Therefore, we do not agree that an added sugars declaration is unnecessary because the total amount of calories in a serving of a food is already displayed on the label.

(Comment 166) One comment stated that by mandating declaration of both total sugars and added sugars, we are creating an arbitrary distinction between two types of sugars which will not lead to any nutritional differences for consumers.

(Response) We do not agree with the comment that the distinction between total and added sugars is arbitrary and will not lead to any nutritional differences in the foods that consumers select. The addition of added sugars to foods provides additional calories which can make it difficult for consumers to meet nutrient needs within calorie limits and can lead to issues with weight management. Sugars, added in excess, do not provide any health benefits. In addition, foods high in added sugars tend to be lower in beneficial nutrients. By providing a declaration of added sugars on the label, consumers will have additional information about a product that can assist them in determining how much sugars have been added to a food. Moreover, the intake of added sugars from sugar-sweetened foods and beverages needs to be reduced as part of a healthy dietary pattern. A healthy dietary pattern, when compared to less healthy dietary patterns, such as the dietary pattern of the current U.S. general population, is strongly associated with a reduced risk of CVD. The intake of foods with naturally occurring sugars, such as fresh fruits and vegetables, is encouraged as part of a healthy dietary pattern and not recommended to be reduced.

(C) Comments on a Lack of a Chemical or Physiological Distinction Between Naturally Occurring and Added Sugars

(Comment 167) In the preamble to the proposed rule (79 FR 11879 at 11905), we recognized a lack of a chemical or physiological distinction between added and naturally occurring sugars. Many comments agreed that naturally occurring and added sugars are the same and argued that, because there is no chemical or physiological distinction, we should not require the mandatory labeling of added sugars. One comment cited a paper by Murphy and Johnson (2003) that discusses added sugars in the context of the 2000 DGA and suggested that it would be challenging to require a declaration of added sugars on the label because they are not chemically or physiologically distinct from naturally occurring sugars (Ref. 100).

However, other comments suggested that there is evidence that not all sugars are chemically the same. The comments suggested that different sugars are metabolized differently in the body. One comment stated that naturally occurring sugars have more nutritional value than those added to foods. Another comment stated that sugars that are found naturally in foods are consumed in combination with all other ingredients and nutrients in that food and that the body reacts to inherent sugars in such combinations. The comment noted that emerging studies suggest that inherent sugars in combination with plant nutrients, for example, behave differently in the body than added sugars without such accompanying nutrients. These comments indicated that it is important for consumers to know how much added sugars are in their products because they are inherently different from naturally occurring sugars.

(Response) A physiological or chemical distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. We explained in the preamble to the proposed rule that our scientific basis for the added sugars declaration, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition, or a physiological endpoint (see 79 FR 11879 at 11904). Rather than relying on a causal relationship between added sugars to obesity or heart disease, we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars as part of healthy dietary patterns and the impact to public health from such patterns for the purposes of the general population. Thus, the comments did not focus on added sugars as a component of sugar-sweetened foods and beverages that have been found to have health implications as part of a dietary pattern, or as a nutrient that provides a source of empty calories consumed by the U.S. population in excess, which make it difficult for consumers to meet nutrient needs within calorie limits. Providing consumers with information about the amount of added sugars in a serving of a product will assist consumers in

planning a healthy diet. We have concluded that the consumption of added sugars is related to health for a number of reasons, and consumers will benefit from information about the added sugars content of a food on the label.

(Comment 168) Many comments did not support an added sugars declaration because added sugars are not chemically or physiologically distinct from naturally occurring sugars, and a separate declaration of added sugars implies that there is a distinction. The comments suggested that an added sugars declaration would arguably be false and misleading because it would convey to the reasonable consumer that added sugars are chemically different than naturally occurring sugars and/or that added sugars has different health effects than naturally occurring sugars. One comment further asserted that implying superiority of one source of a nutrient versus another, when they are not materially different and are chemically, nutritionally, and functionally equivalent, is inherently misleading. Another comment suggested that a separate declaration for added sugars could cause consumers to believe that naturally occurring sugars are more beneficial.

(Response) As we explained in our response to comment 167, a physiological or chemical distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. In fact, some nutrients currently declared on separate lines in the Nutrition Facts label may be related to the same chronic disease risk or physiological endpoint (*e.g.,* saturated fat and *trans* fat and risk of CVD). Therefore, we disagree that a separate declaration necessarily implies a chemical or physiological distinction. Furthermore, the comments may not have considered the basis for why the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. A dietary pattern characterized, in part, by larger amounts of sugar-sweetened foods and beverages is associated with greater risk of CVD than a healthy dietary pattern that includes less sugar-sweetened foods and beverages. Moreover, added sugars provide excess calories in the U.S. diet (see our responses to comment 29 and comment 177), and these additional empty calories make it difficult for consumers to meet nutrient needs within their calorie limits and can lead to issues with weight management. Therefore, the intake of added sugars in the current U.S. dietary pattern is a public health concern. The declaration of added sugars provides factual, accurate information about the amount of added sugars in a serving of food, and we are requiring the declaration consistent with our authority in section 403(q) of the FD&C Act. The added sugars declaration is not inherently misleading as the comments suggest, as is addressed further in part II.C.3.

(Comment 169) Some comments suggested that we are being inconsistent in our treatment of the evidence for nutrients because we are considering whether certain dietary fibers have a beneficial physiological effect, but we are not considering whether added sugars have a separate and distinct physiological effect in our determination that added sugars should be declared on the label.

(Response) In the case of dietary fiber, we are requiring that a dietary fiber have a beneficial physiological effect to human health for the purposes of declaration because there are dietary fibers currently present in foods that are being declared on the label indicating to consumers that they have the same beneficial physiological effects to human health as other fibers, when in fact, they do not. We previously have discussed in this section that added sugars, independent of sugars naturally present in foods, can have a negative impact on health. A decision to not require a separate declaration of added sugars on the label would not allow consumers to determine the additional sugars which have been added above and beyond what is naturally present in a food which are contributing extra calories to their diet and could also contribute to a dietary pattern that is associated with disease risk.

(Comment 170) One comment stated that the Nutrition Facts label must remain a source of information about nutrients that are chemically distinct based on analysis. The comment asserted that we have not provided a reasonable basis for defining added sugars based on source rather than chemical composition.

(Response) We disagree with the comment that a chemical distinction must be a requirement for declaration of a nutrient on the label. Section 403(q)(2)(A) of the FD&C Act provides discretion to the Secretary, and by delegation, to FDA, to determine whether providing nutrition information regarding a nutrient will assist consumers in maintaining healthy dietary practices and when to require information relating to such additional nutrient be included in the label or labeling of the food. This section does not include limitations on chemical distinctions.

(D) Comments Questioning our Reliance on Conclusions and Information From the 2010 DGA and the 2015 DGAC

(Comment 171) Many comments questioned our reliance on conclusions and information in the 2010 DGAC Report and 2010 DGA. One comment asserted that it is a gross expansion of the law governing the DGA to use selective dietary guidance from a single edition to promulgate food labeling regulations. Some comments suggested that the evidence cited by the 2010 DGAC and 2010 DGA was not strong enough to support a declaration of added sugars. One comment stated that neither the 2010 DGA nor the 2010 DGAC Report provided a preponderance of scientific information or conclusive, documented, or strong scientific evidence to support these suppositions. The comments asserted that we did not address the strength of the evidence that the 2010 DGAC reviewed as the basis for their recommendations. One comment also noted that the 2010 DGAC addressed few or limited questions related to impact of added sugars on health due to lack of available evidence. The comment stated that what evidence there was at the time that the 2015 DGAC Report was published was not conclusive.

(Response) We note that we did not specifically rely on conclusions or recommendations made by the 2010 DGAC Report or in the 2010 DGA. We considered the information and underlying data presented in the 2010 DGAC Report and 2010 DGA that was used as the basis for their conclusions and recommendations and determined that, for the purposes of nutrition labeling, the evidence in the 2010 DGAC and 2010 DGA, along with other data and information we considered, supports the declaration of added sugars on the Nutrition and Supplement Facts labels (79 FR 11879 at 11902 through 11908). The DGAs have recommended that Americans reduce their intake of what we are defining to be added sugars since the early 1980s, so the recommendation to limit consumption of added sugars is not new. Since publication of the 2010 DGA and 2010 DGAC Report, new evidence has become available on added sugars and dietary patterns that we have considered. We have determined that this evidence further supports a declaration of added sugars on the label.

The comment suggesting that the evidence on added sugars is not conclusive, documented, or strong is referring to the factors that we considered for mandatory declaration of nutrients on the label for which there is

an independent relationship between the nutrient and chronic risk of disease. Our determination that added sugars should be declared on the label for the general population (see part II.H.3) was not based on the factors used to determine mandatory or voluntary declaration for these other non-statutory nutrients that have an independent relationship related to a chronic disease, a health-related condition, or health-related physiological endpoint. Instead, our review is based on the need for the declaration of nutrient information on the labels to assist consumers in limiting their consumption of calories from added sugars found in sugar-sweetened foods and beverages and consuming a healthy dietary pattern that is associated with a reduce risk of CVD.

(Comment 172) Many comments took issue with the 2010 DGA's use of food pattern modeling to support the recommendation to reduce the intake of calories from added sugars. One comment stated that the amount of solid fats and added sugars in the USDA food patterns is the outcome of using the remaining calories in that pattern rather than the evidence-based research. Other comments said that the USDA Food Patterns lack the scientific underpinning on which to base official recommendations.

Some comments said that the same issues that prevent FDA from using food consumption data, menu modeling, and dietary survey data to determine DRVs are also applicable when considering the mandatory declaration of non-statutory nutrients. One comment noted that we have concluded that menu modeling is not related to disease risk and is not suitable for determining recommended intakes.

Some comments also noted that the 2010 DGA clearly states that the USDA Food Patterns are only one example of suggested eating patterns and that the USDA Food Patterns have not been specifically tested for health benefits. Another comment said that the extremely low suggested intakes of 6 to 12 teaspoons of added sugars in the USDA Food Patterns have no historical basis and lack context.

(Response) We disagree with comments that questioned the use of evidence based on food pattern modeling to support the added sugars declaration so that consumers can use the information to reduce calories from solid fats and added sugars. While the food pattern modeling used to create the USDA Food Patterns was used to compare current consumption data with recommended intakes from the USDA Food Patterns, the 2010 DGA also considered information about the impact of added sugars on nutrient density and on their implications for weight management (Ref. 77). Furthermore, the fact that the USDA food patterns were not studied for health effects until recently, does not lessen our reliance on the information as part of our basis for a mandatory declaration of added sugars. Since publication of the proposed rule, the USDA Food Patterns have been studied for their association with disease risk (Ref. 101). We also have evidence that dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a reduced risk of CVD that further supports a mandatory declaration of added sugars on the label for the general U.S. population. It is not clear what is meant by the comment which stated that the extremely low suggested intakes of 6 to 12 teaspoons of added sugars in the USDA Food Patterns have no historical basis and lack context. To the extent the comment disagrees with the suggested intakes of 6–12 teaspoons of added sugars, we note that there is evidence showing that Americans are consuming too many calories from added sugars as well as evidence that it is difficult to meet nutrient needs within calorie limits when excessive amounts of added sugars are consumed.

(Comment 173) In the preamble to the proposed rule (79 FR 11879 at 11890), we discussed the factors that we considered for mandatory and voluntary declaration of non-statutory nutrients. We considered the scientific evidence from other U.S. consensus reports or DGA policy reports (79 FR 11879 at 11890). We also listed the DGA policy reports among other reports that we would consider to be U.S. consensus reports.

One comment questioned whether the DGA is a consensus report because it is a report that is issued jointly every 5 years by the USDA and HHS. The comment said that the DGAC Report is an advisory report, and the Secretaries of USDA and HHS have sole responsibility and discretion as to the final content of the DGA. The comment also noted that the DGAC Report does not undergo independent external review.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11885 through 11887), we listed new dietary recommendations, consensus reports, and national survey data as sources of information that we considered when developing the proposed amendments to the regulations. Furthermore, our review of the scientific evidence in the 2010 DGA relates to the intake of added sugars and the role of such information in assisting consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (79 FR 11879 at 11891). Therefore, whether the 2015 DGAC Report is or is not a consensus report is not relevant for the added sugars declaration. Furthermore, we considered the underlying evidence related to added sugars that supported the recommendation to limit consumption of calories from solid fats and added sugars and did propose to require a declaration of the amount of added sugars in a serving of a product on the label because of the 2010 DGA recommendation related to calories from solid fats and added sugars. We considered the evidence in the 2010 DGAC Report and 2010 DGA, along with other data and information in the proposed rule to support a declaration of added sugars on the Nutrition Facts and Supplement Facts labels (79 FR 11879 at 11902 through 11908).

(Comment 174) One comment said that the proposed rule incorrectly assumes that reduced consumption of added sugars will reduce the problem of obesity, but noted that we acknowledged in the proposed rule that solid fats and added sugars do not contribute to weight gain any more than another source of calories.

(Response) We have not changed our position with regard to the effect of calories from solid fats and added sugars on weight gain. However, as noted in the 2010 and 2015–2020 DGAs, consumption of excess solid fats and added sugars make it difficult to meet nutrient needs within calorie limits (Refs. 28, 30). Because sugars added to foods during processing increase the calorie content of the food without increasing other nutrients in the food, added sugars as an ingredient could conceivably lead to weight gain if a consumer striving to meet their nutrient needs does so by consuming foods containing too many added sugars. Further, we stated in the proposed rule that we know that foods containing solid fats and added sugars make up a significant percentage of the American diet and are a source of excess calories (79 FR 11879 at 11904).

(Comment 175) Some comments said that we are not being consistent with the dietary recommendations we use for requiring nutrients on the label because the 2010 DGA also recommended replacing saturated fats with mono and polyunsaturated fats, yet the labeling of mono and polyunsaturated fats is voluntary on the label.

(Response) We do not rely on the 2010 DGA recommendation to reduce calories from solid fats and added sugars. Instead, we examined the underlying evidence and concluded that added sugars should be declared on the label. Furthermore, the 2010 DGA recommendations related to mono and polyunsaturated fats are about replacing saturated fats with the mono and polyunsaturated fats, because reduction of saturated fats is associated with reductions in blood LDL cholesterol and, therefore, the risk of CVD. The 2015 DGA corroborates this finding. Saturated fats are already declared on the label, so consumers have the information they need to reduce their intake of saturated fat. In addition, current evidence does not show that there is an inherent benefit to consumption of mono and polyunsaturated fats by themselves. The benefit comes from reduction of saturated fats in the diets by way of replacement. Furthermore, the scientific evidence supports consuming a healthy dietary pattern that is low in saturated fats. A healthy eating pattern limits saturated fats, and the scientific evidence supports consumption of added sugars to to less than 10 percent of calories per day from saturated fats (Ref. 19). Therefore, Americans currently have the information on the label which will allow them to limit saturated fats in their diet.

d. Nutrient Density

(Comment 176) Many comments suggested that including a declaration of the amount of added sugars in a serving of a product can help consumers select foods that contribute to a more nutrient-dense diet. The comments noted that the 2010 DGA suggested that reduced intake of added sugars allows for increased intake of nutrient-dense foods which may help individuals to control their total caloric intake and better manage their weight. The comments also said that sugars intrinsic to foods are accompanied by nutrients, whereas added sugars are not. The comments referred to the discussion in the proposed rule related to intake of added sugars and its association with a lower intake of essential nutrients (79 FR 11879 at 11903) and suggested that most major sources of added sugars are high in calories and fats, but lack meaningful amounts of dietary fiber, essential vitamins or minerals. The comments said that, when added sugars intake is 10 to 15 percent of calories, the median intakes of nine nutrients (vitamin A, vitamin E, vitamin C, folate, magnesium, potassium, vitamin K, fiber, and total choline) are significantly lower than the median intakes of those nutrients for someone consuming 0 to 5 percent of their calories from added sugars (Ref. 102). Another comment noted that IOM recommends that the intake of added sugars not exceed 25 percent of energy to ensure adequate intake of essential micronutrients that are typically not present in foods high in added sugars (Ref. 75). One comment said that consumers who eat less added sugars consume fewer calories and more foods rich in essential nutrients.

In contrast, many comments said that a declaration of added sugars on the label will not assist consumers in constructing a more nutrient dense diet. The comments said that there is a lack of science to support the contention that added sugars intake displaces nutrients or causes a decrease in the intake of nutrient-rich foods in the diet of the general population, at current intake levels. One comment cited the 2010 DGA conclusion that added sugars replace nutrient-dense foods and beverages and make it difficult for people to achieve the recommended nutrient intake while controlling their calorie intake, but noted that no evidence-based review was conducted on this topic, and no conclusive, documented, or strong evidence was cited to support that added sugars intake causes nutrient displacement, or decreased consumption of nutrient-rich foods. Another comment noted that although a recent analysis of NHANES data (Ref. 102) reaffirmed the conclusion of the 2002 IOM report (Ref. 75), individuals with intakes of greater than 25 percent of calories from added sugars appear to be at greater risk for nutrient inadequacy based on comparison with the DRIs. The comment said that the authors of the study also clarify the real-world impact from these higher intake amounts, and stated ''However, high levels of added sugars intake occur among only a small proportion of the population and cannot explain the existing problem of poor nutrient intake in the U.S. population as a whole.''

(Response) We agree that a declaration of the amount of added sugars can assist consumers in selecting foods that contribute to a more nutrient dense diet. The IOM did not establish a UL for sugars or added sugars, however they did conclude that increased consumption of added sugars can result in decreased intakes of certain micronutrients based on their review of the evidence available at the time that the IOM Dietary Reference Intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids were published (Ref. 103). As noted in comments, additional evidence has become available since the IOM DRI reports were published, which supports their conclusion (Ref. 102). Therefore, although the 2010 DGAC did not conduct an evidence-based review on this topic, there is documented evidence that increased consumption of added sugars can make it difficult for individuals to meet nutrient needs.

We disagree with the suggestion added sugars consumption is not contributing to poor nutrient intake in the U.S. population as a whole and thus should not be required on the label because only a small proportion of the population is consuming large amounts of added sugars. The 2015 DGAC found that the general U.S. population is consuming 13.4 percent of its calories from added sugars. As the comments noted, Marriott et al. found that median nutrient intakes were lower when added sugars intake was 10 to 15 percent of calories (Ref. 102). Therefore, even at intake levels below 25 percent of calories, nutrient intake can be negatively impacted by increased consumption of added sugars. Furthermore, based on NHANES data from 2007 to 2010, males aged 9 to 50 are consuming more than 300 calories per day from added sugars, and females aged 9 to 30 are consuming more than 250 calories per day from added sugars (Ref. 104). Males between the ages of 14 to 18 years old consumed almost 400 calories per day from added sugars (Ref. 104). Although these subpopulations may not make up a majority of the population, these groups include children and young adults who are growing and need nutrients for proper growth. Therefore, the impact of added sugars consumption on nutrient density in these specific populations is an important consideration for the declaration of added sugars.

As for the comment which said that consumers who eat less added sugars consume fewer calories and more foods rich in essential nutrients, the comment did not provide evidence to support this statement. Therefore, we are unable to determine if this information adds to other evidence we have, which suggests that added sugars can decrease the nutrient density of the diet.

(Comment 177) Many comments suggested that the added sugars declaration does not assist consumers in constructing a nutrient dense diet because there are nutrient dense foods which contain added sugars, and the declaration may obscure the fact that some foods with added sugars may actually be good sources of beneficial nutrients. One comment argued that the added sugars declaration does not meet

the proposed rule's stated goal to convey information necessary to meet recommendations to construct diets containing nutrient-dense foods because the declaration does not provide consumers with any means to differentiate between foods that will contribute phytonutrients to their diet from foods with empty calories. The comments provided examples of nutrient-dense foods, such as yogurt, cranberries, tart cherries, and cereal, which contain added sugars.

Some comments from the cranberry industry asked that we make an exception to added sugars labeling for cranberries, which require sweetening for palatability. The comments noted that cranberries are a nutrient-dense fruit with many known health benefits. Unlike other fruits, cranberries have little natural sugar and, therefore, have a uniquely tart taste. The comments expressed concern that cranberry products would be considered ''unhealthy'' based solely on their added sugars content. The comments said that the evidence shows that cranberries are rich in polyphenols, specifically flavonoids, and have a positive impact on urinary health. The comments also cited evidence that the addition of sugar to cranberry products does not decrease the polyphenol content. Furthermore, according to the comments, the calorie content of each serving of dried cranberries is similar to that of other dried fruits, and cranberry juice cocktail (27 percent juice) is the standard equivalent to other 100 percent juices with similar total calorie and sugar levels. The comments also noted that they contribute to recommended fruit intake amounts in the DGA.

The comments said that requiring the declaration of added sugars on cranberry products may mislead consumers to believe that nutrient-dense foods, such as cranberries, with their proven health benefits, are somehow less nutritious than foods with the same amount of naturally occurring sugar, or even those with more total sugars. The comments expressed concern that a focus on added sugars may have the unintended consequence of driving consumers away from nutrient dense products with moderate amounts of sugar.

Many comments said that a mandatory declaration of added sugars could be damaging for the cranberry industry or for the tart cherry industry. One comment noted that the drying operation used by the tart cherry industry reduces the moisture content while simultaneously increasing the percentage of sugar. The use of sugar as a natural preservative combats the threat of mold and yeast contamination.

Several comments noted that USDA grants an exemption, which is similar to that which the comments requested for the labeling of added sugars on cranberry products, for cranberry products offered for sale in our nation's schools. One comment noted that the IOM, in its report titled ''Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth,'' made recommendations for nutrition standards for competitive foods offered in schools, and has made an exception for yogurt from its recommended general sugar standard of 35 percent or less of calories from total sugars.

One comment suggested that the added sugars declaration will not help consumers select foods that contribute to a nutrient dense diet because information on total calories and nutrient content (*e.g.* fiber plus vitamins and minerals) already allows for the identification of nutrient-dense foods.

(Response) Consumers now have access to nutrient information provided on the nutrition label that they can use to plan a nutrient dense diet. We have required those nutrients that are of the greatest public health significance be declared in nutrition labeling (58 FR 2079, 2107). An added sugars declaration is an important piece of information because consumers need to ensure their diet does not contain excess calories from added sugars which can make it difficult for consumers to meet nutrient needs within calorie limits and can lead to issues with weight management.

As mentioned in the 2010 DGA, many foods that contain added sugars often supply calories, but few or no essential nutrients, and no dietary fiber (Ref. 77). However, there are some foods, such as dried fruits, yogurt, and cereal, that contain significant amounts of beneficial nutrients as well as added sugars. The declaration of added sugars will enable consumers to understand the relative significance of the added sugars content in a serving of dried fruit, yogurt, cereal, and other foods that may contribute beneficial nutrients to the diet and determine how to incorporate those foods into a healthy dietary pattern and meet their nutrient needs within calorie limits. As discussed in the 2015 DGAC report, there is room for Americans to include limited amounts of added sugars in their eating patterns, including to improve the palatability of some nutrient-dense foods, such as fruits and vegetables that are naturally tart (*e.g.* cranberries and rhubarb). Healthy eating patterns can also accommodate other nutrient dense foods with small amounts of added sugars, such as whole-grain breakfast cereals or fat-free yogurt, as long as the calories from added sugars do not exceed 10 percent per day, total carbohydrate intake remains within the AMDR, and total calorie intake remains within limits (Ref. 19).

The added sugars declaration is just one piece of information that consumers can use to help them construct a healthful dietary pattern that may include some added sugars. We acknowledge that some consumers may focus in on the amount of added sugars in a product and may judge it to be a less nutritious product even though it contains beneficial nutrients. The added sugars declaration on the label is new information that consumers will not have seen before. In collaboration with Federal and other partners, we plan to engage in educational and outreach activities for consumers and health professionals about the use of information on the Nutrition Facts and Supplement Facts labels. Part of that education will include information about added sugars. A key message related to added sugars will be that consumers should consider all of the information on the label when constructing a healthful dietary pattern and not focus in on one specific nutrient, such as added sugars. The message related to consumption of added sugars is not to eliminate added sugars or foods high in added sugars from the diet; instead, the message is to limit overall consumption of added sugars in the diet to less than 10 percent of total calorie intake. Therefore, if consumers choose to eat foods with sugars added to them for palatability, such as cranberries, they may do so in moderation, and cut back on added sugars elsewhere in the diet.

We decline to exempt certain nutrient dense foods containing added sugars from the requirement to declare the amount of added sugars in a serving of a product on the label. If such products are exempt from added sugars labeling, consumers may assume incorrectly that they contain no added sugars. Providing added sugars information on the label for all foods allows consumers to compare foods and make informed choices. It allows them to also make trade-offs in their diet to achieve an overall healthy dietary pattern that contains less than 10 percent of total calories from added sugars. As part of our education and outreach activities, we plan to educate consumers that the amount of added sugars in a serving of a product should be considered along with other information on the label

when constructing a healthy dietary pattern.

While other government programs and consensus bodies have excluded cranberries and yogurt from their programs or recommended limits on sugars, the purpose of those programs and reports are different than the purpose of the information on the Nutrition and Supplement Facts labels. The purpose of the Nutrition and Supplement Facts labels is to provide nutrition information to consumers to allow them to make informed choices about the foods that they eat. Therefore, although some nutrient-dense foods containing added sugars have been excluded from government programs or recommendations, the same approach does not apply to the Nutrition and Supplement Facts labels.

With regard to the comment that said that the drying operation used by the tart cherry industry reduces the moisture content while simultaneously increasing the percentage of sugar, we would not consider sugars that naturally exist in the tart cherries prior to the drying process to be added sugars. Only sugars that have been added to the fruit would be required to be declared as added sugars on the label.

e. Reformulation

(Comment 178) While some comments said that an added sugars declaration will be an incentive for food manufacturers to reformulate, other comments said that reformulation of products to reduce the added sugars content may not result in products that are healthier. Some comments said that an added sugars declaration may lead to reformulation or changes in consumer behavior that would not improve overall nutritional profile or nutrient density of the diet and may result in overconsumption of other macronutrient sources (*e.g.* fat) without a reduction of calories. The comments said that added sugars could be replaced with bulking agents, which provide calories and carbohydrate. Another comment said that reformulation of products containing added sugars could result in an increased use of artificial sweeteners (*i.e.* low calorie sweeteners), which could be bad for health. Other comments noted that consumers have many food and beverage choices that are reduced in total and added sugars.

(Response) Absent data, we do not know whether manufacturers will reformulate their products if we require the declaration of added sugars on the label. Likewise, absent data, we do not know whether consumers will select reformulated products that may be higher in fat, calories, or low-calorie sweeteners. In our efforts to educate consumers and health professionals about the use of the label, we intend to encourage consumers to consider all of the information on the label when making decisions about what foods to eat and how much rather than focusing on one specific nutrient, such as added sugars. If consumers take all label information into consideration when making dietary choices, they will recognize when a product is low in added sugars, but still contains a significant amount of calories and carbohydrate or fat per serving. They can also see if low-calorie sweeteners have been added to a product by looking at the ingredient list.

With respect to the comment which suggested that low-calorie sweeteners may be harmful to health, as noted in our Overview of Food Ingredients, Additives & Colors, there is no convincing evidence of a cause and effect relationship between these sweeteners and negative health effects in humans. We have monitored consumer complaints of possible adverse reactions for more than 15 years (Ref. 105).

(Comment 179) One comment asked what studies we used to suggest that declaring added sugars on the label will result in firms reducing the amount of added sugars in products and result in an overall reduction of sugar consumption.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11904), we said that the mandatory declaration of added sugars may prompt product reformulation of foods high in added sugars like what was seen when *trans* fat labeling was mandated. We do not know whether or how manufacturers will reformulate their foods as the result of a mandatory added sugars declaration.

f. Calories From Solid Fats and Added Sugars

(Comment 180) The 2010 DGA provided a key recommendation that Americans should reduce their intake of calories from solid fats and added sugars (SoFAS). In the preamble to the proposed rule (79 FR 11879 at 11904), we concluded that the disclosure of saturated fat and *trans* fat on the label not only provides information to consumers which can be used to reduce their intake of these nutrients, and thus reduce their risk of CVD, but the declaration of saturated and *trans* fats on the label could also provide a marker for foods that contain solid fats that are abundant in the diets of Americans and contribute significantly to excess calorie intake. We stated that similar information is not available on the label for calories from added sugars (id.).

Several comments disagreed that the declared amounts of saturated and *trans* fats can be used as markers for solid fats in the diet. The comments stated that the calculation of calories from SoFAS is not feasible based on the information that is proposed for the label, and the nature of the calculation that consumers would need to perform would not be consistent with our objectives to make the label more usable and understandable for consumers. The comments noted that it is not feasible to determine the amount of solid fats from the saturated and *trans* fat declarations alone because the label does not provide the quantity of solid fat that USDA used in its menu modeling analysis. The comments further stated that, while saturated fat and *trans* fat may be components of solid fats, those values alone cannot be used to determine the solid fat content of a food because it is not known what portion of these declarations would be identified in the menu modeling program used by USDA.

One comment said that the declaration of saturated and *trans* fat declarations are for the purposes of lowering risk of CVD and not for estimating the SoFAS content of a food. The identification of SoFAS is for the purposes of developing the USDA Food Patterns and is not a suitable approach for mandating an added sugars declaration.

Another comment suggested that the sugars declaration on the label can serve as a marker for added sugars in the same way that saturated fats serves as a marker for solid fats. The comment also suggested that saturated fats in certain foods are not solid fats (such as in nuts) in the same way that sugars in certain foods are not added sugars (such as fruit juice and milk).

(Response) We used the term ''marker'' in the preamble to the proposed rule to mean that the amount of saturated and *trans* fats on the label would give consumers a very good idea or a reasonable estimate of the quantity of solid fats in a serving of a food. Although many fat containing foods have a mixture of fats, such as nuts and oils that may contain some solid fats and some unsaturated fats, the saturated fat and *trans* fat declarations would account for these differences. In addition, even though one would need more information on how saturated fats were quantified for the development of the USDA Food Patterns to determine the exact amount of calories from solid fats, such specificity would not be needed to obtain a reasonable estimate of solid fats using the declared value of

saturated fat and *trans* fat combined. Furthermore, unlike solid fats, there is no information currently on the label that could give consumers an estimate of the amount of added sugars in a serving of food when the food contains both naturally occurring and added sugars. In such a case, the amount of total carbohydrate or total sugars in a serving of a food cannot be used as a reasonable estimate of the amount of added sugars in a serving of the food.

We disagree with the comment suggesting that the total sugars declaration can serve as a marker of added sugars in the same way that the saturated fat and *trans* fat declaration can serve as a marker for solid fat. When both naturally occurring and added sugars are present in a food, the consumer has no way of knowing from the total sugars declaration what portion of that total sugars declaration represents the amount of added sugars in a serving of the food.

Since the publication of the proposed rule, the 2015 DGAC Report became available. In that report, the solid fats and added sugars were divided within the ''empty calories'' category with 45 percent of the empty calorie allowance allocated to added sugars and 55 percent of the empty calorie allowance allocated to solid fats. Furthermore, the scientific evidence in the 2015 DGAC Report for limiting calories from added sugars is separate from that for limiting saturated fats, which are a key contributor of solid fats to the diet. There is adequate information available to consumers on the label to assist them in meeting the key recommendation to limit calories from saturated fats to less than 10 percent of total calories; however, there is no such information on the label to help consumers limit their consumption of added sugars to no more than 10 percent of total calories. Whether there is adequate information on the label to assist consumers in limiting solid fats is not related to an added sugars declaration.

(Comment 181) The comments were divided on whether calories from added sugars should be declared on the label. One comment said that, if added sugars are declared on the label, we should require the declaration of calories from added sugars. Another comment stated that concerns about the scientific evidence on the health effects of added sugars and the usefulness of a declaration to improve food choices apply to whether the declaration of added sugars is in gram units or declared as calories from added sugars. Other comments suggested that a declaration of calories from added sugars is unnecessary and not beneficial. The comments noted that the total number of calories in a serving of food is prominently displayed in the proposed format. The comments said that a declaration of calories from added sugars could cause consumer confusion, particularly for consumers who are unable to readily understand the distinction between a gram value and calories from added sugars. The comments noted that consumers are already familiar with the gram unit from the total sugars declaration. The comments said there is no evidence from consumer research that a declaration of calories from added sugars in lieu of grams would lead consumers to greater reductions in intake of added sugars.

(Response) Evidence shows that heathy dietary patterns associated with a decreased risk of chronic disease are lower in sugar-sweetened foods and beverages. Consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened beverages are associated with increased adiposity in children. Thus, the added sugars declaration is information that is necessary for consumers to construct a healthy dietary pattern lower in added sugars and that is less than 10 percent of calories from added sugars. The information on the label includes the gram amount of added sugars in a serving of a food product and the percent DV declaration for added sugars. There is no need for consumers to be able to determine the amount of calories from added sugars in a serving of a food because we are establishing a DV that is based on 10 percent of total calories (50 grams in children and adults 4 years of age and older and 25 grams for foods purported to be for children 1 through 3 years of age). Consumers can use the percent DV declaration to determine what percentage of total calories a serving of a food contributes. They can also use the gram declaration of added sugars to construct a diet that is low in added sugars by comparing the amount of added sugars between products and by using trade-offs in the diet if they choose to include certain foods which have a large amount of added sugars.

g. Consumer Research and Consumer Use of Added Sugars Declaration

(Comment 182) One comment said that research does not substantiate a causal effect between including added sugars information on the Nutrition Facts label and decreased added sugars intake. The comment cited a study in which data from the 1994–96 Continuing Survey of Food Intakes by Individuals (CSFII) was used to model total consumption of added sugars and the Diet and Health Knowledge Survey conducted by the USDA was used to determine usage of labeling information on total sugars (Ref. 106).

(Response) Although the results of the study showed that regular use of sugar information on nutrition labels is associated with a significantly lower density of added sugar in the diet, the results of this study cannot be used to determine whether there is a causal effect between including added sugars information on the Nutrition Facts label and decreased added sugars intake. The study did not assess use of labeling information on added sugars, but rather use of information on total sugars.

(Comment 183) One comment noted that the use of the ''no added sugars'' or ''without added sugars'' nutrient content claim focuses on ingredients used in a product (§ 101.60(c)). The comment said that manufacturers must put a disclaimer on the label of their product if the food is not low or reduced in calories so that consumers are not misled about the calories associated with such products. The comment suggested that consumers could potentially be misled because when the amount of added sugars in a serving of a product is declared on the label, manufacturers who are currently using a ''no added sugars'' or ''without added sugars'' claim would be less likely to use the claim because the amount of added sugars is stated on the label, and thus, a disclaimer with regard to the calorie content of a product would not be declared.

(Response) We do not have data or information about whether manufacturers may elect to use a voluntary nutrient content claim once they are required to declare the amount of added sugars in a serving of their product. Consequently, we also cannot determine whether consumers might be misled, so we decline to revise the rule in response to this comment.

(Comment 184) Several comments addressed additional consumer research on Nutrition Facts labels that include added sugars declarations. One comment included two reports that described methods and results of two studies, including one controlled experiment and one cross-sectional survey study, both on cranberry and other fruit products. Both studies included, among other formats of the Nutrition Facts labels, Nutrition Facts labels with declarations of the gram amount of added sugars in a serving of the product and the percent Daily Value for added sugars displayed below a ''Total Sugars'' declaration. Regarding

the experiment on cranberry and other fruit products, the comment described an online study conducted in a sample of 1,448 adults age 18 or older in the United States At the start of the study, participants were shown a set of five statements, including two statements that referred to added sugars: ''Americans should reduce consumption of sodium, saturated fat, refined grains and added sugars;'' and ''Too much added sugar in a person's diet can be bad for them and their total added sugar intake should not exceed 10 percent of their total calorie intake.''

The comment described selected results including, but not limited to, findings related to study participants who viewed a single Nutrition Facts label, in FDA's proposed format, either for cranberry juice cocktail or 100 percent grape juice. The cranberry juice cocktail label showed 110 calories, 28 grams of total sugars, and 25 grams (50 percent DV) of added sugars. The 100 percent grape juice label showed 140 calories, 36 grams of total sugars, and 0 grams (0 percent DV) of added sugars. The comment noted that when both groups of participants were asked to describe ''the amount of sugar'' that the product contains on a scale of 1 to 10, where 10 equaled ''extremely high,'' the average rating of the sugar content for the cranberry juice cocktail was statistically significantly higher than the average rating of the sugar content for the grape juice. The comment also described findings from a group of participants who viewed a single Nutrition Facts label, in FDA's proposed format, for dried cranberries, and another group of participants who viewed a single nutrition label, in FDA's proposed format, for raisins. The dried cranberries label showed130 calories, 3 grams (12 percent DV) of dietary fiber, 29 grams of total sugars, 26 grams (52 percent DV) of added sugars; 0 percent DV of vitamin D, calcium, and iron; and 1 percent DV of potassium in a serving of the product. The raisins label showed 130 calories, 2 grams (8 percent DV) of dietary fiber, 29 grams of total sugars, 0 grams (0 percent DV) of added sugars, 0 percent DV of vitamin D, 2 percent DV of calcium, 6 percent DV of iron, and 9 percent DV of potassium. The comment said that when both groups of participants were asked to describe ''the amount of sugar'' and ''the amount of calories'' that the product contains by rating each item on a scale of 1 to 10, where 10 equaled ''extremely high,'' the average ratings of the sugar and calorie content for the dried cranberries were statistically significantly higher than the average ratings of the sugar and calorie content for the raisins. In the same study, a subset of participants also completed a ''forced choice task'' in which they were shown Nutrition Facts labels for two products presented, displayed in FDA's proposed label format, side-by-side, and were asked to choose which of the two products was ''better described'' by eight different phrases. Some participants were shown a Nutrition Facts label for dried cranberries plus a Nutrition Facts label for raisins, both in FDA's proposed format. The report submitted in the comment said that among those who completed this task, statistically significantly more participants selected the dried cranberries as being ''better described'' as containing ''more sugar'' and ''more calories,'' whereas statistically significantly more participants selected the raisins as being ''better described'' as ''healthy.''

The same comment described selected results from a cross-sectional survey study on cranberry products. The survey was conducted online in September 2015 and included 1,000 adults of 18 and over in the United States. The study participants were asked how likely they are to consume or purchase cranberry juice cocktail, apple juice, and grape juice for their household on a regular basis. Participants were then asked how strongly they agreed or disagreed with four statements: (1) ''Too much added sugar in a person's diet can lead to obesity and risk of chronic health problems;'' (2) ''Many Americans do not meet dietary recommendations for servings of fruit;'' (3) ''One should reduce consumption of sodium, saturated fat, refined grains and added sugar;'' and (4) ''Dried fruits and fruit juices can form a nutritious part of a well-balanced diet and help provide nutrients and servings of fruit.'' Participants were then shown nutrition information for three juice products, displayed in FDA's proposed label format, in a rotating order. One product was cranberry juice cocktail of which label showed 110 calories, 28 grams of total sugars, and 25 grams (50 percent DV) of added sugars. One product was grape juice of which the label showed 140 calories, 36 grams of total sugars, and 0 grams (0 percent DV) of added sugars. One product was apple juice of which the label showed 120 calories, 24 grams of total sugars, and 0 grams (0 percent DV) of added sugars. As each product label was shown, participants were asked, ''How does the information on this label affect your likelihood to consume or purchase [name of juice] for your household?'' The comment said that 39 percent of participants were less likely to consume or purchase the cranberry juice cocktail after viewing the FDA-proposed nutrition label, versus 29 percent for the grape juice and 18 percent for the apple juice. Participants were also asked to identify ''how many grams of sugar'' were in each juice. The comment said that 30 percent of participants could not answer the question correctly when viewing the label for cranberry juice cocktail, versus 7 percent for the grape juice and 7 percent for the apple juice. After answering questions about the grams of sugar in each juice, participants who indicated that they would be less likely to consume or purchase cranberry juice cocktail were asked, ''Why do you say that?'' The comment said that the ''main reason'' for most of the participants who answered this question was ''sugar content.'' The comment reported similar research findings for participants who viewed Nutrition Facts labels, in our proposed format, for dried cranberries versus raisins.

Based on the research findings from the two cranberry studies, the comment said that consumers misunderstood the sugar content of cranberry juice cocktail and dried cranberries, and believed that cranberry products contain more calories and more sugars and are less healthy than competitive products, when presented with FDA-proposed labels for each, both alone and as compared to competitive products. Therefore, the comment said that requiring a naturally unpalatable fruit product that has been sweetened to label the gram amount and percent DV for added sugars, in comparison with naturally sweetened fruit products labeled as having zero grams and zero percent DV for added sugars, is misleading because it implies that a sweetened unpalatable fruit with the same or fewer total calories and sugars as the naturally sweetened fruit product is less nutritious and ''generally unhealthy.''

Both cranberry studies also tested an alternative label format in which the declaration of the grams and percent DV for added sugars was replaced by a double asterisk symbol on the declaration of ''Total Sugars,'' (instead of ''Sugars''), and a footnote placed at the bottom of the label that stated, ''** Total sugars include sugars added for fruit palatability.'' The comment said that the alternative label format alleviated the confusion regarding the sugar content of cranberry juice cocktail compared to grape juice and the confusion regarding the sugar content of dried cranberries compared to raisins.

Another comment described a separate, online experiment that tested

Nutrition Facts labels for fictitious products without any product identities. The study, co-sponsored by five trade associations, was conducted in October, 2015, among a sample of 2,014 U.S. adult consumers aged 18 years or older. Half of the sample saw ''Control labels'' that included only gram amounts of ''Sugars.'' The other half of the sample saw ''Added Sugars labels'' that featured gram amounts of added sugars and the percent Daily Value for added sugars displayed below a ''Total Sugars'' declaration. All participants performed two product comparison tasks. In the first product comparison task, participants who saw the ''Control labels'' were shown two labels side-by-side that displayed identical nutrition profiles, whereas participants who saw ''Added Sugars labels'' saw two labels side-by-side which were almost nutritionally identical, except that one declared 4 grams of added sugars whereas the other declared 0 grams of added sugars. All participants were asked to indicate which of the two products was: (1) The ''healthier'' choice and (2) the ''best choice for maintaining weight.'' The comment said that the results showed that compared to those who saw two ''Control labels'' side-by-side, participants who saw two ''Added Sugars labels'' side-by-side were less likely to say that the product declaring 4 grams of added sugars was equally healthy to, or equally helpful in maintaining a healthy weight as, an identical product that declared 0 grams of added sugars. In the second product comparison task, participants were shown two labels side-by-side that displayed different nutrition profiles. One product contained 190 calories, 2 grams (3 percent DV) of total fat, 37 grams (12 percent DV) of total carbohydrates, 7 grams (28 percent DV) of dietary fiber, 16 grams of total sugars, and, in the ''Added Sugars labels'' but not the ''Control labels,'' 0 grams (0 percent DV) of added sugars. The other product contained 190 calories, 3 grams (5 percent DV) of total fat, 35 grams (12 percent DV) of total carbohydrates, 10 grams (40 percent DV) of dietary fiber, 8 grams of total sugars, and, in the ''Added Sugars labels'' but not the ''Control labels,'' 8 grams (16 percent DV) of added sugars. All other nutrients were declared in identical amounts for both products. In this case, the comment said that of the participants who saw ''Control labels,'' 56 percent selected the product with 10 grams (40 percent DV) of dietary fiber and 8 grams of total sugars as the healthier choice, versus 32 percent of participants who saw the ''Added Sugars labels.''

Many comments referenced a study that was initially submitted as a comment and report to the proposed rule and subsequently published in 2015 (Ref. 107). The report provided qualitative and quantitative results of a study conducted with 1,088 U.S. adults recruited from an online consumer panel. The report said that study participants generally did not understand the term ''added sugars'' and had difficulty correctly identifying the amount of ''sugars'' on the label when ''added sugars'' were declared. Some study participants perceived that products with an ''Added Sugars'' declaration had a higher sugar content than was actually present. The published paper of the study also said that participants were shown three Nutrition Facts labels, side-by-side, for three products that were nutritionally identical, except that two of the three labels included ''Added Sugars'' declarations whereas one of the three included only a ''Sugars'' declaration. The paper said that, when participants were asked to rank in order of descending preference which product they would buy based on the label information, 76 percent of the participants gave the highest preference to the label that included only a ''Sugars'' declaration.

(Response) The findings from the research submitted in the comments and from our own added sugars study suggest more limited conclusions than the comments assert. Regarding the findings that some study participants appeared to have overestimated the sugar content of the products included in the study as a result of summing total and added sugar amounts, we address this issue in our response to comment 188. Regarding the comments' assertions that the study findings demonstrate that our proposed label declaration of the percent Daily Value and grams of added sugars would ''mislead'' consumers based on study participants' responses to questions posed (which reflect participant perceptions), we disagree that the results support such a conclusion (see our response to comment 35).

Our consumer study on added sugars was conducted to help inform our consumer education. In particular, we were interested in better understanding how the inclusion of added sugars declarations on the Nutrition Facts label might influence consumer perceptions of various products and comprehension of the label. A consumer's belief, opinion, or previous exposure to information about added sugars and the impact added sugars may have on health may affect how a consumer may view a label with an added sugars declaration, whether the belief, opinion, or information is grounded in scientific evidence or not. These factors can influence how a consumer perceives information on a label and may result in some consumer confusion and misunderstanding, *e.g.,* when a consumer thinks a food, which can be part of a healthy dietary pattern for the day, is not ''healthful'' simply because it has a certain amount of added sugars. We want to ensure, through our consumer education, that consumers understand how to include a variety of foods in their diet as part of a healthy dietary pattern and focus on providing consumers the tools they need to understand how to include added sugars in their diets and where calories from added sugars can be included within calorie limits. FDA's consumer research on added sugars suggests that in comparison to participants who saw the current label without any added sugars declarations, some study participants' perceptions of the healthfulness of a given product varied when added sugars declarations were included on the Nutrition Facts label. Specifically, the study showed that when participants compared two products that declared added sugars, and the more nutritious product had more added sugars, some participants had difficulty assessing the relative healthfulness of the more nutritious product. This variation in healthfulness perceptions suggests that, when presented with Nutrition Facts labels that included added sugars declarations, some FDA study participants may have applied their own understanding of added sugars in deciding how to evaluate this new information, relative to other, more familiar nutrients shown on the label, which may have, in turn, affected these participants' perceptions about the healthfulness of a given food. A variety of factors may account for some of the product perceptions (*e.g.,* healthfulness of a product) found in our research, including but not necessarily limited to: (1) Dietary advice disseminated since 1980 about limiting ''sugar'' intake, particularly from sources of added sugars; (2) preexisting perceptions and knowledge (both correct and incorrect) about ''sugars'' and ''added sugars;'' and (3) potential confusion among some consumers about the fact that the existing ''Sugars'' declarations on the current Nutrition Facts label refers to the components of ''sugars,'' which include both naturally occurring and added sugars.

The information on the Nutrition Facts label provides consumers with

information they need to maintain healthy dietary practices. Our consumer research on added sugars was informative with respect to the need for information about the amount of added sugars in a serving of food to enable consumers to incorporate added sugars into a healthy eating pattern. Our consumer research on added sugars demonstrated that, without the added sugars declaration, consumers will not have information they need to construct a dietary pattern that is low in added sugars. Not all consumers understand the distinction between ''Sugars'' and ''Added Sugars,'' and, therefore, some consumers do not understand that added sugars, along with naturally occurring sugars, are components of ''Sugars.'' We found that some study participants think a food with added sugars is less ''healthful,'' even though the food could be included as part of a healthy dietary pattern.

Without the factual information about the amount of added sugars in a serving of food and percent DV declaration, consumers would not be able to choose from a variety of foods for a healthy dietary pattern and would not be provided with information about appropriate limits on calories from added sugars in their diet. It is important to provide consumers with the information on the amount of added sugars in a serving of food so they can better manage their daily intake of added sugars, rather than having consumers avoid foods with added sugars in the ingredient list or conversely consume excess amounts of added sugars because they are uninformed about the contribution of added sugars in a serving of food. Information about added sugars on the nutrition label will provide material information to the consumer to better enable them to construct a healthy dietary pattern from a variety of foods.

In addition to our consumer study on added sugars, the comments provided consumer research on added sugars related to consumer perceptions. The research provided in the comments was designed to show differences in how people view added sugars on the label, but did not discuss the need for the added sugars declaration and its importance in enabling consumers to construct healthy dietary patterns. If we do not include added sugars on the label, based on how consumers may misperceive added sugars or be confused about how to include it as part of a healthy dietary pattern on intake, consumers could be harmed by not having critical information needed to maintain healthy dietary practices.

The studies submitted in comments demonstrate the same issue we have noted with respect to some consumers adding total and added sugar declarations together, which led to our revisions to the final declaration of added sugars to clarify that added sugars is a subcomponent of total sugars (''included'' in total sugars). Furthermore, due to a number of deficiencies in the information provided about the cranberry studies as well as in the described study methodologies, we are not able to assess the merits of any conclusions described in the comments related to cranberry products. For example, in the cranberry experiment, one dietary statement that participants were shown at the beginning of the study about added sugars said: ''Too much added sugar in a person's diet can be bad for them and their total added sugar intake should not exceed 10 percent of their total calorie intake.'' A DRV for added sugars of less than 10 percent calories suggests that some added sugars can be part of a healthy diet. In fact, the food pattern modeling that was part of the basis for establishing the DRV for added sugars included 4 to 9 percent of calories from added sugars. Therefore, some study findings in the cranberry experiment may be attributable to participants having seen the negative dietary statement before evaluating the label formats tested in the study.

Additionally, it is not clear whether the cranberry experiment tested how participants would have evaluated the cranberry juice cocktail versus grape juice, or dried cranberries versus raisins when using the current Nutrition Facts label and, more importantly, the proposed Nutrition Facts label without the proposed declaration of added sugars. Without such test results, it is not possible to ascertain whether the reported results could be attributed, as the comment asserted, to the added sugars declaration or were influenced by other label elements. Moreover, although the comment said that the cranberry experiment reduced confusion with an alternative label in which the declaration of the grams and percent DV for added sugars was replaced by a footnote that stated, ''** Total sugars include sugars added for fruit palatability,'' based on findings from eye-tracking studies (Refs. 15, 108), we suspect that the reduced confusion is related more to participants overlooking the information in the footnote, which is located at the bottom of the label. Regardless of the findings described in the comment, the alternative label format included in the cranberry experiment would not provide consumers with essential information about the quantity of added sugars in a food or what that amount of added sugars contributes to a daily diet. Without this information, consumers will not be able to consume less added sugars or put the added sugars declaration in the context of their daily diet. Finally, although we acknowledge that the cranberry experiment showed that statistically significantly more participants selected raisins as being ''better described'' as ''healthy'' in comparison to the dried cranberries, we note that there were other differences between the dried cranberries and the raisins besides the amount of added sugars. For example, the raisins contained more protein, iron, potassium and calcium than cranberries. It is unclear from the study results if the participants solely chose raisins based on their lack of added sugars or if the increased levels of these other nutrients may have impacted the participant's choice for the ''healthy'' product.

In the cranberry survey study, selective reporting of the verbatim results that were used to identify the reported reasons for the decreases in purchase or consumption intentions, the absence of a baseline assessment of how participants would respond to the study questions using the current Nutrition Facts label, and the sequence and nature of the questions described preclude a determination of the extent to which the findings produced in the study are attributable to the FDA-proposed label or to added sugars declarations. For example, the cranberry survey study first asked participants to express agreement or disagreement with a statement, ''Too much added sugar in a person's diet can lead to obesity and risk of chronic health problems.'' Given that 91 percent of the study sample said that they strongly or somewhat agreed with this statement, it is reasonable to infer that the study participants' preconceived beliefs and/or heightened attention on added sugars may account for many of the cranberry survey study findings reported in the comment, rather than the declaration of added sugars. Given that study participants have various preconceived perceptions about added sugars, it is not surprising that participants have different purchase intentions or perceptions. Furthermore, because the cranberry survey study led participants through a sequence of questions where they answered questions about grams of sugar in the products before viewing an alternative label that was advocated by the authors of the comment, the study methods

deliberately led participants to focus on information that they may not have naturally focused on in other circumstances, therefore calling into question whether the alternative label would produce less confusion while also producing better comprehension about the added sugars content of the tested foods if a different set or sequence of questions had been employed.

In the experiment that was co-sponsored by five trade associations, we are unable to conclude that added sugars declarations were the reason for the findings in the second product comparison task because the experimental conditions included variations in total fat and dietary fiber values, in addition to varying added sugars. For example, in the second product comparison task, in which respondents viewed ''nutritionally different'' products, 50 percent of participants who selected the product that declared 0 grams of added sugars as ''better for maintaining healthy weight'' indicated ''it was low in fat'' as a reason for their selection; in addition, our analysis of the raw data submitted by the commenter shows that, 36 percent indicated ''has no grams of added sugars'' as a reason for their selection. On the other hand, our analysis of the raw data shows that among participants who selected the product that declared 8 grams of added sugars as ''better for maintaining healthy weight,'' 55 percent indicated ''is higher in fiber'' as a reason for their selection, and 39 percent indicated ''contains less sugar'' as a reason. As for the findings from the first comparison task, in which participants viewed two labels that were almost nutritionally identical, we do not agree that participants ''misjudged'' the healthfulness or weight-related attributes of the foods in the presence of added sugars information, because the difference in added sugars content between the foods meant that the two foods were, in fact, nutritionally different. Without added sugars declarations, participants were unable to discern that such a difference existed. Similarly, in the paper by Laquatra et al., participants who expressed a purchase preference for the label that included only a ''Sugars'' declaration may not have understood that the food contained added sugars and may have based their preference on that mistaken understanding.

Some research referenced different approaches for the labeling of added sugars for certain nutrient-dense fruit products that are high in acid. The proposed alternative approach to added sugars labeling for dried unpalatable fruit and juices made with at least 27 percent juice of an unpalatable fruit includes a proposed definition for an unpalatable fruit. We note that there are other fruits, such as lemons and limes, which contain nutrients, but have a low Brix value. When the juices of such fruits are consumed, they typically have sugar added to them for palatability. It is not clear what the impact of this approach suggested in the comment, which includes a definition of dried unpalatable fruit as well as use of a Brix-to-acid ratio that is not defined by regulation, would have on other dried fruit products or products made from juices of other fruits that typically have sugars added to them. An alternative approach provided in comments includes the use of a footnote in the Nutrition Facts box to explain that added sugars are added to increase the palatability of the food. However, we are concerned about the use of the Nutrition Facts label to convey this type of information and the precedent such an approach may set for other possible statements related to a nutrient declared on the label, such as the purpose for its addition, and information related to the characteristics or use of the nutrient. We consider it important to maintain the consistency of the information contained within the Nutrition Facts label, which provides factual information about the amount of a nutrient in a serving of food. This ensures that consumers can continue to readily use the Nutrition Facts label to make comparisons across all packaged foods. Manufacturers who are interested in communicating, through labeling, how products made from fruits that have sugars added to them in order for the product to be acceptable to consumers are free to make a statement elsewhere on the label or in labeling, outside of the Nutrition Facts box, to explain the purpose for which the sugars has been added, provided the information is consistent with other labeling requirements, *e.g.,* is truthful and not misleading. Thus, for example, manufacturers could include a truthful and not misleading statement explaining that total sugars include sugars added for fruit palatability.

(Comment 185) One comment described a reanalysis of the raw data from our added sugars study, the availability of which we announced in the **Federal Register** of September 10, 2015 (80 FR 54446). The reanalysis confirmed some of the findings reported in an FDA memo (see part II.H.3.g), but also found that participant perceptions of the products in the study were inconsistent depending on race, education level, or both. Based on the findings from the reanalysis and prior published research that has examined how nutrition label use varies with education level and ethnic minority status, the comment said that the presence of added sugars information on the label produced misperceptions and confusion, and that low-education consumers and ethnic minorities seemed especially prone to ''unintended consequences'' when added sugars was displayed on the label. The comment said that more research is needed to thoroughly understand how the provision of added sugars on the Nutrition Facts label would affect ''at-risk segments'' of the population.

(Response) We agree that some findings suggest the potential for consumer responses to labels vary depending on race, ethnicity, and education level; this type of variation has been shown in prior published research. On the other hand, because the reanalysis ventured beyond the primary objectives of what the study was designed to explore and because some findings reported in the comment were based on fewer than five participants, many findings of the reanalysis are unreliable. We also disagree with the comment's basis for asserting a need for additional research as discussed in our response to comment 40. Due to the limitations of the sample, limitations which the comment acknowledged, we view the reanalysis as exploratory and inconclusive, although potentially informative for future education efforts. Furthermore, as addressed in our responses to comments 1 and 244, we have considered, and will continue to consider, a variety of educational efforts to assist consumers in comprehending and using the Nutrition Facts label to maintain healthy dietary practices.

h. Voluntary labeling. In the preamble to the proposed rule (79 FR 11879 at 11905), we considered the appropriateness of the voluntary declaration of added sugars. However, we said that we were concerned that voluntary declaration of added sugars may not ensure that consumers have the information that will allow them to follow the current dietary recommendations (id.). We also said that added sugars declared voluntarily by manufacturers could be confusing to consumers and would not provide consumers with the information they need to plan their dietary pattern to reduce consumption of calories from added sugars (id.).

(Comment 186) Several comments disagreed with our tentative conclusion that the labeling of added sugars should be mandatory and provided a number of

reasons why the declaration of added sugars should be voluntary rather than mandatory. Most comments suggested that labeling of added sugars should be voluntary rather than mandatory for the same reasons that they opposed mandatory labeling of added sugars. The comments, and our responses to the comments, are provided in part II.H.3.a. Other comments, which recommended that if we determine that added sugars should be declared on the label, the label declaration should be voluntary rather than mandatory, provided the following reasons:

- One comment referred to our discussion of voluntary labeling of added sugars in the proposed rule (79 FR 11879 at 11905), and said that whether declaration of a nutrient on the Nutrition Facts label is mandatory or voluntary does not correspond to its bearing on maintaining healthy dietary practices;
- The sole macronutrient made mandatory by regulation is *trans* fat due to its established relationship to risk of chronic diseases and health-related conditions;
- Other voluntary nutrients, such as polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, and sugar alcohol, are the subject of authorized health claims;
- Executive Order 13563 requires us to consider less burdensome alternatives;
- Consumers' understanding of the differences between added and naturally present sugars should be determined before becoming mandatory;
- Voluntary labeling would be consistent with the labeling of added sugars in the United Kingdom, Canada, Australia, and New Zealand, and would not run afoul of the World Trade Organization's Agreement on Technical Barriers to Trade (''TBT Agreement''); and
- Manufacturers of foods containing a significant amount of added sugars would likely be disinclined to declare added sugars if labeling is voluntary, however manufacturers of foods containing an insignificant amount of added sugars would likely use the added sugars declaration to highlight the added sugars content by juxtaposing sugars and added sugars declarations on the label.

(Response) Since the publication of the proposed rule, additional evidence has become available that further supports the need for a mandatory declaration of added sugars. The scientific evidence supports Americans limiting their calories from added sugars by consuming an eating pattern low in added sugars. We explained that consumers need to know how much added sugars is in a serving of a product in order to consume a healthy dietary pattern that is low in added sugars because we have evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages when compared to less healthy dietary patterns are associated with a decreased risk of CVD. We have the authority to require the declaration of a nutrient on the label if we determine the declaration will assist consumers in maintaining healthy dietary practices. Our discretion includes whether to permit the voluntary declaration or require the mandatory declaration of a nutrient (56 FR 60366, November 27, 1991).

With respect to the comment which noted that the only nutrient which has been added to the label by regulation is *trans* fat, which was based on its relationship to CVD risk, our basis for requiring the declaration of added sugars for the general population is not its independent association with the risk of chronic disease, a health-related condition, or a physiological endpoint. Instead, we are requiring the mandatory declaration of added sugars because evidence shows that heathy dietary patterns associated with a decreased risk of chronic disease are lower in added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened beverages are associated with increased adiposity in children.

With respect to the comment that suggested that a declaration of added sugars should be voluntary because it is not the subject of an authorized health claim, our authority to add additional nutrients to the label under section 403(q) of the FD&C Act is distinct from our authority to authorize health claims.

With respect to the comment suggesting that we should consider less burdensome alternatives as directed by Executive Order 13563, we did consider voluntary labeling of added sugars in the preamble to the proposed rule (79 FR 11879 at 11905) and determined that a voluntary declaration would not provide the information consumers need to understand the relative contribution of added sugars from all food in the context of a total daily diet and achieve a healthy dietary pattern that is associated with a reduced risk of chronic disease. The 2015 DGA provides further support for this conclusion.

With respect to the comment that consumers' understanding of the differences between added and naturally present sugars should be determined before we can require the declaration of added sugars, that is not consistent with our authority for when we can require a nutrient declaration, as discussed in our response to comment 156.

Concerning the comments raised with the TBT Agreement, the comments have not explained why we would be acting inconsistently with our WTO obligations if we require the declaration of added sugars, as compared to other countries that allow for the voluntary declaration of added sugars on their labels. As we have explained, our objectives will not be fulfilled by voluntary labeling. Rather, the scientific evidence supports the mandatory disclosure of the amount of added sugars in the nutritional labeling of food. The dietary pattern of the general United States population contains excessive calories from solid fats and added sugars. The consumption of excess calories above calorie needs can lead to overweight and obesity. There is public health need to reduce excess calories from solid fats and added sugars to ensure that nutrient needs are met within calorie limits. Moreover, a healthy dietary pattern that is characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy dietary patterns is associated with a reduced risk of CVD. Thus, we have determined that there is a public health need for Americans to be able to determine the amount of added sugars in a serving of foods and to be able to put that amount into the context of their total daily diet so that they can consume a healthy dietary pattern that is lower in added sugars. We have a legitimate regulatory objective to provide nutrition information to consumers that includes the added sugars content in a serving of food to protect the health of United States consumers. The scientific evidence indicates that requiring disclosure of added sugar content is necessary to achieving this objective. We address comments related to international trade in part II.H.3.m.

We have considered the comment about the possible inclination of manufacturers to declare added sugars on their labels as a basis for determining whether to require or permit the declaration of added sugars on the label and consider the required declaration of added sugars to be necessary to assist consumers in maintaining healthy dietary practices. If consumers do not have information on the amount of added sugars in foods available in the marketplace, they will not be able to compare products so that they can avoid excess calories from added sugars and

construct an overall healthy dietary pattern that has less than 10 percent of calories from added sugars.

i. How added sugars are declared. Many comments provided recommendations for how information about added sugars in products should be conveyed to consumers on the label.

(i) Changing ''Sugars'' to ''Total Sugars''

In the preamble to the proposed rule (79 FR 11879 at 11902), we said that we were considering whether to use the term ''Total Sugars'' instead of ''Sugars'' on the label if we finalize a declaration of added sugars. We also said that we planned to conduct consumer research that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help or enhance our understanding of how consumers would comprehend and use this new information, and to inform our education activities and outreach. In the preamble to the supplemental proposed rule (80 FR 44303 at 44306), we discussed the results of our consumer research which showed that when an ''Added Sugars'' declaration was indented below a ''Total Sugars'' declaration on the label, participants appeared to be better able to comprehend the total amount of sugars in a food than if an ''Added Sugars'' declaration was indented below a ''Sugars'' declaration. In the preamble to the supplemental proposed rule (id. at 44304), we asked for comment on whether the term ''Total Sugars'' should be declared on the label instead of ''Sugars.''

(Comment 187) Many comments to both the proposed rule and the supplemental proposed rule addressed this topic. The comments generally preferred the term ''Total Sugars'' rather than ''Sugars'' on the label. Although some comments did not support a declaration of added sugars on the label, the comments said that, if we require the declaration of added sugars in the final rule, the term ''Total Sugars'' should be used on the label rather than ''Sugars.'' The comments said that such a change to the terminology used will likely increase consumer understanding that ''Added Sugars'' are included in the ''Total Sugars'' declaration. The comments would change the ''Sugars'' declaration to ''Total Sugars'' to provide a clearer distinction between total and added sugars and to prevent consumers from adding the ''Added Sugars'' and ''Sugars'' declarations together. The comments said that this change would be consistent with the declarations for ''Total Fat'' and ''Total carb.'' Other comments suggested that using the heading ''Total Sugars'' would provide interpretive data that is consistent with the need to make information clearer for consumers with lower levels of health literacy, numeracy, and English language limitations. One comment said that an analysis of our research indicates that replacing the term ''Sugars'' with ''Total Sugars'' on the label will enhance the consumers' ability to discern the overall nutritional value and compare nutrient density of food products at the point of selection (Ref. 109).

Other comments provided evidence that consumer's understanding of label information about sugars is improved when the ''Sugars'' term is replaced with ''Total Sugars.'' One comment provided the results of a qualitative and quantitative study that it conducted showing that, when ''Total Sugars'' was declared on a label rather than ''Sugars,'' participants were more likely to understand that the sugars in an ''Added Sugars'' line would be included in a ''Total Sugars'' line (Ref. 107). These results are consistent with our findings. Another comment cited a study by Laquatra et al., which the comment said suggests that consumers' understanding of the amount of sugar indicated on a food label was improved when the term ''total sugars'' was used rather than ''sugars'' (Ref. 107).

One comment said that our consumer research results are ambiguous, and requested that we undertake sufficient education activities to ensure that consumers understand that ''Added Sugars'' are included in the ''Total Sugars'' declaration. Another comment also said that it is premature to comment on using the term ''Total Sugars'' instead of ''Sugars'' on the label because additional consumer research that includes a label format that represents our proposed added sugars labeling declarations (including a percent DV declaration) is needed to gauge consumer understanding and usage of the new label information.

(Response) Since the publication of the supplemental proposed rule, our finding that participants appear have better comprehension of the total amount of sugars in a food when ''Sugars'' is replaced with ''Total Sugars'' on the label has been replicated by others, as noted in some comments. We disagree that additional consumer research testing the proposed label format with a percent DV declaration for added sugars is needed before we can finalize a change to the label which replaces the term ''Sugars'' with ''Total Sugars.'' ''Total Sugars'' will help improve comprehension of information on the label related to total and added sugars (see part II.H.2.c). Therefore, we are replacing ''Sugars'' with ''Total Sugars'' throughout §§ 101.9 and 101.36.

(Comment 188) Many comments raised concerns about our proposal to require added sugars declarations due to findings from consumer research conducted by FDA and others. The comments said consumer research showed that added sugars declarations decreased the ability of some participants to correctly identify the quantity of total sugars in a food. Specifically, FDA's studies as well as other studies cited in the comments showed that when viewing nutrition labels with added sugars declarations, some participants mistakenly summed the value for total sugars and the value for added sugars when they were asked to identify the total amount of sugars in a serving of a product. Some comments also said that the research suggests that the proposed label is more likely than the current label to mislead or confuse consumers with regard to total grams of sugars in the product; the comments would exclude an added sugars declaration from the label. Another comment suggested that FDA should conduct additional research to find other ways to present added sugars and total sugars declarations to reduce consumer confusion.

(Response) We acknowledge that our consumer research and those referenced in the comments showed statistically significant decreases in participants' understanding of total sugars in a serving of a product when a label included an added sugars declaration, either with or without the corresponding percent Daily Value of added sugars, compared to when a label did not include an added sugars declaration. Our study showed that the most common error was for our study participants to overestimate the quantity of total sugars in the product by summing the product's ''total sugars'' (or just ''sugars,'' depending on which label format was used) and ''added sugars.'' We note, however, that in our study and in a study conducted by IFIC, including ''total'' in front of ''sugars'' helped study participants better comprehend the total amount of sugars in a serving of a product. Therefore, the final rule includes ''total'' in front of ''sugars'' to better enable consumers to correctly assess the quantity of total sugars in a product.

We also note that in our research, when compared to the control group viewing the current label with no ''added sugars'' declaration, some study participants still did not report the correct amount of ''sugars'' in one serving of the product, even when the

word ''total'' was included in front of ''sugars.'' It is also important to note that when using the sugars declaration on the current label, some participants were unable to determine the total amount of sugars, even when only ''sugars'' was listed on the label. Additionally, our research found that the majority of study participants could not identify the correct amount of ''added sugars'' on the label when it was not declared, thereby not giving participants a key piece of information needed to maintain healthy dietary practices.

We plan to include ''added sugars'' in our consumer education and outreach efforts on the Nutrition Facts label. This will address some consumer confusion. However, to the extent some confusion was identified in the studies, we want to correct this potential confusion by adding the word ''includes'' in front of added sugars. The added sugars declaration will now read ''Includes X g Added Sugars'' below the ''Total Sugars'' line. The addition of ''includes'' will enable consumers to understand that ''added sugars'' are a sub-component of ''total sugars.'' We also are minimizing the hairline between total sugars and added sugars to help denote that ''added sugars'' are a subcomponent of ''total sugars.'' Minimizing the hairline between the two sugars will ''chunk'' the sugars together instead of them being distinct and separate. We base our decision on the expert opinion of two scientists in the fields of consumer research and risk communication and a review of literature as explained below surrounding the use of connecting words to clarify relationships between subject matter.

We enlisted the aid of two independent FDA experts, one whose expertise is in consumer research and the other whose expertise is in risk communication. These experts were not affiliated with our current consumer studies work on added sugars and were asked to evaluate whether using the word ''includes'' as well as minimizing the line between ''total sugars and ''added sugars'' are likely to ameliorate the consumer confusion found in our consumer research as well as the research of others. The experts independently agreed that these changes should help consumers better understand that ''added sugars'' is a subcomponent of ''total sugars'' (Refs. 110–111). The consumer research expert noted that including the word ''total'' in front of ''sugars'' should be particularly helpful to regular label users since this format is consistent with what is used for ''total fat'' and ''total carbohydrate.'' The expert also suggested that use of the word ''includes'' should reinforce for consumers that ''added sugars'' is a component of ''total sugars'' and not merely a complement. The expert also noted that any lingering confusion with the format related to determining total amount of sugars in a serving of a product should dissipate over time as users of the Nutrition Facts label become accustomed to the new label.

The second expert in risk communication noted that the presence of the word ''includes'' provides clarity that she expects will reduce confusion among those consumers who summed ''Added Sugars'' and ''Total Sugars'' and allow consumers to determine the total amount of sugars in one serving of a product.

In addition to the expert opinion, some literature suggests linking terms (words or phrases that reveal relationships between ideas in content) are useful for increasing comprehension, indicating that using the word ''includes'' may help consumers understand that ''added sugars'' are a subcomponent of ''total sugars.'' Comprehension of information in text takes place when the reader can identify new text information and relate it to the information already given or known. The more information that coincides with what readers already know, the easier it will be for them to integrate new information into their existing knowledge base, hence coming to understand the material presented in the information (Ref. 112). One principle commonly used to facilitate comprehension is to make each sentence explicitly related to the next. One possible approach to implement this principle is to use sentence connectors to clarify relationships between sentences. Similarly, Spyridakis 1989 (Ref. 113) suggested that because comprehension of text requires readers to make inferences, a text that provides clues to the links between discrete units of information can help readers make appropriate inferences and therefore contribute to overall learning of the content of the text. There are different types of ''connector'' or ''signal'' words, phrases, or statements that preannounce content and/or reveal a relationship between ideas in content (Ref. 114). The latter, sometimes called logical connectors, can be words or phrases such as ''first,'' ''moreover,'' ''because,'' ''for example,'' and ''in other words.'' The literature has demonstrated that logical connectors can be helpful in improving text comprehension (Refs. 113–115). We acknowledge that text and tables are different formats of presentation, however the understanding of tabular information and understanding of textual information share similar psychological processes (Ref. 116). The literature thus lends support that a linking word such as ''includes'' may help consumers better comprehend that ''added sugars'' are a sub-component of ''total sugars.''

Furthermore, in the previous final rule implementing the NLEA (57 FR 32070 at 32071), we noted that several comments suggested using terms such as ''includes,'' ''including,'' and ''of which,'' before the subcomponent for fats and carbohydrates to indicate that the subcomponent is a part of a broader classification. We agreed that these words would add clarity to the label but declined to include them at that time because they could ''clutter'' the label. While label clutter is a concern, decreasing potential consumer confusion outweighs any cluttering of the label that would result from the addition of a word before ''added sugars.'' We also note that the European Union, in its new nutritional labeling requirements, is requiring ''of which'' to help denote the sub-components of fats and carbohydrates, which is a similar linking phrase.

With regard to the comment that asked us to conduct further consumer research on this topic, we decline to do so at this time. While we may consider additional consumer research in the future to help inform consumer education regarding the ''added sugars'' or other declarations, we have incorporated changes intended to minimize consumer confusion regarding the ''added sugars'' declaration on the label and have finalized this requirement. We have sufficient information to move forward with the requirement for the added sugars declaration based on a review of the scientific evidence and other available data and information which support the need for added sugars information to be available to the consumer as part of the nutrition label.

(ii) Declaration of Added Sugars in Teaspoons

(Comment 189) While one comment said that a gram disclosure for added sugars would be more readily understood by consumers because it is consistent with the manner in which total sugars are disclosed on the label, a number of comments suggested that added sugars should be declared in teaspoons or in teaspoons as well as grams. The comments said Americans understand household measures better than they do the metric system because they use household measures at home.

The comments said that listing the amount of added sugars in both grams and teaspoons would improve the clarity of the information provided about added sugars. The comments also suggested that a gram and teaspoon declaration for added sugars would help consumers readily observe and comprehend the information on sugars and to understand its relative significance in the context of a total daily diet.

The comments provided the results of survey data to support an added sugars declaration in teaspoons. One comment provided the results of a 2010 telephone survey which it said showed that 72 percent of respondents favored listing teaspoons of sugar on the label. Another comment referenced the results of a 2012 survey of readers by Consumer World, an Internet-based publisher of a consumer resource guide. The comment said that, when exposed to label information in which the amount of added sugars in a product was expressed in grams, up to 80 percent of survey participants could not accurately say how much sugar was contained in a product, and many participants underestimated the actual amount of sugar in the product.

(Response) We decline to revise the rule as suggested by the comments. We address issues regarding the use of household measures (such as teaspoons) in part II.B.3.

Additionally, we note that there are many ingredients that supply added sugar, so it would be difficult, if not impossible, for a manufacturer to determine the volume contribution that each ingredient provides towards the added sugars declaration. For example, a cookie made with white chocolate chips and dried fruit would have added sugars in the form of sugar in the batter as well as in the white chocolate chips and the dried fruit.

Because many products would not have amounts of added sugars in a serving of a product that would result in the declaration of an even teaspoon or multiple thereof, the requirement to declare added sugars in teaspoons rather than in grams would result in fractional declarations of teaspoons of added sugars. Indeed, under § 101.9(c)(6)(iii) of the final rule, a statement of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. The final rule also states that if a product contains an insignificant amount of added sugars, the added sugars content may be expressed as zero.

Additionally, the USDA Food Patterns provide limits for added sugars that can be reasonably consumed while meeting all other nutrient and food group requirements that are listed in grams rather than in teaspoons. The declaration of added sugars in teaspoons rather than in grams would make it difficult for consumers to determine how their consumption of added sugars relates to the recommended limits in the USDA Food Patterns.

There is limited space on the label, so the declaration of both gram and teaspoon amounts of added sugars on the label could cause clutter and make the label more difficult to read. We have determined that the amount of other nutrients on the label should not be declared in teaspoons, so if added sugars were declared in both grams and teaspoons, it could draw the reader's attention to the added sugars declaration and make it appear as though the information should be more important or considered in a different way than declarations of other nutrients when the declarations of other nutrients are just as important to consider when constructing a healthful dietary pattern.

While we take into consideration consumer preference, manufacturers must provide information on the label that is as accurate as possible. Although consumers may prefer the declaration of added sugars in teaspoons because household measures are more familiar to them than gram amounts, the need for accurate labeling of added sugars is of greater importance.

We have conducted our own research, and that research showed that when the gram amount of added sugars is declared on the label, study participants are able to determine the amount of added sugars in a serving of a product. Furthermore, the percent DV declaration for added sugars is also required. Therefore, we disagree that consumers are unable to determine the amount of added sugars when the gram amount is declared on the label.

(iii) Distinguishing Between Naturally Occurring and Added Sugars on the Label

(Comment 190) Some comments thought that we proposed to require both a declaration for naturally occurring and added sugars. Other comments suggested that the Nutrition Facts label include separate declarations for naturally occurring and added sugars so that consumers could clearly identify the amount of both naturally occurring and added sugars on the label.

(Response) We did not propose to require separate declarations for naturally occurring and added sugars on the label. The comments did not provide a basis upon which we can rely to support a separate declaration of naturally occurring sugars, and so we decline to revise the rule as suggested by the comments.

(Comment 191) One comment recommended that we propose a Nutrition Facts label format that clearly distinguishes added sugars from naturally occurring sugars in whole fruit and from sugars from dairy ingredients. The comment also recommended replacing ''sugars'' with ''fruit & milk sugars''.

(Response) We address this comment in part II.H.2.

(iv) Replacing ''Sugars'' With ''Added Sugars''

(Comment 192) Some comments would replace ''Sugars'' with ''Added Sugars.'' One comment said that foods like fruits have natural sugars in them, but when people see the amount of sugars they may think the food is bad for them.

(Response) We decline to revise the rule as suggested by the comment. The consumption of sugars continues to be associated with an increased risk of dental caries (Ref. 75); thus, a declaration of the total amount of sugars in a serving of a product continues to be necessary to assist consumers in maintaining healthy dietary practices.

(v) Distinguishing Between Different Types of Sugars or Sweeteners

(Comment 193) One comment suggested listing all sugars separately on the label.

(Response) We decline to revise the rule as suggested by the comment. There are many different kinds of sugars and ingredients containing sugars. The declaration of the amount of each type of sugar in a serving of a product would result in a very large and cluttered Nutrition Facts label. While all nutrient declarations are important to build healthy dietary patterns, current science focuses on added sugars in total rather than focusing on specific sugars. If consumers are interested in knowing whether certain sugars are in a product, specific sugars are listed in the ingredient list.

(Comment 194) One comment requested that we allow the inclusion of ''nutritive sweetener'' in a parenthetical after added sugars so manufacturers could identify the name of the added sugar. The comment also requested that, if the added sugar is high fructose corn syrup, we allow manufacturers to identify the percentage of fructose on the Nutrition Facts label (*e.g.,* high fructose corn syrup-42 or high fructose

corn syrup-55). The comment said that listing ''nutritive sweetener,'' the name of the added sugar, and the percentage of fructose in high fructose corn syrup is essential for the consumer to make a fully informed choice about the caloric contribution of sweeteners and the composition of ingredients in the product they are consuming.

Other comments supported the declaration of the amount of fructose in a serving of a product on the label. One comment said that the information is needed because metabolizing fructose puts an extra load on the liver. The comment suggested that adding fructose and deleting added sugars in the quantitative information would add value without adding complexity.

(Response) We decline to revise the rule as suggested by the comments. Added sugars are nutritive sweeteners, so it is not clear why ''nutritive sweetener'' needs to be declared in parentheses behind the words ''added sugars'' on the label. As previously discussed in our response to comment 193, current science focuses on added sugars in total rather than focusing on specific sugars.

(Comment 195) One comment objected to the use of the term ''added sugars'' because, according to the comment, it improperly combines compositionally and metabolically distinct caloric sweeteners.

(Response) We are not basing our declaration of added sugars on an independent relationship between added sugars, or different types of added sugars, and risk of chronic disease. To the extent that the comment is suggesting that different types of sugars are chemically distinct, so the term added sugars is inappropriate, there are different types of naturally occurring sugars as well as different types of carbohydrates, but we use the terms ''total sugars'' and ''total carbohydrate'' to capture all sugars and all carbohydrates respectively. Therefore, using one broad term to capture all sugars that have been added to a food is consistent with the approach that we have taken for other nutrients. Furthermore, caloric sweeteners that have been added to a food are added sugars, therefore we do not agree that it is inappropriate to use the term added sugars to include caloric sweeteners that have different chemical structures.

(vi) Warning Statements

(Comment 196) Several comments suggested that we require various warning statements on the label related to added sugars to warn consumers of the negative health effects of added sugars. One comment suggested that we require a warning statement that says ''WARNING: THIS PRODUCT CONTAINS A SIGNIFICANT AMOUNT OF ADDED TEASPOONS OF SUGAR WHICH STUDIES HAVE LINKED TO OBESITY, TYPE II DIABETES, CARDIOVASCULAR DISEASE AND CERTAIN CANCERS. CONSULT YOUR PHYSICIAN ABOUT AN APPROPRIATE DIET WITH A REDUCED AMOUNT OF ADDED SUGAR.'' Another comment suggested that we should require a warning label that says ''IT [added sugar] IS ADDICTIVE. IT CAN LEAD TO OBESITY. OBESITY CAN LEAD TO DIABETES, HEART DISEASE, ETC.''

One comment suggested that we require, or offer an incentive for, a disclaimer about added sugars and sodium. The disclaimer would explain the health effects on the body and connections to disorders such as diabetes and hypertension. The comment said that, similar to cigarette packets, consumers should be warned of the health effects of added sugars.

(Response) We decline to revise the rule as suggested by the comments. The statements are not consistent with our review of the evidence (see our response to comments 136 and 137), and we do not require warning labels or disclaimers for other nutrients on the label. Furthermore, some added sugars can be included as part of a healthy dietary pattern.

(Comment 197) Several comments suggested that we use wording to convey that the DRV of 10 percent of calories from added sugars is a maximum amount rather than a recommended amount. One comment would include language to state that ''no consumption is recommended. But if you choose to consume, then this absolute maximum should be observed to avoid increasing adverse health exposure.'' Another comment would require a statement on the label that the average woman should consume no more than 24 grams of sugar per day, and the average man should consume no more than 34 grams of sugar per day.

(Response) We decline to revise the rule as suggested by the comments. In response to the comment that would include language to convey that the DRV is a maximum amount rather than a recommended amount, such language would not be appropriate because we do not require this information for other nutrients with DRVs or RDIs that are based on an amount not to exceed.

As for a statement regarding ''no consumption,'' the current evidence does not support a need to eliminate all added sugars from the diet. In fact, the USDA Food Patterns show that one can carefully construct a healthful diet that includes calories from added sugars.

Finally, regarding a statement on the label with limits for the amount of added sugars that the average man or woman should consume, we do not provide this information for any other nutrients which are to be limited in the diet, and it is not clear what the scientific basis is for the suggested limits.

j. Variability in sugar content.

(Comment 198) One comment noted that manufacturers may add varying amounts of sugars due to variation in maturity of a fruit or vegetable ingredient during the course of a growing season to attain a consistent level of soluble solids and a consistent taste profile of the food. The comment further said that food manufacturers and marketers would not prepare multiple labels for different batches, so the declared amount would reflect the highest possible amount of added sugars and may overstate the actual amount.

(Response) Variation in the sugar content of fruits and vegetables due to growing conditions is something that manufacturers have had to take into account with their labeling of total sugars since 1993. Manufacturers are in the best position to determine how much of a nutrient is in their product given the variability of the nutrients in their product. They are also in the best position to determine when a label change is needed because the declaration would no longer be in compliance with our requirements under § 101.9(g).

k. Non-enzymatic browning and fermentation. In the preamble to the proposed rule (79 FR 11879 at 11906), we recognized that sugars in some foods may undergo changes mediated by chemical reactions from non-enzymatic browning (*i.e.* Maillard reaction and caramelization) and fermentation that would result in compounds that are no longer recognizable or detectable as sugars through conventional analytical methods. We tentatively concluded that the amount of added sugars transformed during non-enzymatic browning reactions is insignificant relative to the initial levels of sugars. We also tentatively concluded based on the information available to us that the amount of added sugars present in foods prior to undergoing fermentation, with the exception of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a ''malt beverage'' as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)) with sugars added during the formation process, will not be

significantly affected by virtue of the food having undergone fermentation (79 FR 11879 at 11907). We acknowledged that we do not have adequate information to assess the degradation of added sugars during fermentation for yeast-leavened bakery products, wine with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before fermentation. We requested the submission of available data and information on our tentative conclusions as well as the submission of data on the amount of variability that occurs among various types of products where added sugars are transformed into other compounds as a result of chemical reactions during food processing.

The proposed rule, at § 101.9(g)(10)(v), would require a manufacturer of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before and during the fermentation process to make and keep records of added sugars necessary to determine the amount of added sugars present in the finished food. The proposed rule would require manufacturers of such foods to make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of fermented food manufactured. Alternatively, under the proposed rule, manufacturers would be able to make and keep records of the amount of added sugars added to the food before and during the processing of the food and, if packaged as a separate ingredient, as packaged. We said that the amount of added sugars declared should not exceed the amount of total sugars on the label (79 FR 11879 at 11908).

(Comment 199) One comment said that we have not demonstrated why distinguishing between a fermented added sugar and a fermented naturally occurring sugar or why the type of sugar that participates in reactions due to heat treatment improves the health of consumers. The comment questioned what the compelling government interest is in knowing which molecule of sugar participates in these reactions.

(Response) To the extent that the comment is suggesting that our focus on added sugars is misplaced because added sugars are not chemically distinct from naturally occurring sugars and are not associated with health or the risk of disease, we respond to such issues in part II.H.3.i. We also have stated, in part II.H.3.a, that added sugars consumption is a significant public health concern which warrants mandatory declaration.

(Comment 200) Several comments suggested that there are a wide variety of fermented foods (*e.g.,* fermented vegetables, beverages, fruits, condiments, products made with grains and/or pulses, dairy replacement products, and meat products) and ingredients (*e.g.,* vinegars, enzymes, vitamins, and amino acids in pure form or in mixtures) to which sugars are added, and where the sugars content is significantly diminished or entirely removed through fermentation. The comments also disagreed with our tentative conclusion that the amount of added sugars transformed by fermentation will be insignificant relative to the initial levels of sugars in foods and ingredients other than yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage. The comments noted that the effect of fermentation is variable. According to the comments, the net effect can depend on details of the starting materials, fermentation process, and length of fermentation.

Several comments noted that there are many processing and ingredient variables that influence the fermentation process in yeast-leavened bakery products. The comments said that our assumption that manufacturers have information about reduction of added sugars in yeast-leavened bakery products is incorrect. One comment stated that, because manufacturers would be unable to determine the amount of added sugars consumed during fermentation in yeast-leavened bakery products, manufacturers would have to declare the amount of sugars added before leavening under the proposed rule, resulting in an overstatement of the amount of added sugars in the finished product, which is false and misleading.

Other comments suggested that added sugars that are converted through fermentation to other compounds should be subtracted from the added sugars declaration, and any sugars produced during fermentation should be omitted from the declaration of added sugars.

One comment suggested that proposed § 101.9(g)(10)(v), which would permit manufacturers of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage to make and keep records of scientific data and information to demonstrate the amount of added sugars remaining in the finished food, when that amount is less than the initial amount of added sugars, be extended to all food manufacturers that must declare added sugars in the labeling of their products.

Other comments disagreed with our tentative conclusion that the amount of added sugars transformed by non-enzymatic browning reactions will be insignificant relative to the initial levels of sugars. One comment provided the example of the manufacture of caramel. The comment suggested that this process converts sugars into thousands of new chemical compounds that include oligomers, dehydration and hydration products, disproportionation products, and colored aromatic products. The comment noted that the decrease in added sugars in a wide variety of products undergoing such chemical reactions may depend on the ingredients, moisture levels, presence of acids or bases, exposure to heat, etc., but that the decrease is not uniformly insignificant.

(Response) Although comments said that the amount of added sugars converted to other compounds during fermentation and non-enzymatic browning is significant in a wide variety of foods, few comments provided data to support their conclusions. One comment provided information about the amount of sugars which are converted to other compounds in kimchi, a fermented vegetable product (Refs. 117–118). Another comment provided information about caramel candy (Ref. 119). In a memo to the file for the proposed rule (Ref. 120), we tentatively concluded that the amount of added sugars which are converted to other compounds through Maillard browning, a type of non-enzymatic browning, is insignificant. Although the comments generally disagreed with our conclusion that all products participating in non-enzymatic browning have an insignificant reduction in the amount of added sugars, no comments specifically disagreed with our conclusion about products that participate in Maillard browning. Therefore, in products affected by Maillard browning, the amount of sugars added before Maillard browning is a reasonable approximation of the amount of added sugars in the finished product in most, if not all, products.

With the exception of the comment which cited caramelization as an

example of a non-enzymatic browning process where the reduction in the amount of added sugars present in a finished food could be significant, we did not receive any other specific data or information about foods that undergo non-enzymatic browning to support the comments' position that the amount of added sugars converted to other compounds is significant. Therefore, we expect that the amount of sugars added before non-enzymatic browning in these foods would be a reasonable approximation of the amount of added sugars in the finished product. We also expect that manufacturers of such products would be able to make and keep documentation to show a reasonable basis for how they determined the declared value for added sugars.

We recognize that there may be a larger amount of variability in fermented products with respect to the amount of added sugars that are converted to other compounds. Although the comments provided examples of products that participate in fermentation, the comments provided very little data or information to support the assertion that the added sugars content is significantly reduced in a large number of fermented foods. We are aware of only a small number of fermented foods where the reduction in added sugars may significant (where the reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars) after fermentation. Therefore, we expect that the majority of manufacturers would be able to use the amount of added sugars added as an ingredient as a reasonable approximation of the amount of added sugars in a serving of their product.

If a manufacturer has a basis on which to support a declaration of added sugars based on the amount of added sugars present in a food after non-enzymatic browning or fermentation, the label declaration must be supported by records demonstrating the accuracy of the declared amount. The records should include all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food.

There may be a small number of foods which undergo non-enzymatic browning and/or fermentation for which manufacturers have reason to believe that the amount of added sugars in a serving of the finished food product is significantly less (*i.e.,* where the reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars) than the amount added prior to non-enzymatic browning and/or fermentation, and the manufacturer has no way to reasonably approximate the amount of added sugars in a serving of the finished food. Therefore, we have revised § 101.9(g)(10)(v)(C) to state that manufacturers may submit a petition, under § 10.30 (21 CFR 10.30), to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within current good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

We recognize that labeling of added sugars in products that undergo fermentation and non-enzymatic browning may not be exact, but manufacturers of most products that participate in these reactions should be able to provide a reasonable approximation of the amount of added sugars in a serving of their product based on information in the literature and their own analyses. Most manufacturers should be able to provide documentation to support the value that they declare on the label. Therefore, the majority of manufacturers of such foods will be able to provide a reasonable approximation of the amount of added sugars in a serving of their product as well as documentation showing a reasonable basis for how they determined the declared value.

As some comments recommended, we agree that it is appropriate to allow manufacturers of all products which undergo non-enzymatic browning and/or fermentation to make and keep records of the type that we proposed. Therefore, we have revised § 101.9(g)(v) to say that when the amount of sugars added to food products is reduced through non-enzymatic browning and/or fermentation, manufacturers must:

- Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food manufactured; or
- Make and keep records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or
- Submit a petition, under § 10.30, to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation.

A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within current good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(Comment 201) One comment noted that sugar content of products can be increased through hydrolysis and enzymatic reactions using carbohydrate containing ingredients. The comment questioned what the classification would be of the sugars (natural or added) produced by such reactions during food processing. The comment also noted that the possibility of having sugars produced ''in situ'' (meaning in place or in position) shows the difficulty of drawing a clear line between the two types of sugars.

(Response) Sugars content can be increased through acid, heat, or

enzymatic hydrolysis of complex carbohydrates (*e.g.* starch). Sometimes, the increase is incidental as a consequence of other food manufacturing processes, such as acidification, heating, and/or fermentation. For example, during yeast bread fermentation, natural enzymes present in the flour can hydrolyze starch into maltose. Other than sugar syrup types of products where the sugars are specifically and purposely produced via hydrolysis, we do not have information suggesting that sugars produced through incidental hydrolysis of complex carbohydrates results in a significant increase in the sugar content of foods. Sugars which are produced through incidental hydrolysis would be captured in the total sugars declaration, but we do not have any comments or other information suggesting that these sugars should be captured under the added sugars declaration. Therefore, they are not included in our definition of added sugars and would not be declared as added sugars on the label. In the previous example of the enzymatic hydrolysis of maltose from starch during bread fermentation, we would not require the maltose formed during this process to be declared as added sugar. However, sugar present in corn syrup produced from hydrolysis of corn starch would be considered added sugar because the hydrolysis was specifically done to generate mono- and di-glycerides. In addition, if a manufacturer purposely employs a hydrolysis step as part of a food manufacturing process to increase the sugar content of a food product (*e.g.* enzymatic hydrolysis of corn starch to make corn syrup in the same facility as part of the cookie-making process), we would consider the sugar generated from the hydrolysis step to be added sugars, since hydrolysis was purposely used by the manufacturer to increase the sugar content of the product.

l. Impact on nutrient databases.

(Comment 202) One comment said that we failed to provide a framework and/or an approved database that harmonizes implementation across industry. The comment also said that it is unclear how FDA-approved databases would be revised in order to be used to calculate added sugars or to distinguish between amounts of naturally occurring sugars and added sugars, such as how to calculate the varying sugar content of a food that contains naturally occurring and added sugars given the common fluctuations in foods containing naturally occurring sugars.

(Response) Under § 101.9(g)(8), we allow for compliance with § 101.9(g)(1) through (g)(6) by use of an FDA approved database that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current GMPs to prevent nutrition loss. Our Guidance for Industry: Nutrition Labeling Manual—A Guide for Developing and using Data Bases, the manual provides generic instructions for developing and preparing an acceptable database, as well as the recommended statistical methodology to develop nutrition label values. The guide is based on doing laboratory analyses of food samples. Because added sugars and naturally occurring sugars are not chemically distinct, it is not possible to do a laboratory analysis to determine the amount of added sugars in a product that contains both naturally occurring sugars and added sugars. If a product contains only added sugars, the procedures outlined in our guidance could be used by manufacturers to develop a database of values for added sugars. However, if both naturally occurring and added sugars are present, manufacturers will have to use other information that they have to determine a label value. They will also have to make and keep records to support the declared value, as discussed in part II.H.3.p.

With respect to calculating the varying sugar content of foods that contain naturally occurring and added sugars given seasonal variability and variability due to other growing conditions in products containing naturally occurring sugars, such as fruits and vegetables, manufacturers should know how much sugars they add to a product to account for the variability in the sugars naturally present in a food. They should be able to use the amount that they add to determine the value that they declare on the label. The variability in naturally occurring sugar content would not be a new variable for manufacturers to consider.

m. International labeling guidelines.

(Comment 203) Some comments noted that Codex Alimentarius Guidelines on Nutrition Labeling require the labeling of total, but not added sugars (Ref. 121). The comments said that our proposal to require the mandatory declaration of added sugars is not in line with international guidelines on nutrition labeling. The comments said that a revision of the Guidelines was undertaken by a working group within the Codex Committee on Food Labeling (CCFL) and discussed at the 38th Session of the CCFL (2010). The comments also said that, based on reports from that CCFL meeting, the Codex Committee considered the following evidentiary support for labeling only total sugars: (1) The body cannot differentiate between added sugars and total sugars in physiologic response; (2) the absence of any analytical differentiation between added and inherent sugars, which would create difficulties for enforcement; and (3) the importance of declaration of total sugars for certain populations including diabetics. The comment also said that the WHO advised that ''total sugars is the only practical way of labeling the sugars content of food since sugars cannot be distinguished analytically from intrinsic sugars.''

Other comments said that no other country has adopted mandatory added sugars declarations as part of nutrition labeling of foods and beverages. The comments noted that the purpose of the Codex Guidelines on Nutrition Labeling is to promote fair trade through international harmonization in the approach to nutrition labeling.

Other comments said that we need to be in compliance with the TBT Agreement, which insures that technical regulations ''do not create unnecessary obstacles to international trade.''

Some comments referred to previous positions that we have taken with respect to Codex and said that our proposal to require the mandatory declaration of added sugars is a total reversal from those previous positions.

(Response) The Codex standards are recommendations for voluntary application by countries. For nutrition labeling, the Codex Guidelines on Nutrition Labeling provide that where a nutrient declaration is applied, the declaration of total sugars should be mandatory. Although Codex does not state or imply that the declaration of added sugars should be mandatory, the guidelines provide for mandatory declaration when ''The amount of any other nutrient [is] considered to be relevant for maintaining a good nutritional status, as required by national legislation or national dietary guidelines.'' ((Ref. 121) at section 3.2.1.4). We have determined that the declaration of added sugars in necessary to assist consumers in maintaining healthy dietary practices, consistent with our authority in section 403(q) of the FD&C Act for when the labeling of a nutrient is required. The provision of such information is necessary to achieve our legitimate objective of protecting human health. We have established elsewhere in this section that the mandatory declaration of the amount of added sugars in a serving of a product is necessary to protect human health because scientific evidence supports that healthy dietary patterns

characterized, in part, by lower intakes of added sugars are associated with a decreased risk of CVD, sugar-sweetened beverage consumption is associated with adiposity in children, added sugars can lead to displacement of nutrient-dense foods in the diet, and intake data shows that Americans, on average, are exceeding the recommended limit for added sugars consumption. As such, our requirements to include the declaration of added sugars in nutrition labeling and for manufacturers to make and keep records of the amount of sugars they add to their products do not constitute an unnecessary obstacle to trade. Firms, whether domestic or foreign, must include an added sugars declaration on the label and must make and keep records, as appropriate, to verify the amount of added sugars in a product.

Manufacturers already know how much sugar is added to their product based on the formulation or should be able to reasonably estimate the amount of sugars added in products that undergo non-enzymatic browning and fermentation. We also do not consider that the records we are requiring would be unnecessarily burdensome for manufacturers to make and keep (see part II.C.1).

Our position on requiring the labeling of added sugars has developed in response to additional information that we did not have in the past. At the time that previous statements with respect to our official position on labeling of added sugars were made, the 2010 DGA and 2015 DGAC Report were not yet available. Based on information provided in the 2010 DGA and the 2015 DGAC Report, such as the underlying evidence used to support the 2015 DGAC conclusion that there is strong evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods or beverages are associated with a decreased risk of CVD and evidence that it is difficult to meet nutrient needs within calorie limits when individuals consume large amounts of added sugars, we had reason to revisit the requirement for a declaration of added sugars on the Nutrition and Supplement Facts labels in the proposed rule and in the supplemental proposed rule. We considered comments to the proposed rule and the supplemental proposed rule and have concluded that the evidence supports the mandatory declaration of added sugars on the label to fulfill the legitimate objective of protecting human health.

With respect to the comments that suggest no other country has adopted mandatory labeling of added sugars, we note that the comments do not address the relevance of these circumstances with respect to our objectives and the scientific evidence before us.

With respect to the comments on the evidentiary support considered by the CCFL on the reporting of added sugars, we have addressed these points in response to comments in this final rule. Furthermore, we require records, as appropriate, to verify the declaration of added sugars, and do not rely on analytical methods, as addressed by the WHO. In the six years since that decision, the evidence that has developed indicates that reporting of added sugars is of clear benefit in terms of public health.

n. Definition of added sugars. Added sugars are not currently defined by regulation. We proposed to define added sugars in § 101.9(c)(6)(iii) as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.* fruit juice concentrates), and other caloric sweeteners. We also clarified in preamble to the proposed rule (79 FR 11879 at 11906) that the definition would include single ingredient foods such as individually packaged table sugar, and that sugar alcohols are not considered to be added sugars. We provided the following examples of names for added sugars: Brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose. We note that this is not an exhaustive list of all added sugars.

Although some comments supported the proposed definition, other comments said that the proposed definition is ambiguous, confusing, and will lead to inconsistent application across the food industry. As discussed in the following responses to comments on the definition of added sugars, the final rule revises the definition of added sugars in § 101.9(c)(6)(iii) that is specific and provides clarity on issues raised in the comments. As such, the definition of added sugars can be applied by the food industry in a consistent manner.

(i) Fruit and Vegetable Juice Concentrates

(Comment 204) Many comments related to the inclusion of juices and juice concentrates in the definition of added sugars. Some comments suggested that the definition include sugars from fruit juice as well as fruit juice concentrate. However, many other comments disagreed with the inclusion of both fruit juices and fruit juice concentrates in the definition of added sugars. The comments said that 100 percent fruit juices, and 100 percent juice reconstituted from concentrate should not be considered to be added sugars. The comments suggested that fruit juice concentrates should be considered an added sugar only if they are not brought back to single strength by dilution with water in the product or by the end-user. One comment stated that 100 percent juice from concentrate and 100 percent juice not from concentrate are nutritionally identical, and there is no reason to require declaration of the added sugar content differently. One comment questioned why we are proposing to require different labeling for fruit juice depending upon whether it is a stand-alone product or an ingredient in another product. Another comment stated that a juice product formulated with juice that is reconstituted from a juice concentrate would appear as if it is making a greater calorie contribution because the juice concentrate would be deemed an ''added sugar'' when in fact, the calorie contribution of these two products is exactly the same. The comments argued that, if a juice product is sweetened with added sugars, the underlying juice before sweetening should not be considered an added sugar.

(Response) Single strength or 100 percent fruit juices (which, for purposes of this document, we will refer to collectively as 100 percent fruit juice) contribute calories from sugars as well as nutrients. The comments did not provide data or other information to demonstrate that exclusion of information on sugars from fruit juices would be scientifically unjustified, potentially disadvantageous for consumers, and inconsistent with growing expert opinion and international approach. We note that sugars from 100 percent fruit juices have never been considered to be added sugars in the DGA. In fact, the USDA Food Patterns include 100 percent fruit juices in the fruit group, and the DGA has recommended increased consumption of fruits for many years (Refs. 28, 30, 78–83). It was not our intent to include the sugars from 100 percent fruit and vegetable juices in the definition of added sugars in the proposed rule. Therefore, the final rule does not include 100 percent fruit or vegetable juices in the added sugars definition.

While fruit or vegetable juice concentrates can supply the same

nutrients as single strength or 100 percent fruit juice, they are a highly concentrated source of sugar. They may be used in small quantities for purposes other than to sweeten a food; however they are increasingly added to foods for sweetening purposes. They are identified in the ingredient list as concentrated fruit or vegetable juice. Some consumers could assume that the sugars that a concentrated fruit or vegetable juice contributes to a product are beneficial because they come from fruits or vegetables rather than from a more refined source. While foods sweetened with concentrated fruit or vegetable juices can be a part of a healthful diet, the sugars contributed by the concentrated fruit or vegetable juice provide additional calories to a product just as another source of refined sugar would provide additional calories. Over the course of the day, small amounts of calories in sugar-sweetened foods and beverages can add up and can make it difficult to balance the amount of calories consumed with the amount of calories expended. We consider foods sweetened with concentrated fruit or vegetable juices to be sugar-sweetened foods. The 2015 DGAC concluded that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a reduced risk of CVD. Therefore, it is important for consumers to be aware that when products are sweetened with concentrated fruit or vegetable juices; the extra sugars and calories that they contribute to products are like any other source of added sugars. When added to foods for the purpose of sweetening, we consider the sugars in a fruit juice concentrated which are used for sweetening purposes to be added sugars.

We recognize that juice concentrates may be added to food products in varying levels of concentration. For example, a product may use juice concentrate as an ingredient to achieve equivalent juice percentage as discussed in this section (*e.g.* a juice drink with 50 percent juice) or at 100 percent juice (*e.g.* 100 percent juice, from concentrate) based on our juice percentage declaration regulation in § 101.30 (also see our response to comment 205). An applesauce may have concentrated fruit juice added which has not been reconstituted at all. Because the nutrient profiles of fruit juice concentrates are the same as 100 percent fruit juices, we consider the amount of sugars above and beyond what would be contributed by the same volume of the same type of juice which is reconstituted to 100 percent juice to be added sugars. For example, if 15 grams of concentrated apple juice, which has 6 grams of sugars, is added to sweeten an applesauce and the same amount (15 grams) of 100 percent apple juice contains 1.7 gram of sugar, we would consider 4.3 grams of the sugars contributed to the applesauce (6 grams sugar in 15 grams apple juice concentrate 1.7 gram sugar in 15 grams 100 percent apple juice = 4.3 grams added sugars) by the apple juice concentrate to be added sugars. Another example to consider is an apple juice concentrate added to 100 percent pear juice for the purposes of sweetening. If 30 grams of apple juice concentrate, which contributes 10 grams of sugars is present in a serving of the finished product, the amount of added sugars which should be declared can be calculated by subtracting the amount of sugars present in 30 grams of 100 percent apple juice (3.4 grams) from the amount of sugars present in 30 grams of the fruit juice concentrate (10 grams of sugar in 30 grams apple juice concentrate 3.4 grams sugar in 30 grams 100 percent apple juice = 6.6 grams added sugars).

Fruit juice concentrates made from 100 percent juice that are sold directly to consumers (*e.g.* in grocery stores or on the Internet) are typically reconstituted with water by consumers before consumption. The packaging of these fruit juice concentrates typically provides information about the amount of water that consumers should use to reconstitute the juice. Concentrated juice products must bear a percentage juice declaration and that declaration may not be greater than 100 percent (Ref. 122). The label may explain that when the product is diluted according to label directions, the product yields a ''____ percent juice from concentrate,'' with the blank being filled in with the correct percentage based on the Brix values set out in 21 CFR 101.30(h)(1), as applicable (Ref. 122). We expect that consumers will reconstitute these types of fruit juice concentrates to 100 percent juice based on the instructions provided on the label for reconstituting frozen fruit juice. Therefore, we do not consider 100 percent juice concentrate sold directly to consumers as added sugar.

Accordingly, we have revised the definition of added sugars to exclude frozen fruit juice concentrates from 100 percent juice and to include only additional sugars contributed by fruit juice concentrates not reconstituted to full strength to be declared on the label. This approach is consistent with our position that only the amount of sugar which is above and beyond what would be expected in the same type of 100 percent juice is considered added sugar. However, concentrated juice cocktails, drinks, or beverages do not reconstitute to 100 percent juice and often contain sweeteners, such as sugar and syrup. For these types of products, all sugar except the sugar from the juice ingredients should be declared as added sugar on the label.

We note that we are also excluding fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in § 150.140 and § 150.160 as discussed in our response to comment 211.

As for juice concentrates, juice concentrates may be added for many different purposes and they may have multiple functions in a food. For example, an orange juice concentrate could be added to a muffin batter to give it orange flavor, to add vitamin C, and to provide sweetness. If one purpose of adding the juice concentrate to a product is to provide sweetness, manufacturers should declare the amount of sugar provided from the juice which is in excess of what would be provided from the same volume of the same type of 100 percent juice as added sugars on the label.

We are aware that there are syrup-like products made by concentrating fruit juice that has been processed specifically to remove organic acid, minerals, and insoluble fruit materials. These types of products are not fruit juice concentrates, but are fruit syrups. All of the sugar contents in these types of ingredients should be declared as added sugars on the label.

We proposed to require manufacturers to make and keep records to verify the amount of added sugars in a serving of a product when the product contains both naturally occurring and added sugars. If a juice concentrate is added to a food and is not brought back to 100 percent juice, we are unable to determine how much of the sugars provided by the juice is in excess of what would be expected for the same volume of the same type of 100 percent juice, therefore, manufacturers of such products must include a calculation of how they determined the amount of sugars from the juice concentrate that contribute to the added sugars declaration. Because juice concentrates contain naturally occurring sugars, all manufacturers of products containing juices that are not brought back to 100 percent strength in the finished food must make and keep records to verify how they arrived at their determination of the amount of added sugars which are contributed by the concentrated juice.

(Comment 205) Some comments noted that juice concentrates are commonly used to adjust the Brix levels of directly expressed juice, and these juice concentrates are not required to be reflected in the common or usual name of such juices under the regulation for beverages that contain fruit or vegetable juice (§ 102.33(g)(2)). The comments said that fruit juice concentrates are not added sugars if they qualify to be included in the percent juice declaration found on beverage labels. The comments asked us to clarify that added sugars do not include fruit or vegetable juice concentrates used to formulate 100 percent juice or 100 percent juice blends, or dilute juice beverages, and do not include juice concentrates that are added to juices and dilute juice beverages to adjust soluble solids content in accordance with § 102.33 (21 CFR 102.33) and the standards of identity in parts 146 and 156 (21 CFR parts 146 and 156).

(Response) We do allow for the use of juice concentrates in the formulation of 100 percent juice, 100 percent juice blends, and diluted juice beverages under § 101.30 (percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice), § 102.33 (beverages that contain fruit or vegetable juices), part 146 (requirements for specific standardized canned fruit juices and beverage), and part 156 (vegetable juices). For consistency with our current regulations, we agree that juice concentrates should be exempt from the definition of added sugars if they are: (1) Counted towards percentage juice declaration in accordance with § 101.30 for 100 percent juice and juice beverages (§ 102.33); and (2) used to standardize the Brix values of a single species juice consisting juice directly expressed from a fruit or vegetable in accordance with § 102.33(g)(2). Therefore, we have revised the definition of added sugars to make an exception for juice concentrates which contribute to the percentage juice label declaration under § 101.30 and for Brix value standardization under § 102.33(g)(2).

(Comment 206) One comment noted that, under the proposed definition for added sugars, a fruit juice concentrate that is 45 percent sugar, 50 percent water, and 5 percent other components would not be considered an added sugar because sugar would not be the primary component. The comment said that this is a potential loophole that manufacturers could exploit.

(Response) The comment is referencing the language in our proposed added sugars definition which would state that ''naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.,* fruit juice concentrates)'' are added sugars. We recognize that there could be fruit juice concentrates that do not have sugar as the primary component. Therefore, we have revised the definition of added sugars to remove the language regarding naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.,* fruit juice concentrates), and instead specifically listing the types of fruit juice concentrates that we consider to be added sugars.

(ii) Intended Purpose of Sweetening

(Comment 207) Many comments argued that sugars are an ingredient which may have multiple functions in a food. The comments recommended that we exclude certain ingredients which are not added for the intended purpose of sweetening a food. Most comments suggested defining added sugars based on the intended use of the sugar which has been added and not exclusively on the nature of the product. The comments would define added sugars as the sum of all mono- and disaccharides that are added to a food for purposes of sweetening the food.

Other comments said that, even when added as an ingredient in foods (as opposed to beverages), fruit juice concentrates are not always used for a sweetening purpose. One comment stated that apple juice concentrates can be added to produce a browning color as the food is heated and the sugars in the concentrate are caramelized. Many yogurt manufacturers, for example, use small amounts of fruit juice concentrates (such as carrot juice concentrate) in their yogurt products for purposes of coloring or flavoring. The comments suggested that fruit juice concentrates which are not used to sweeten a food not be counted as ''added sugars'' given that they: (1) Are not being used as a sweetener; (2) do not materially sweeten the product when used in the amounts necessary for their intended purpose of coloring or flavoring; and (3) only contain naturally occurring sugars derived from fruit.

(Response) We acknowledge that fruit juice concentrates, sugars, honey, or syrups may be added for many reasons to a food, and they may have many affects in a food other than adding sweetness. As previously discussed in this part, we have evidence that excess calorie consumption from added sugars is a public health concern. In determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report.

(Comment 208) One comment recommended that mono and disaccharides from any pure (*i.e.* with no added sugars) fruit ingredient, such as juices, concentrates, fruit pieces, pulps, and purees should not count as added sugars if these ingredients are not added for sweetening purposes.

(Response) We decline to revise the rule as suggested by the comment. We agree that whole fruit, fruit pieces, pulps, purees, 100 percent fruit juices, and certain fruit juice concentrates should not be considered added sugars because they are nutrient rich and maintain the basic properties of a fruit, which is not considered to be an added sugar. We have, in the final rule's definition of added sugars, excluded whole fruits, fruit pieces, pulps, purees, and certain concentrated fruit juices that are reconstituted to full strength or that may be added to other fruit juices, jellies, jams, and preserves under our standards of identity. However, we consider other mono and disaccharides from fruit ingredients to be added sugars. Sugars from fruits as well as fruit juices can be isolated (removed from the fruit), concentrated (decreased in volume by removing water), and stripped of nutrients such that they are essentially sugars that provide a concentrated source of calories to a food without other redeeming qualities (*e.g.* fruit syrups). Therefore, we are not excluding all mono and disaccharides from any pure fruit ingredient.

(Comment 209) Many comments opposed the inclusion of dried and concentrated dairy ingredients in the definition of added sugars. The comments explained that a number of dairy-based ingredients are isolated from milk and concentrated such that lactose, the naturally occurring sugar in milk, is the primary component. Examples of such ingredients include non-fat dry milk powder, dry whole milk, some forms of concentrated whey and dried whey, and milk and whey permeate. According to the comments, under the proposed definition of added sugars, the lactose in these dried and concentrated dairy ingredients would be considered an added sugar because it is the ''primary ingredient.''

The comments also explained that lactose is not added to foods for the purpose of sweetening, and is instead added for other functional properties. Lactose contributes viscosity and mouthfeel, serves as a fermentation

source in yogurt, increases shelf-life, provides foaming properties which are beneficial for cakes and frozen desserts, and serves as an emulsifier in sausages, soups, sauces, beverages, and salad dressing. Milk and whey protein concentrates, some of which contain lactose as the primary component, are typically used to increase the protein content of foods or as salt replacers to reduce the amount of sodium in a broad range of foods because of their unique salt enhancement characteristics.

The comments said that it would not be possible to make foods if lactose were used as the sole sweetener in the formulation, replacing the traditional sugar (*e.g.,* sucrose). Lactose has about one sixth of the sweetness of sucrose. The amount of lactose required to achieve the same level of sweetness would compromise basic attributes of the product itself. For example, if lactose were added to a typical ice cream, the amount of lactose that would have to be added to sweeten the product would either depress the freezing point of the ice cream mix such that the product would not be able to freeze under normal conditions, or if it did freeze, would result in an extremely gritty texture defect which would make the product unacceptable to consumers.

One comment said that the common and usual names for dairy ingredients would cause confusion with added sugars declarations. For example, according to the comment, we allow manufacturers to identify skim milk, concentrated skim milk, and nonfat dry milk as ''skim milk'' or ''nonfat milk'' in an ingredients listing. In addition, two nonfat yogurt products could be formulated to the same final product composition, and the ingredient statements for both could read ''nonfat milk and culture.'' However, under the proposed definition of added sugars, a yogurt made using fluid skim milk as the sole dairy ingredient would have no added sugars, while a yogurt made using nonfat dry milk powder as the sole source of dairy solids would have to declare added sugars on the Nutrition Facts label.

One comment said that, when dry milk ingredients are added, consumers may be confused about the source of added sugar in the food if the food contains no obvious sweetener. For example, if a food with a dairy-based ingredient, such as nonfat dry milk or whey protein concentrate, would be required to declare the inherent lactose as added sugars on the Nutrition Facts label and the food contained no easily identifiable source of added sugars, consumers reading the ingredient list likely would not expect or recognize dairy ingredients as sources of ''added sugars.''

The comments noted that dairy ingredients containing lactose may be added so that a dairy product meets the standards for identity. One comment stated that California's standard for fluid milk mandates higher milk solids than the Federal standard of identity, requiring the addition of nonfat dried milk or condensed skim milk containing lactose. The comment said that the lactose in these milk solids should not be considered an added sugar because it is not added for sweetening purposes. The comments also noted that for standardized dairy products such as milk and yogurt, current regulations do not require that a sweetener be added. The comments said that the exclusion of dairy-based ingredients as sweeteners in the standards is acknowledgement by FDA that the lactose in these dairy-derived ingredients is not primarily added to provide sweetness.

(Response) Lactose is a major component of milk solids. Many common concentrated or dried dairy ingredients, such as nonfat dry milk and whey powder contain lactose as the primary component. We agree that many dairy ingredients, even though high in lactose, are not considered a source of added sugars. Dairy ingredients and nutritive carbohydrate sweeteners are often considered to be in two separate ingredient categories during food formulation. The proposed definition of added sugars captured such dairy ingredients because it included naturally occurring sugars that are isolated from a whole food and concentrated so that sugar (in this case lactose) is the primary component. We did not intend to capture dairy ingredients under this portion of the definition. Therefore, we have removed the language from the definition of added sugars stating that naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component are added sugars.

FDA regulations, at § 168.122, establish a standard of identity for lactose. The standard of identity for lactose states that it must contain not less than 98 percent lactose, mass over mass (m/m), calculated on a dry basis. We have historically considered purified lactose as a sweetener as it is included in 21 CFR part 168 under sweeteners and table syrups. We consider lactose as defined in § 168.122 to be an added sugar. Lactose, as defined under § 168.122 would be captured under the definition of added sugars because it is a free disaccharide. Therefore, with the revised definition, dairy ingredients, except lactose as defined in § 168.122, are not included in the definition of added sugars.

(iii) The ''No Added Sugars'' Nutrient Content Claim

(Comment 210) Many comments argued that the proposed definition is inconsistent with the regulation for the ''no added sugars'' nutrient content claim in § 101.60(c)(2) because the regulation recognizes that ingredients that contain sugars do not preclude the use of the claim unless the ingredients ''functionally substitute for added sugars.'' The comments noted that, if the definition of added sugars is not consistent with the ''no added sugars'' nutrient content claim regulation, products could conceivably bear ''no added sugars'' claims but have a gram amount of added sugars declared on the Nutrition Facts label, which would be confusing and misleading. One comment provided the example of a juice that is reconstituted from juice concentrate which meets the Brix standard for single-strength juices. The comment said that such a product can factually claim that it is ''unsweetened'', but the manufacturer would have to disclose the amount of added sugars under the proposed rule.

Other comments noted that in the 1993 preamble to our rule defining the ''no added sugars'' nutrient content claim, we clarified that sugars inherent in a product, such as those found in fruit juices, would not disallow a no added sugars claim. One comment further noted that we advised that ''the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a ''no added sugar'' claim; however the other conditions for the claim must still be met'' (see 58 FR 2328). The comment said that this statement makes it clear that the presence of a fruit juice concentrate in a food does not prevent the use of a no added sugar claim. Another comment suggested that, in addition to fruit juice concentrates that are reconstituted to single strength in 100 percent juices, juice blends, juice drinks, and juice drink blends also should be excluded from the definition of added sugars because doing so would align with the current definition of no added sugars.

(Response) The comments expressed concern that fruit juice concentrates added to a single strength juice or dairy ingredients that are not added for the intended purpose of sweetening can currently bear the ''no added sugars'' claim, but sugars from the concentrated fruit juice or dairy ingredient would have to be declared as added sugars

under the proposed definition. We have revised the rule to exclude certain fruit juice concentrates that are added to juices and that dilute juice beverages to adjust soluble solids content in accordance with § 102.33 and the standards of identity in parts 146 and 156. We are also excluding fruit juice concentrates that are reconstituted to 100 percent single strength juice. In addition, we have removed the language from the definition of added sugars which states that naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component are added sugars. Therefore, dairy ingredients containing lactose, except lactose as defined in § 168.122, are no longer captured under the definition of added sugars. With these revisions to the definition of added sugars, there is no longer a conflict between the definition of added sugars and the requirements for use of the ''no added sugars'' nutrient content claim.

We decline to define added sugars based on the intended purpose of the ingredient as suggested by the comments because we are providing specifics of what we consider to be added sugars in the definition. In addition, in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report.

(iv) Fruit Jellies, Jams, and Preserves

(Comment 211) Several comments suggested that fruit jellies, jams, and preserves not be considered as added sugars. The comments noted that fruit jellies, jams, and preserves are subject to standards of identity set forth in § 150.140 and § 150.160 and are manufactured using certain fruit and fruit juice ingredients in combination with added sugars. One comment suggested that it is appropriate for such ingredients, regardless of whether they are derived from cane sugar, fruit juice syrup, fruit juice concentrates, etc., to count towards an added sugars declaration when used as sweeteners. The comment said that characterizing fruit and fruit juices in jellies, jams, and preserves (before the addition of sweeteners) should be excluded from the definition of added sugar because they do not serve as sugar substitutes, and are not ''added'' to a food for purposes of sweetening a food.

(Response) The definition of added sugars excludes fruits and 100 percent fruit juices. However, sugars from certain fruit juice concentrates fall within what we consider to be added sugars. Because fruit juice concentrates may be used as ingredients in fruit jellies, jams, and preserves, we have excluded those fruit juice concentrates that are used in accordance with the standards of identity in § 150.140 and § 150.160 from the definition of added sugars. However, any additional sugars that are added to the jelly, jam, or preserve would need to be declared as added sugars on the label.

(v) Dried Fruits

(Comment 212) Some comments said that dried fruit added to a product should not be considered to be an added sugar.

(Response) We agree that dried fruits which have not had any sugar added to them should not be considered to be an added sugar because they are essentially a dehydrated whole fruit and still retain the nutrients and other components of a whole fruit. However, if additional sugar is added to a dried fruit, the sugar added to the dried fruit must be declared on the label as added sugars.

(vi) Other Sugars/Sweeteners

(Comment 213) One comment would exempt isomaltulose and D-tagatose from labeling as added sugars due to their effect on reducing the risk of dental caries. The comment said that the proposed declaration for added sugars would not allow for adequate information to be provided to the consumer about carbohydrates such as isomaltulose (a disaccharide) and D-tagatose (a monosaccharide) that are ''sugars'' from a regulatory standpoint, but at the same time have very different and beneficial physiological properties than traditional ''sugars.'' The comment noted that isomaltulose and D-tagatose are noncariogenic carbohydrate sweeteners, and products containing these sweeteners can bear the dietary noncariogenic carbohydrate sweeteners and dental caries health claim if they meet the requirements of § 101.80. The comment also stated that these dental health benefits of isomaltulose and D-tagatose can also be the subject of a health claim under EU regulation 432/2012. The comment said that, aside from the dental health benefits, isomaltulose and D-tagatose are low-glycemic carbohydrate(s) resulting in a reduced blood glucose response and that this health effect is the subject of EU health claim 432/2012. The comment argued that such a health benefit provides the basis for a structure-function claim under the FD&C Act.

(Response) We have recognized through our health claim for noncariogenic carbohydrate sweeteners and dental caries that the sugars D-tagatose and isomaltulose may reduce the risk of dental caries (tooth decay). However, D-tagatose and isomaltulose are chemically sugars. Because these sweeteners are chemically sugars, and other substances are included or excluded from the definition of sugars and added sugars based on whether they are a free mono or disaccharide rather than on their physiological effects, including D-tagatose and isomaltulose is consistent with how we have characterized other sugars. As such, we are not excluding D-tagatose and isomaltulose from the added sugars declaration. However, manufacturers may still use the noncariogenic carbohydrate sweeteners and dental caries health claims on their products to make consumers aware that sugars contained in a food may reduce the risk of dental caries.

(Comment 214) Some comments would exclude Allulose (psicose) from the definition of added sugars because ketohexose sugars, such as Allulose, do not provide calories, are not metabolized, and do not raise blood sugar levels.

(Response) As discussed in our response to comment 124, we received a petition on this subject after the comment period closed. We intend to address this issue at a later date when we have had time to consider the information presented in the petition.

(Comment 215) Some comments stated that the proposed language, which states that ''other caloric sweeteners'' are considered added sugars, is confusing and unclear. One comment provided the example of applesauce, which can be used to replace oil in baking. In this example, unsweetened applesauce contains no added sugars, but can be used to both replace an oil and sweeten baked goods.

(Response) We agree that the language that states that ''other caloric'' sweeteners are considered to be added sugars may not be clear to manufacturers or consumers. We have removed this language from the definition of added sugars because caloric sweeteners, which are chemically sugars, are free mono or disaccharides and are captured elsewhere in the definition.

(vii) Other Comments

(Comment 216) Some comments noted that ingredients such as fruit juice concentrates, high fructose corn syrup, honey, and molasses contain significant amounts of water (*e.g.,* 30 percent). The

ingredients may contain a range of naturally occurring constituents besides sugars (*e.g.,* polysaccharides, anthocyanins, vitamins, minerals, etc.). Therefore, to avoid overstating the amounts of added sugars, the comments said that it is important to take into account the actual ''sugars'' content of the ingredients. The comments suggested adding language to clarify that the quantity of added sugars declared in labeling will include only the actual ''sugars'' portion of the ingredient.

(Response) We agree that some ingredients containing sugars, such as syrups, contain water and other components that are not sugars, and that those components should not be considered as part of the added sugars declaration. Therefore, when such ingredients are included in foods, only the sugar portion of the ingredient should be declared on the label. The definition of added sugars states that free mono and disaccharides are considered added sugars, thus water and other components of sugar-containing ingredients are not added sugars and should not be declared as such. We have also revised the definition to say ''sugars from syrups'' to clarify that only the sugars component of the product should be declared as added sugars.

(Comment 217) Several comments would not consider natural sources of sugar (*e.g.,* honey or maple syrup) to be added sugars. One comment would exempt natural, unrefined honey and other natural liquid or semi-liquid, unrefined, un-concentrated, whole-food sweetening agents because they are whole food products in an unrefined, un-concentrated, whole-food form. Conversely, the comment suggested that other sweeteners which are extracted, refined, and concentrated such as agave syrup, maple syrup, and evaporated cane juice syrup should be considered added sugars.

(Response) We disagree that all natural sources of sugar which have not been processed or refined should not be considered added sugars. In determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report. The processing history (*e.g.,* concentration or refinement) does not entirely determine whether or not sugar in an ingredient is added sugar. For example, natural sources of sugar present in foods, such as whole fruits, 100 percent juice, and dried fruits, are not considered added sugars because these foods are nutrient rich. However, products such as maple syrups or honey are included in the ''empty calories'' or ''calories for other uses'' category in the USDA Food Patterns. Therefore, we decline to exclude sugars from honey and maple syrup from the added sugars definition.

(Comment 218) One comment stated that consistency is needed in the definition of added sugars across Federal Agencies as well as by scientists, health professionals, manufacturers, and others. The comment identified fruit juice concentrate as one example of inconsistency among Federal Agencies. The comment cited a paper on the development of USDA estimates of added sugars (Ref. 123).

(Response) When establishing a regulatory definition for the purposes of nutrition labeling, we consider other regulatory aspects such as the impact on other regulations. We expect that establishing a regulatory definition of added sugars for the purpose of nutrition labeling will help other Federal Agencies and the scientific community in determining a definition for added sugars for Federal guidelines, programs, and research.

(Comment 219) One comment would not consider incidental additives or flavors containing sugars, such as dextrose, which are not added for sweetness as added sugars.

(Response) The comment did not explain what ''incidental additives'' are. However, we disagree that dextrose should be excluded from the definition of added sugars. Dextrose is a sugar, and, when added to a food, it acts in the same manner as other types of added sugars.

(Comment 220) Some comments said it will be difficult for manufacturers to obtain information about added sugars content of sourced ingredients that they get from suppliers. The comments questioned whether ingredients used in the formulation that are not an isolated sugar but are part of a compound ingredient must be labeled. One comment noted that, aside from the ingredients used in traditional food processing, there are ingredients that are used in ''better for you'' formulated foods that would be required to be listed on the label.

(Response) The added sugars declaration in the finished product includes added sugars present as sub-ingredients. For example, if a cookie product uses strawberry jams as an ingredient, the added sugar present in the strawberry jam would count towards the added sugars declaration for the finished cookie product. Manufacturers need to collect nutrient information for ingredients in their products from suppliers. Manufacturers have the ability to select which suppliers they use. If a supplier is not willing or able to provide information about the added sugars content of an ingredient, the manufacturer may wish to consider another supplier.

With respect to the comment suggesting that manufacturers may have difficulty obtaining information about the added sugars content of ''better for you'' formulated foods, manufacturers need to obtain information about the added sugars content of all ingredients in order to provide accurate labeling, regardless of whether they are used to formulate ''better for you foods.''

(Comment 221) One comment would expand the added sugars definition to encompass all added sweeteners.

(Response) It is not clear from the comment which sweeteners that the comment is suggesting are not included in an added sugars declaration. Therefore, we are not revising the added sugars definition in response to the comment.

o. Establishing a DRV and mandatory declaration of the percent DV for added sugars.

(i) Mandatory Declaration of a Percent DV and Whether a DRV Should Be Established

(Comment 222) Many comments both to the proposed rule and the supplemental proposed rule discussed establishing a DRV that can be used to calculate a percent DV for added sugars as well as a mandatory declaration of a percent DV for added sugars on the label. Most comments favored establishing a DRV and requiring the percent DV declaration of added sugars. Many comments to the proposed rule recommended establishing a DRV for added sugars of 10 percent of calories, and provided several rationales to justify the suggested DRV. The comments said that, since the 1977 Dietary Goals, health officials have consistently recommended an upper limit of 10 percent of calories from added sugars. The comments referred to the WHO recommended limit of 50 grams or 10 percent of total calories from added sugars and the American Heart Association recommendation to limit added sugars consumption to 25 grams per day for women and 37.5 grams per day for men. The comments also noted that the 1992 USDA Food Guide Pyramid suggested an upper limit of 6, 12, and 19 teaspoons of sugars, respectively, for diets of 1,600, 2,200, and 2,800 calories, respectively. This comes to 7, 10, and 13 percent of calorie

intake, respectively, for an average of 10 percent of total calories from added sugars. One comment said that the 2010 DGA stated that no more than 5 to 15 percent of calories should come from a combination of solid fats and added sugars. The comment stated that this implies that added sugars should be less than 10 percent of calories. Another comment quoted a pediatric endocrinologist who says that a ''dose'' of added sugars of up to 50 grams a day poses little risk for metabolic or chronic disease, but that the amount consumed by Americans is toxic.

One comment to the proposed rule suggested that the discretionary calorie allowance from the USDA Food Patterns presented in the 2005 DGA could serve as a basis for a DRV. The comment suggested that, using the food patterns provided in the 2005 DGA at the 2,000 calorie level, one would have a limit of 267 discretionary calories to use on solid fats and added sugars (assuming no alcohol consumption). The discretionary calorie allowance could be divided equally between solid fats and added sugars resulting in a limit of no more than 133 calories, 33 grams, or 8 teaspoons of added sugars per day. This would result in a DRV for added sugars of 6 percent of total calories.

Other comments in favor of a percent DV declaration suggested that a percent DV declaration is necessary for consumers to be able to put the amount of added sugars in a serving of a food into the context of their total daily diet. The comments said that, without a DV, consumers could only compare the relative amounts of added sugars among products, but would not know how much of a day's worth of added sugars a food contains. The comments said that the percent DV advises the consumer of how much of a recommended intake of that nutrient is provided by a particular food. The comments also suggested that a percent DV declaration could help parents and other caregivers make informed decisions about the food products children consume and be more confident that their intake of added sugars does not exceed healthy daily limits. One comment provided survey data showing that consumers would like to have a DV for added sugars on the label.

Many comments supporting a mandatory declaration of a percent DV of added sugars also suggested that the information is necessary because added sugars consumption is associated with the risk of chronic diseases and health-related conditions such as diabetes, CVD, and metabolic syndrome.

One comment noted that the 2014 IOM workshop summary on Health Literacy and Health Numeracy documents that most Americans have limited numeracy skills, and disparities exist in those skills. The comment further stated that providing simpler, clearer food labeling information is needed to reach a larger segment of the population, and suggested that providing a percent DV declaration may be an easier way for consumers with limited numeracy skills to understand an added sugars declaration.

In contrast, many comments opposed establishing a DRV for added sugars and the mandatory declaration of a percent DV for added sugars. The comments said there is no scientific basis upon which to base a DRV for added sugars. Other comments said that we should not establish a DRV for added sugars or require the percent DV declaration for added sugars because the declaration of any information related to added sugars is not scientifically supported. The comments' rationale relates to our basis for requiring an added sugars declaration, and we address those topics are provided elsewhere in this part.

The comments also opposed the mandatory declaration of a percent DV for added sugars because sugars are converted to other products during processing (caramelization, Maillard browning, and fermentation), and thus the amount declared on the label may be inaccurate for some products. (We respond to comments pertaining to non-enzymatic browning and fermentation in part II.H.3.k and have determined that it is possible for manufacturers of products which undergo these chemical reactions to provide a reasonable approximation of the amount of added sugars in a serving of their product.)

Many comments also said that added sugar is not a necessary nutrient and should be avoided or should not be consumed in any amount. The comments said that it is inappropriate for us to recommend the consumption of any amount of added sugars in the diet. One comment suggested that added sugars should be viewed similarly to *trans* fats because they are not essential in the diet and are detrimental to health. The comment said that we should not set a recommended level of added sugars because, like *trans* fats, Americans should be consuming as little added sugars as possible in their diet.

One comment said that a percent DV declaration for added sugars just confuses the public, many of whom have diabetes, and should be focused on their intake on total carbohydrates rather than sugars or added sugars. Another comment said that, because there are no studies which support the proposed value, if the value is determined to be incorrect at a future date, it will remain in the public's mind long after it has been proven to be incorrect.

(Response) Consumers need to know how much added sugars are in a serving of a product in order to maintain healthy dietary practices. As discussed in part II.H.3, our rationale for the declaration of added sugars for the general U.S. population is focused on assisting consumers in maintaining healthy dietary practices by providing the information that consumers need to construct a healthful dietary pattern that meets nutrient needs within calorie limits and is associated with a decreased risk of chronic disease. While the gram declaration for added sugars gives consumers the information that they need to construct a healthy dietary pattern that is low in added sugars, it does not provide the information that they need in order to put the amount of added sugars in a serving of a product in the context of their total daily diet. The gram amount of added sugars also does not give consumers the information that they need to determine if a food is relatively high or relatively low in added sugars or a frame of reference that they can use to determine how to include a food in their overall diet. The percent DV declaration provides that missing piece of information that will allow consumers to more easily compare products and determine the relative contribution that a serving of a food will provide towards their diet.

After publication of the proposed rule, the 2015 DGAC recommended that Americans limit their consumption of added sugars to a maximum of 10 percent of total calories (Ref. 19). The 2015 DGAC based this recommendation on modeling of dietary patterns, current added sugars consumption data, and a published meta-analysis on sugars intake and body weight. We considered the evidence that the 2015 DGAC relied on in making this recommendation, and tentatively concluded in the supplemental proposed rule that limiting consumption of added sugars to 10 percent of daily calories is a reasonable goal for consumers to achieve and would assist consumers in choosing and maintaining a healthful dietary pattern. We proposed to require the mandatory declaration of a percent DV for added sugars, and we proposed a DRV of 50 grams for added sugars for children and adults 4 years of age and older from which the percent DV can be calculated. The DRV of 50 grams is determined by first multiplying the 2,000 reference calorie intake by 10

percent (2,000 × 0.1 = 200 calories) and then by dividing the resulting 200 calories by 4 calories per gram for carbohydrates (200 ÷ 4 = 50 grams). We proposed a DRV of 25 grams of added sugars for children 1 through 3 years of age. A 1,000 calorie reference amount would be used to calculate the DRV for children under the age of 4 (1,000 calories × 0.1 = 100 calories and 100 calories ÷ 4 calories per gram for carbohydrates = 25 grams).

Before proposing a DRV for added sugars, we considered the approaches suggested in comments to the proposed rule for establishing a DRV of 10 percent of total calories for added sugars, but declined to accept the comments' various approaches for supporting a DRV of 10 percent of calories from added sugars because the approach provided a recommended limit for added sugars, which was not based on total added sugars information (*e.g.* the WHO recommendations which are based on ''free sugars'' and include fruit juices), because it is not clear how the recommended limits were derived and whether they were based on any scientific data or evidence (*i.e.,* AHA recommendation and recommendation from an endocrinologist), or because the 2015 DGAC provided updated USDA Food Patterns that are specific to added sugars, unlike previous editions of the USDA Food Patterns included in the 1992, 2005, and 2010 DGAs.

With respect to the comments suggesting that we do not have a scientific basis to establish a DRV for added sugars, we have a recommended limit for added sugars of no more than 10 percent of total calories that was developed using food pattern modeling. We address these issues later in this part.

We want to clarify that the DRV for added sugars should not be viewed as a recommended amount for consumption. The percent DV declaration for nutrients, which is calculated based on the DRV or RDI, represents a reference value that serves as a general guide to consumers. It would be inappropriate to view all DRVs and RDIs as recommended amounts to consume because some are based on amounts to limit (*e.g.,* sodium and saturated fat) while others are based on amounts that individuals should strive to consume (*e.g.,* calcium and potassium). Furthermore, individuals have varying nutrient and calorie needs, so consumers may need more or less of a particular nutrient based on their specific nutrient needs. As such, consumers with higher calorie needs can consume more added sugars in their diet relative to individuals with lower calorie needs.

While consumers are interested in seeing a DV for added sugars on the label, as discussed in part II.C.1, consumer interest alone cannot be used to justify a label declaration. There is a need for a percent DV declaration for added sugars so that consumers can put the amount of added sugars in a serving of a product into the context of their total daily diet so that they can meet nutrient needs within calorie limits and construct a healthy dietary pattern that is associated with a reduced risk of CVD.

We disagree with the comment suggesting that we should take the same approach that we have taken with *trans* fat and not establish a DRV for added sugars because Americans should be consuming as little added sugars in their diets as possible. The current evidence on added sugars does not show a linear relationship with chronic disease risk, and therefore, the evidence does not support limiting added sugars to as little in the diet as possible, similar to current recommendations for *trans* fat. In fact, individuals can carefully incorporate limited amounts of added sugars into a healthy diet. The USDA Food Patterns suggest that individuals who need between 1,000 and 3,200 calories per day can reasonably consume between 4 to 9 percent of their calories from added sugars and still meet their nutrient needs within calorie limits.

As for the assertion that a percent DV declaration for added sugars will confuse the public, the comments did not provide evidence to support the assertion. Some comments submitted consumer research that included a percent DV declaration for added sugars in the labels, and the participants were shown the percent DV declaration. However, the research did not isolate the effect of the percent DV declaration from that of the gram amount declaration, so it is not possible to determine if the effects seen in those studies were due to confusion about a percent DV declaration for added sugars or more generally about information on the label related to added sugars. Other consumer research showed that participants reported similar responses about percent DV declarations for saturated fat and for added sugars, which suggests that a percent DV declaration for added sugars may not have specifically caused the confusion shown in the research. In both cases, it is unclear what conclusions related to confusion about a percent DV declaration for added sugars can be drawn from the evidence provided in comments.

With respect to the suggestion that, if the DRV for added sugars is determined to be incorrect later, the DRV will remain in the public's mind long after it has been proven to be incorrect, a change in the science related to added sugars in the future should not prevent us from establishing a DRV at this time that is based on currently available evidence. Science evolves over time, and it is possible that we could have additional evidence in the future that would lead us to re-evaluate the DRV for added sugars. In fact, we are updating DRVs and RDIs for a number of different nutrients on the label based data and information that has become available since 1993.

(Comment 223) Some comments to the proposed rule recommended that we commission the IOM to review the evidence and recommend a figure that could be used as the basis for a DV. The comments suggested that a quantitative limit will help consumers reduce added sugars by giving them a specific target or goal to work towards.

(Response) We have evidence that added sugars are a public health concern, and a percent DV declaration that is calculated based on a DRV for added sugars will assist consumers in putting the amount of added sugars in a serving of a product into the context of the total daily diet. We also have scientific evidence to support limiting calories from added sugars to less than 10 percent of calories that can be used to establish a DRV. We are acting on the evidence that we currently have available to us because a percent DV declaration for added sugars is important to assist consumers in maintaining healthy dietary practices.

(Comment 224) Some comments opposed establishing a DRV and requiring the mandatory declaration of a percent DV for added sugars when we have not established a DRV for total sugars. The comments said that establishing a DRV and requiring the percent DV declaration for added sugars without a DRV or percent DV declaration for total sugars will cause confusion. One comment questioned our conclusion that there is adequate evidence to establish a DRV for added sugars but not total sugars, especially when much data used to support the declaration of added sugars was based on research looking at total sugars. Another comment said that a percent DV declaration for total sugars is more important than one for added sugars because a percent DV for added sugars does not represent the true caloric or metabolic contributions of sugars to a food product.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11902), we do not have a reference value upon which we can derive an appropriate DRV for total sugars. The IOM has not set a UL for sugars. We also do not have scientific evidence to support a reference value for total sugars from another U.S. consensus report. However, we have considered the scientific evidence that supports the 2015 DGAC recommendation (which we note is also included in the 2015–2020 DGA) to limit calories from added sugars to no more than 10 percent of calories. Although this reference level is different than other scientifically supported quantitative intake recommendations that have been used to establish DRVs and RDIs for other nutrients, it was derived from food pattern modeling of a healthy dietary pattern that is low in added sugars. We are focusing on what healthy dietary patterns look like and what information is needed for consumers to construct a healthy dietary pattern. The USDA Food Patterns that support limiting consumption of calories from added sugars to less than 10 percent of calories per day, are examples of the type of healthy dietary pattern that consumers could use to reduce their risk of disease. Therefore, although a limit of calories to no more than 10 percent of calories provides a reference value that is different than other scientifically supported quantitative intake recommendations, it was derived using a dietary pattern approach, which is consistent with our basis for requiring the declaration of added sugars on the label.

In response to the comments suggesting that consumers will be confused if there is a percent DV declaration for added but not total sugars, the comments did not provide data or other information to support this assertion. A declaration of the gram amount of sugars has been on the label for over 20 years without a declaration of a percent DV for sugars, so consumers are familiar with the information that will be on the label for total sugars.

With respect to the comment stating that it is more important to require a percent DV declaration for total rather than added sugars because a percent DV for added sugars would not represent the true caloric or metabolic contributions of sugars to a food product, we have concluded that consumption of too many added sugars has health implications. Consumers need specific information on how much added sugars is in a serving of a product and the contribution that a serving of a product makes towards the total daily diet.

To the extent that comments are suggesting that we should be able to establish a DRV for total sugars because much evidence which is being used to support an added sugars declaration is on total sugars, we disagree. Total sugars includes both naturally occurring and added sugars. Although a small number of the studies that we are relying on to support an added sugars declaration included fruit juices, which contain naturally occurring sugars, the vast majority of the evidence was on only added sugars, or on foods and beverages to which sugars have been added. Furthermore, we are basing the DRV on food pattern modeling and not on the Chapter 2 analysis related to dietary patterns and health outcomes.

Although we do not currently have a reference value that can be used to establish a DRV for total sugars, information could become available in the future that may cause us to reconsider.

(Comment 225) One comment said that we should not require a percent DV declaration for added sugars because other countries have evaluated added sugars and have concluded that the declaration of added sugars should not be mandatory as there is little evidence to support such identification.

(Response) We address similar comments related to the declaration of the gram amount of added sugars on the label in part II.H.3.

(Comment 226) Some comments suggested that additional research needs to be conducted to determine how much added sugars is harmful before establishing a DRV for added sugars or requiring a percent DV declaration on the label.

(Response) We disagree that additional research on added sugars should be conducted before we establish a DRV for added sugars or to require a percent DV declaration on the label. Although a linear relationship has not been established between added sugars intake and risk of disease upon which a UL can be based, we do have evidence showing that consumption of too much added sugars is harmful to health. We also have scientific evidence that supports limiting added sugars consumption to less than 10 percent of calories that includes modeling of healthy dietary patterns.

(Comment 227) One comment, as part of its argument that the declaration of added sugars information is not material and provides no added importance to consumer product purchase or use decisions, stated that, based on its own research of our eye-tracking study data, participants spent statistically significantly less time on added sugars than on carbohydrate on the Proposed label and spent statistically the same amount of time on carbohydrate and added sugars on the Proposed label as that on carbohydrate on the Current label. The comment also asked how we made the distinction between participants' attention on carbohydrate and on added sugars on the proposed label. Another comment questioned whether adding percent DV for added sugars will increase consumer attention to the added sugars declaration, including the percent DV for added sugars. The comment stated that, although percent DV for added sugars was not specifically tested in our eye-tracking study, the study showed that: (1) There were no statistically significant differences between the current and the proposed formats in the proportion of participants who noticed percent DV information or the share of time they spent on the information; and (2) the added sugars declaration received relatively little attention (on the proposed label). The comment concluded that these results suggest that the percent DV information receives low priority from consumers or the information is not prominent or easy to understand and it is not clear if including the percent DV for added sugars will enhance consumer attention to the added sugars declaration.

(Response) We disagree that our eye-tracking study findings on the percent DV information and on added sugars declaration mean that adding percent DV for added sugars will not increase consumer attention to the added sugars declaration. Our study did not include a percent DV for added sugars on any labels tested, did not compare participants' responses to a label with a percent DV declaration for added sugars and responses to a label without such a declaration, and did not examine participants' attention to this percent DV information. Therefore, the cited findings cannot be used to infer the amount of attention the percent DV for added sugars would receive by consumers if and when it is present on labels. We also disagree that one can infer from our eye-tracking study findings that an added sugars declaration, including the percent DV, is of no value to consumers. Our decision to require the declaration is not determined by how much attention it receives from the study participants. Instead, we are requiring the declaration of added sugars on the label because consumers need the information in order to maintain healthy dietary

practices. We clarify that, in our eye-tracking study, the label element ''carbohydrate'' on the Proposed label included these areas of the label: Total carbohydrate, dietary fiber, sugars and protein. ''Added sugars'' was considered in the study as a separate area on the label.

(ii) DRV of 10 Percent of Total Calories From Added Sugars

In the supplemental proposed rule, we proposed to establish a DRV for added sugars of 10 percent of total calories (50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age). The scientific evidence from the 2015 DGAC Report supports Americans keep added sugars intake below 10 percent of total energy intake, based on modeling of dietary patterns, current consumption data, and a published meta-analysis on sugars intake and body weight (80 FR 44303 at 44308). We concluded that the scientific information from the 2015 DGAC Report provides a basis for FDA to establish a DRV for added sugars. The 2015 DGAC relied on both food pattern modeling information from the USDA Food Patterns as well as information from the Te Morenga et al. paper for their recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake.

(Comment 228) One comment cited work sponsored by ILSI North America that suggests a lack of strong evidence for a dietary recommendation to limit added sugars to no more than 10 percent of calories. The comment cited reviews by ILSI North America related to dental caries and BMI which led it to conclude that frequency of consumption of fermentable carbohydrates is a driver of dental caries along with oral hygiene, exposure to fluoride, and salivary flow and composition and that sustained overconsumption of energy, irrespective of the energy sources, leads to weight gain. The comment concluded from the evidence reviewed that the scientific evidence is lacking with respect to quantifying a level of sugar or added sugar relative to health outcomes.

(Response) The comment provided a review of the evidence related to a specific relationship between intake of added sugars and risk of disease. As discussed in our response to comment 224, we are establishing a DRV for added sugars using a different type of intake recommendation than what has been used for other nutrients with a linear relationship with disease risk, which was developed primarily by food pattern modeling. Our rationale for requiring the mandatory declaration of added sugars relates to consuming a healthy dietary pattern that meets nutrient needs within calorie limits and is associated with a decreased risk of chronic disease. The food pattern modeling that was done for the USDA Food Patterns provides a conceptual framework for selecting the kinds and amounts of foods of various types, which together, provide a nutritionally satisfactory diet. Therefore, the scientific evidence that supports limiting calories from added sugars to less than 10 percent of calories per day that was derived from food pattern modeling is related to our basis for requiring the mandatory declaration of added sugars for the general population, which is focused on consumption of a healthy dietary pattern.

(Comment 229) Several comments recommended that the IOM re-evaluate the added sugars intake recommendations. The comments said that the IOM is the appropriate body to establish a DRI upon which to base a DRV for added sugars because:

- The scope of work for the IOM DRI committees is specifically to develop the DRIs, which are intended to inform nutrition labeling;
- The DRI process provides a rigorous and methodological process to determine nutrient values used in nutrition labeling and includes guidance on when a percent DV may be established;
- The IOM DRI considers the risks of adverse effects associated with low as well as high nutrient intakes;
- The IOM adheres to a structured risk assessment approach to ensure that the evidence is systematically and consistently evaluated; and
- The IOM ensures and fosters transparency in decision-making.

The comments said that we have based all other DRVs on the IOM DRI reports. The comments noted that more than a decade has passed since IOM concluded in 2005 that, based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a daily intake for total and added sugars or to set an upper limit for added sugars. The comments said that the process the DGAC used to develop its recommendations did not have the scientific rigor of the IOM process. The comments recommended that we defer any final rule, especially changes related to the declaration of added sugars, until the IOM can review the available evidence and develop a DRI for added sugars.

(Response) While the IOM has been the source of data that we have relied upon when setting other DVs, it is not the only source of information on which we can rely. While we recognize that a DRV that is derived primarily based on food pattern modeling is different from a UL that is determined by IOM, a DRV based on food modeling is a valid approach that provides consumers with a tool that they can use to help them put the amount of added sugars in a serving of a product into the context of their total daily diet. In response to the comments suggesting that the process that is used by the IOM to set ULs is more scientifically rigorous than food pattern modeling, the IOM process is different than food pattern modeling, but we have the ability to use different approaches to set DRVs based on the information we have available to us if the information will assist consumers in maintaining healthy dietary practices.

We also disagree with the comment stating that all other DRVs were established based on IOM DRI reports. Some DRVs were set based on scientific evidence from consensus reports or by other means. In the Reference Daily Intakes and Daily Reference Values proposed rule, we proposed to establish eight DRVs for persons 4 or more years of age based on information presented in the ''Diet and Health: Implications for Reducing Chronic Disease Risk report,'' the ''Surgeon General's Report on Nutrition and Health,'' and the ''Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction'' (55 FR 29476 at 29483). The DRVs were finalized in the 1993 Reference Daily Intakes and Daily Reference Values final rule (58 FR 2206, Jan. 6, 1993).

As new evidence emerges, we will consider whether we need to update the DRV. In the future, there may be more information available that would allow us to establish a DRV for added sugars that is based on a linear relationship with the risk of disease. We intend to monitor the evidence related to added sugars and consider whether changes need to be made to the label based on the evidence in the future.

(Comment 230) One comment referred to the DGA recommendation that Americans consume fatty fish due to their omega-3 fatty acid content, but noted that there is no reference value for omega-3 fatty acids. The comment said that added sugars are no different than omega-3 fatty acids and suggested that added sugars can be reduced in the diet, even while there is not sufficient evidence to recommend that they be limited to a particular intake level.

(Response) We do not agree that omega-3 fatty acids are an appropriate comparison to added sugars. For

example, we do not have scientific evidence to support a reference value for omega-3 fatty acids. We include a reference value for added sugars in the final rule to provide information that allows consumers to put the amount of the nutrient into the context of the total daily diet.

(iii) Food Pattern Modeling

(Comment 231) Food pattern modeling was used to support the 2015 DGAC recommendation that Americans should limit added sugars to a maximum of 10 percent of total caloric intake. For the 2015 DGAC, USDA used a modeling process to develop new USDA Food Patterns based on different types of evidence: The ''Healthy Vegetarian Pattern,'' which takes into account food choices of self-identified vegetarians, and the ''Healthy Mediterranean-style Pattern,'' which takes into account food group intakes from studies using a Mediterranean diet index to assess dietary patterns. The USDA Food Patterns provide suggested amounts of foods to consume from the basic food groups, subgroups, and oils to meet recommended nutrient intakes at 12 different calorie levels. They also show the number of calories from solid fats and added sugars that can be accommodated within each calorie level, in addition to the suggested amounts of nutrient-dense forms of foods in each food group.

Many comments questioned the use of food pattern modeling to establish a DRV for added sugars. The comments noted that, when we considered establishing a DRV for *trans* fat using menu modeling, we said that we continue to adhere to the approach of determining DRVs for a nutrient based on the nutrient's association with a specific health outcome (*e.g.,* LDL cholesterol levels), yet we proposed to use food pattern modeling to establish a DRV for added sugars rather than data on an association with a health outcome. The comment noted that we stated previously in the proposed rule, as well as in 1993, that we do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine DRVs. The comments explained that menu modeling involves individual foods, whereas food pattern modeling involves food group composites, but the process for menu and food pattern modeling is similar. The comments said that the issues that we raised for not using menu modeling for setting a DV for *trans* or saturated fat are the same for a food pattern modeling approach and would therefore apply to added sugars.

(Response) Although we have stated in the past that use of food composition data, menu modeling, or dietary survey data is not a suitable approach to determine DRVs, these statements were made in the context of establishing DRVs for nutrients where a causal relationship between consumption of the nutrient and risk of disease exists. Added sugars are different than *trans* fats in that there is a linear relationship between consumption of *trans* fats and LDL cholesterol whereas, for added sugars we do not have the type of direct association with risk of disease, based on the evidence we are using to support a mandatory declaration of added sugars for the general U.S. population, that we do with *trans* fats. When a linear relationship with disease risk is present, there are other, more appropriate, ways to establish a DRV for the nutrient. Because the current evidence supports more of a dietary pattern approach than a specific nutrient-disease approach, it is appropriate to use methods for the development of a DRV for added sugars that are based on constructing a healthy dietary pattern that is low in added sugars. The food pattern modeling that was done when developing the healthy U.S.-style, the healthy Mediterranean-style, and healthy vegetarian patterns provides a model of what a healthy dietary pattern should look like at different calorie levels. Therefore, the use of food pattern modeling to support a DRV for added sugars is closely aligned with our rationale for requiring the mandatory declaration of added sugars for the general U.S. population on the label.

(Comment 232) Some comments noted that the 2010 DGA states that the USDA Food Patterns are only one example of suggested eating patterns and that the USDA Food Patterns have not been scientifically tested for health benefits.

(Response) We acknowledge that the USDA Food Patterns are only one example of a healthy eating pattern and that it is possible for individuals to consume other patterns that are associated with a decreased risk of disease. However, analyses using diet quality index scores show that there is a great deal of consistency in what is considered a healthy dietary pattern that is associated with a decreased risk of disease (Ref. 86). Although it is possible to eat other healthy dietary patterns, it would be very difficult to meet nutrient needs within calorie limits by consuming enough of the other components of a healthy dietary pattern while consuming high levels of added sugars.

We also recognize that individuals may be able to accommodate more or less than 10 percent of calories in their diet while meeting nutrient needs within calorie limits. The purpose of a percent DV is to provide context to consumers so that they can determine how a food fits within their diet. The percent DV declaration can also allow for consumers to determine if a product is relatively high or low in a nutrient based on a reference amount. Therefore, a DRV of 10 percent of total calories should not be viewed as a recommended consumption level, but rather a reference amount that consumers can use as a guide.

We disagree with the comment that the USDA Food Patterns have not been scientifically tested for health benefits. Schroeder et al. assessed the effects of a diet based on the USDA Food Patterns used in the 2010 DGA, a Korean diet, and a typical American diet on blood lipid (fat) levels and blood pressure in overweight, non-Asian individuals in the United States with elevated LDL cholesterol (Ref. 101). They found that total cholesterol and LDL cholesterol significantly decreased when subjects were on fed a diet that is consistent with the USDA Food Patterns. Although the USDA Food Patterns in the 2015 DGAC Report differ slightly from those included in the 2010 DGA, they were designed in a very similar manner with the goal of meeting nutrient needs within calorie limits.

(Comment 233) Some comments objected to the use of food pattern modeling to establish a DRV for added sugars because, according to the comments, it lacks a scientific basis. The comments said that the reference value of 10 percent of total calories that the 2015 DGAC produced using modeling is a mathematical calculation of empty calories ''left over'' after the recommendations for food groups and nutrients in the different dietary patterns have been met. It does not signify a level at which negative metabolic effects occur. The comments asserted that the calories available for solid fats or added sugars in the ''empty calories'' category would completely change based on one addition or deletion of a serving of food.

The comments cited a number of limitations of food pattern modeling, such as:

- It is not evidence-based or nutrient specific so conclusions cannot be drawn with respect to health-related outcomes;
- It was designed to study the impact of an overall diet, not to evaluate the effect of a single nutrient;
- The nutritional adequacy was derived from a limited number of

representative foods, limiting the ability to extrapolate the nutritional adequacy of the food patterns beyond these ''representative foods;''

- Table sugar was used as a surrogate for added sugar in the USDA Food Patterns. As such, the model only identifies how much pure sugar can be consumed after achieving nutrient requirements, and not how to incorporate foods with added sugars into a dietary pattern;
- The modeling is based on a misperception that added sugars provide no additional nutritional value and are merely ''empty calories.'' Sugars are added to many nutrient-dense foods;
- The contribution of the representative foods to total daily added sugar intake was not considered or reported;
- It presents one modeling scenario with one set of assumptions and presents no uncertainty around their assumptions. Micronutrient requirements in the USDA Food Pattern are not always based on established intakes *i.e.,* the USDA Food Patterns calcium intakes can range from 110 percent of the RDA at the lower calorie range to 138 percent of the RDA at the highest, the RDA range for iron is 110 to 265 percent. As caloric levels increase, there is a disregard for the percent adequacy of micronutrients;
- The model did not test if nutritional adequacy could be achieved at added sugar intake levels above 10 percent and was not tested to assess efficacy or sensitivity;
- The USDA food modeling (with few exceptions) does not take into consideration fortification in the food supply, which could dramatically reduce the number of food servings in the USDA Food Patterns and increase the calories designated as leftover; and
- Food formulations and food consumption is continually changing. With continuing changes to food composition databases, information derived from food pattern modeling could change frequently. Using such changing information to update daily values could be costly to manufacturers for frequent changes to labels especially when based on an approach that has no public health relevance. The comment said that we chose, in part, to not use similar type data (*i.e.,* census data) for using a population weighted approach for setting daily values for vitamins and minerals.

(Response) As previously noted in our response to comment 224, we do not have the type of quantitative intake recommendation for added sugars that we have for other nutrients that have an independent association with the risk of chronic disease. However, we do have evidence that added sugars are a public health concern, and that consumers need information about of added sugars in a serving of food to maintain healthy dietary practices. Consumers also need to know how that amount of added sugars in a serving of food fits into the context of their total daily diet. Although we do not have the same type of reference amount for added sugars that we do for other nutrients that are associated with chronic disease risk, the scientific evidence supporting a limit in consumption of added sugars to a maximum of 10 percent of total calories provides a reference value that can be used to give context to the gram declaration for added sugars. The DRV, in general, should not be viewed as a precisely defined limit, but rather a guide to help consumers when selecting foods and determining how much of those foods they can eat within a healthful diet.

We recognize that empty calories allotment in the USDA Food Patterns represents an amount that is left over once all other requirements of the diet are met. We also recognize that conclusions related to health outcomes cannot be drawn from food pattern modeling. However, the dietary patterns approach to setting a DRV is consistent with the dietary pattern approach that we are taking to the evidence that we have considered to support the mandatory declaration of added sugar. Rather than basing the declaration on a nutrient-disease relationship, we are considering how a dietary pattern that is lower in added sugars is characterized, in part, by lower intakes of sugar-sweetened foods and beverages.

We disagree with the comment that said that the USDA Food Patterns were designed to study the impact of an overall diet and not to evaluate the effect of a single nutrient. The USDA Food Patterns were not designed to study nutrient or diet/disease relationships. They provide a conceptual framework for selecting the kinds and amounts of foods of various types, which together, provides a nutritionally satisfactory diet. The USDA Food Patterns assist Americans in meeting their nutrient requirements based on different caloric needs. In general, food patterns, such as the USDA food patterns, translate recommendations on nutrient intake into recommendations on food intake based on selective nutrient-dense foods.

During the modeling of the USDA intake patterns, 292 representative foods were chosen in order to provide healthy food intake patterns to meet nutrient needs for various age/sex groups of Americans ages 2 years and older within their calorie limits. We disagree with the comment stating that the contribution of the representative foods to total daily added sugar intake was not considered or reported. About 7 percent of these representative foods contain some added sugars (Ref. 124). For all added sugars in the USDA food patterns, the nutrients in granulated white sugar were used for the nutrient profile; however, this does not limit the application of the information for use as a DRV. While sugars are added to many nutrient-dense foods, and the assumption is made for the purposes of the USDA Food Patterns that the sugars do not come along with other nutrients, they provide a way to identify how much added sugars one could consume in various forms in the diet while meeting nutrient needs within calorie limits. The empty calorie allotment in the USDA Food Patterns gives Americans a general sense of how many calories from added sugars they can incorporate into a nutrient-dense diet without exceeding calorie limits. It is up to each individual to determine if he or she wants to consume those extra calories in the form of a food that is nutrient dense (*e.g.,* cereal, yogurt, or dried fruit with sugar added to them) or whether to consume it in a less nutrient-dense form such as a cola. The Nutrition Facts label also provides factual information that consumers can use to make choices about their diet.

With respect to the suggestion that micronutrient requirements in the USDA Food Patterns are not always based on established intakes, we agree. Instead, they are based on nutrient requirements for specific age and sex groups. However, the nutrient profiles of the food groups and subgroups used to construct the USDA Food Patterns are calculated and weighted by consumption of the U.S. population. It is not clear what the comment meant when it said that, as caloric levels increase in the USDA Food Patterns, there is a disregard for the percent adequacy of micronutrients. To the extent that the comment is suggesting that at higher calorie levels, the amounts of nutrients provided in the USDA Food Patterns exceed nutrient recommendations, as long as the food pattern does not exceed the UL for nutrients, it should not be a concern if the USDA Food Patterns exceed nutrient recommendations.

In developing the dietary intake patterns, USDA built nutrient adequacy in its dietary pattern by selecting a nutrient-dense food to represent each item cluster (Ref. 19). The selection of item clusters is based on the

consumption amount of the U.S. population (more than 1 percent of the weighted amount). A limited number of the representative foods for an item cluster were fortified foods. These fortified representative foods were selected when fortification of the food is mandatory, such as folate in enriched cereal grains, the food is typically fortified, or when the market leader for the food is fortified and its consumption in the population was consistent over time. Most nutrients in the USDA Food Patterns come from non-fortified food sources. It is possible that, if other fortified foods are used as representative foods in the model, the quantities of foods in the USDA Food Patterns may increase or decrease thereby increasing or decreasing the empty calorie allotment. The USDA Food Patterns are a theoretical model that is used to help Americans put the dietary recommendations into practice. The amount of added sugars that could be reasonably consumed while eating a healthy dietary pattern may be slightly more or less depending on the foods included when modeling the dietary patterns; however, they show that, across calorie levels, it would be very difficult to consume significantly more than 10 percent of calories as added sugars while still consuming enough foods from the food groups to meet nutrient needs within calorie limits.

We agree that nutrient intake data can be affected due to factors such as nutrient database changes, reformulation, or change of dietary behaviors. This is a limitation with the use of all intake data, and affects evidence that we rely on for other label declarations as well (*e.g.,* assessment of nutrient adequacy when determining what the nutrients of public health concern are). The DRV of 10 percent of calories from added sugars is based on the data that we have available to us at this time. We plan to monitor intake data and other evidence and information on added sugars and will consider whether and how it affects both an added sugars declaration and a DRV for added sugars in the future.

(Comment 234) The 2015 DGAC Report explains that, for purposes of the USDA Food Pattern Food Groups, the term solid fats and added sugars is an analytic grouping, but the 2015 DGAC elected to use the term ''empty calories'' for the food grouping in the USDA Food Patterns which includes solid fats and added sugars. The empty calorie allowance in the USDA Food Patterns is 8 to 19 percent of calories, and, based on current consumption patterns, 45 percent of empty calories were allocated to limits for added sugars with the remainder (55 percent) allocated to solid fats.

Some comments opposed the assignment of 45 percent of empty calories to added sugars based on current consumption data. The comments said that consumption data changes, so the assignment of 45 percent of calories to added sugars could change. Furthermore, the comments noted that Americans are consuming too many calories from added sugars, so using current consumption data to set a limit for added sugars consumption is inappropriate. One comment said that current intake of solid fats and added sugars has no relevance to the intended use of the USDA Food Patterns (*e.g.,* nutrient density). The intent is for these leftover calories to be used at the discretion of the individual as to how they consume these calories all added sugars, all solid fats, or a combination. The comments also said that the assignment of 45 percent of calories to added sugars in the USDA Food Patterns is not linked to a health-related outcome or a healthy diet.

(Response) We agree that consumption data changes and the designation of 45 percent of empty calories to added sugars could change. Consumption of added sugars could change in the future, which may prompt a change to the recommendations and the how empty calories from solid fats and added sugars are divided in the USDA Food Patterns. If changes are made to the USDA Food Patterns in the future related to added sugars, we will consider whether and how those changes impact the DRV for added sugars. We also acknowledge that Americans are currently consuming too much added sugars, so the assignment of 45 percent of the empty calories allotment could reflect overconsumption. However, Americans also are consuming too many solid fats, so the relative proportion of empty calories assigned to both solid fats and added sugars reflects overconsumption of both components of the diet. Although the empty calorie allotment is intended to be used by Americans based on their discretion, using consumption data to provide a percentage of empty calories from solid fats and added sugars can be consumed within a healthy dietary pattern reflects how Americans currently are using those left over calories. The modeling of dietary patterns for the USDA Food Patterns is done for a different reason than to evaluate a dietary pattern for health-related outcomes, so the assignment of 45 percent of calories to added sugars is not expected to be linked to a health-related outcome. However, we disagree that the assignment of 45 percent of calories to added sugars is not associated with a healthy diet. The purpose of the USDA Food Patterns is to assist consumers in putting intake recommendations for nutrients, foods, and food groups into practice so that they can construct a healthful diet. After nutrient needs are met, the left over calories are empty calories which Americans can choose to consume in the form of solid fats and/or added sugars. Therefore, how the empty calorie allowance was derived was based on getting adequate amounts of nutrients from a variety of foods in the diets to make up a healthy diet.

(Comment 235) One comment said that we should not base a DRV for added sugars on the USDA Food Patterns because they have not been validated. The comment noted that, although the 2015 DGAC Report states that an extensive effort was made to validate the food patterns, the DGAC did not actually test the patterns in a clinical study. Instead, it plotted the USDA food groups against those found in published hypothesis-based dietary pattern studies on a graph. The comment questioned whether the data provided by USDA to support a validation of the USDA food patterns is empirical evidence that the USDA food patterns are evidence-based guides for food consumption because, the comment said, the majority of food group intakes from the USDA Food Patterns do not actually fall within the range of intakes in the published dietary pattern study recommendations and because the majority of dietary pattern index studies used for the exercise did not included added sugars criteria.

(Response) The comment is suggesting that the USDA Food Patterns are not evidence based guides for food consumption and have not been validated because it is comparing them to dietary pattern studies where dietary quality indices are used to evaluate dietary patterns and health outcomes. Comparing the USDA Food Patterns, which have been developed through the process of menu modeling, to studies evaluating certain dietary patterns and health outcomes is not an appropriate way to assess the validity of the USDA Food Patterns. The USDA Food Patterns have been developed to be used as an example of a nutritionally adequate and balanced diet. Although the purpose is not to provide an example of a diet that is associated with decreased risk of disease, Schroeder et al. did assess the effects of the USDA Food Patterns from the 2010 DGA and found that total and LDL cholesterol were significantly lower in participants on the 2010 DGA diet

compared to typical American diet (Ref. 101). The proper assessment of the USDA Food Patterns is to consider whether they meet current dietary recommendations. The 2015 DGAC evaluated the Healthy U.S.-style, Mediterranean-style, and Vegetarian-style Patterns and determined that they meet nutritional goals without excess calories, and use a variety of foods (Ref. 19).

(Comment 236) In the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44308), we noted that the 2015 DGAC based its recommendation that Americans limit their added sugars intake to no more than 10 percent of total energy intake, in part, on current consumption data. For many of the same reasons that comments opposed the use of current consumption data to allocate 45 percent of available empty calories in the USDA Food Patterns to added sugars, some comments generally opposed the use of current consumption data to support a DRV of 10 percent of total calories. The comments noted that consumption of added sugars has been declining in recent years although the prevalence of overweight and obesity have increased. One comment said that intake data do not support ''added sugars'' intake as a major source of increased caloric intake. The comment said that, in the past 40 years, U.S. per capita consumption of sugar/sucrose declined by 33 percent as obesity and other serious diseases increased. The comment noted that a recent analysis of U.S. National Health and Nutrition Examination Survey (NHANES) data found that ''added sugars'' consumption has declined to 14.6 percent of energy, which is a decrease of 19.3 percent over a period of 8 years (2000 to 2008) and as the 2015 DGAC noted intake continues to decrease and current intake is now 13.4 percent of energy. The comment also said that, according to USDA data, Americans are consuming 425 more calories per person per day than they did in 1970 and of these 425 calories only 38 calories are attributed to ''added sugars'' intake (2009).

Other comments said that a maximum limit for added sugars should not be based on consumption data but rather on science with meaningful endpoints. While current intake of added sugars (13 percent of calories) is above but near a maximum level of 10 percent of calories, suggesting that this current intake makes 10 percent a reasonable goal is also not a health-based approach for setting a maximum intake level. The comments noted that current average intake of sodium is approximately 3,400 mg/day, but that the IOM panel set the upper level at 2,300 mg/day based on a public health outcome, even though they said it is generally agreed this is not a reasonable intake level that can be achieved in the near future. The comments said that current intakes are used to estimate prevalence of overconsumption by comparing to a maximum intake level tied to an adverse outcome rather using current intake to set the maximum intake level.

(Response) Americans are still consuming 13.4 percent of their calories from added sugars, which is a significant proportion of calories. Despite the fact that consumption of added sugars may have declined in recent years, consumption among the U.S population remains high. While current consumption data was a consideration in the 2015 DGAC's recommendation, it was used more to show that limiting calories from added sugars is a reasonable goal for Americans to strive for than it was to establish a precise limitation. Furthermore, current consumption data was not the only information that was used by the 2015 DGAC to support a recommendation to limit added sugars to a maximum of 10 percent of total calories. Information from the USDA Food Patterns showing that one can reasonably accommodate approximately 4 to 9 percent of calories in a diet that meets nutrient needs within calorie limits as well as data information from a published meta-analysis, also supported the 2015 DGAC's recommendation.

We explain, in our response to other comments in part II.H.3.o, that we are considering how added sugars interact with other components of a healthy dietary pattern. When too many added sugars are consumed, it makes it difficult to meet nutrient needs within calorie limits and it also makes it difficult for one to consume the recommended amount of other foods that make up a healthy dietary pattern that is associated with a decreased risk of CVD. Because our basis for requiring the mandatory declaration of added sugars on the label for the general U.S. population is related to consumption of a healthy dietary pattern that is low in added sugars, it is appropriate to establish a DRV that is based, in part, on information derived from modeling of healthy dietary patterns. The IOM has not set a UL for added sugars so we do not have a maximum intake level tied to an adverse outcome to which we can compare current intake levels. The USDA Food Patterns show that it would be difficult for Americans to consume a nutritionally adequate diet within calorie requirements if they are consuming more than 4 to 9 percent of their calories from added sugars. Because Americans are consuming approximately 13.4 percent of their calories, or even more in some segments of the population, the evidence supports that Americans are consuming too many calories from added sugars.

(Comment 237) Some comments questioned our reliance on findings and recommendations in the 2015 DGAC Report for establishing a DRV for added sugars. The comments asked whether we took the conclusions and recommendations from the 2015 DGAC at face value or whether we conducted our own rigorous review of the scientific evidence. The comments (which were submitted in response to the proposed rule before the 2015 DGAC Report became available) said that the DGAC Report has not yet been sanctioned by the Secretaries of Health and Human Service and the U.S. Department of Agriculture, which are under Congressional mandate to ensure that the general dietary guidance for the American public in the DGA is based on the preponderance of scientific and medical knowledge at the time of the report. The comments noted that the Secretaries not only consider the recommendations in this advisory report to ensure the Dietary Guidelines are based on the preponderance of science and medical knowledge, but also take into consideration public comment, a process that has not yet been completed. The comments said that our reliance on information and conclusions from the DGAC Report is setting a new precedent.

Other comments said that the DGAC was not convened with the purpose and intent of establishing specific reference values for labeling. The comments noted that the 2015 DGAC did not include a carbohydrate and/or ''added sugars'' expert. The comments suggested that a robust review by carbohydrate and sugars experts familiar with the entire body of high-quality scientific literature is necessary for establishing a reference value for added sugars. The comments said that the lack of ''added sugars'' expertise on the DGAC not only calls into question the legitimacy of the DGAC's ''added sugars'' upper daily intake limit intake recommendation, but also disputes the validity of the 2015 DGAC Report as a ''consensus report'' from which we can establish a DRV.

One comment said that the IOM recommendations are based on thorough and systematic reviews of the scientific literature; a process that usually takes 2 to 3 years to complete by experts in the field of investigation. The comment said that the DGAC did not conduct a

thorough review of the evidence to determine its recommendation to limit consumption of added sugars to less than 10 percent of calories. The comment said that the DGAC did not convene the Added Sugars Working Group until a few months before the DGAC process concluded. The comment suggested that, because the Added Sugars Working Group was not established earlier on, the DGAC had only 90 days to collect, review, synthesize and formulate conclusions on the extensive body of literature on sugars, with no experts in carbohydrate metabolism on the 2015 DGAC.

(Response) Since the publication of the supplemental proposed rule, the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture released the 2015–2010 DGA (Ref. 28). During the process of developing the 2015–2020 DGA, government officials considered the recommendations from the 2015 DGAC as well as comments from the public. The scientific evidence in the 2015–2020 DGA related to added sugars corroborates the scientific evidence in the 2015 DGAC. The scientific evidence supports limiting calories from added sugars and saturated fats and reducing sodium intake. Americans can achieve this by consuming an eating pattern low in added sugars, saturated fats, and sodium as well as by cutting back on foods and beverages higher in these components to amounts that fit within healthy eating patterns. A healthy eating pattern accounts for all foods and beverages within an appropriate calorie level and limits saturated fats and *trans* fats, added sugars, and sodium. The scientific evidence, from the 2015 DGAC (that is corroborated by the 2015–2020 DGA) supports the recommendation from the 2015 DGAC for Americans to consume less than 10 percent of calories per day from added sugars. Therefore, because the 2015–2020 DGA is in agreement with the 2015 DGAC, the concern related to us basing an added sugars declaration on the evidence from the 2015 DGAC have been addressed.

(iv) The Te Morenga et al. Meta-Analysis

(Comment 238) The 2015 DGAC reported that its recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake is supported by scientific evidence on added sugars and chronic disease risk conducted by the DGAC. The 2015 DGAC Report also says that the data analyzed by Te Morenga et al. supports limiting added sugars to no more than 10 percent of daily total energy intake based on lowest versus highest intakes from prospective cohort studies (Ref. 125). The Te Morenga et al. study is a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies that was commissioned by the WHO to look at the relationship between dietary sugars and body weight (Ref. 125). Several comments criticized the Te Morenga paper, stating that:

- It is a meta-analysis commissioned by the WHO and not a U.S. consensus report;
- Although Te Morenga et al concluded that among free living people consuming ad libitum diets, intake of free sugars or sugar-sweetened beverages is a determinant of body weight, the comments noted that in the WHO report on sugars intake for adults and children, they graded their own evidence for free sugars intake and body weight for both adults and children to be of moderate quality at best;
- The Te Morenga et al. interpretation did not establish a reference value for intake of free sugars and body weight;
- The definition of free sugars differs from our proposed definition of added sugars. The WHO defines ''free sugars'' as all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus the sugars that are naturally present in honey, syrups and fruit juices. In particular, the definition of free sugars includes natural sugars from fruit juices which are not included in our proposed definition of added sugars;
- Te Morenga et al. investigates the relationship between added sugars intake and body weight rather than CVD risk;
- The authors' conclusion that any role of sugars on body weight results from alteration in energy balance rather than a physiological or metabolic consequence of monosaccharides or disaccharides. The paper further stated that ''the extent to which population-based advice to reduce sugars might reduce risk of obesity cannot be extrapolated from present findings'' because few studies lasted longer than 10 weeks;
- Many studies in the meta-analysis fail to provide any comparative associations between total sugar intakes and metrics of obesity (*i.e.,* BMI, adiposity measures) in comparison with their analyses of free sugar intakes. The comments said that this may be a source of bias for their conclusions that only ''free sugars'' contribute to weight gain and fatness;
- Of the 77 studies evaluated for full review, only 11 isoenergetic studies were identified and composite results from those studies provided ''no evidence of difference in weight change as a result of difference in sugar intakes when energy intakes were equivalent.'' The comments concluded that it cannot be assumed that ''free sugars'' is linked to fatness when excess energy intake was not taken into consideration in the meta-analysis for non-isoenergetic studies;
- The authors noted significant heterogeneity (the studies included in the meta-analysis were not undertaken in the same way using the same experimental design) and potential bias in some of the trials examined;
- The authors concluded that comparison of the lowest to highest intakes in cohort studies was compatible (not supportive as the 2010 DGAC Report indicates) with a recommendation to restrict intake to below 10 percent of total energy. However, there is no evidence of a dose-response relationship, a key component of elucidating potential mechanisms, was provided through the array of research studies evaluated;
- The findings are consistent with the 2010 DGA advice that states, ''Foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits; and
- The research included in Te Morenga et al. is not current. Less than 10 percent of the studies included in the report were published after 2010, more than 50 percent of the studies are over 10 years old, more than 70 percent of the trials (in children and adults) are over 10 years old, and 80 percent of the randomized trials on adults are over 10 years old.

Other comments questioned our reliance on the Te Morenga et al. paper due to a number of factors and suggested that the results of this study should not be extrapolated to nutrient-dense foods and beverages with small amounts of added sugars.

The comments questioned our reliance on a meta-analysis for the proposed DRV of 10 percent of calories from added sugars and said that a meta-analysis does not provide sufficient scientific support to make an intake recommendation of 10 percent of energy.

One comment noted that the Te Morenga et al. paper was published and available to us at the time of the March 2014 proposed rule, but we said, in the preamble to the proposed rule (79 FR 11879 at 11906), that we reviewed scientific evidence and recommendations of consensus reports

and concluded that we could not propose to establish a DRV for added sugars. The comment questioned why we now have determined that the Te Morenga et al. paper provides suitable evidence to establish a DRV, but not when we developed the proposed rule.

(Response) We are relying on information from the USDA Food Patterns showing that it would be difficult for one to consume more than 10 percent of their calories from added sugars and still be able to consume enough of the other components of a healthy dietary pattern to meet nutrient needs within calorie limits to support a DRV for added sugars. We are also relying on consumption data showing that, on average, Americans are consuming 13.4 percent of calories from added sugars. Therefore, because we are not relying on the Te Morenga et al. paper to support a DRV for added sugars, we need not address specific comments on the merits of the Te Morenga et al. paper. We have determined that, because we are focusing on a healthy dietary pattern, the interactions that sugar-sweetened foods and beverages have with other components of a healthy dietary pattern, and how that healthy dietary pattern is associated with health outcomes, and basing a DRV for added sugars on data that takes into consideration the whole of a healthy dietary pattern, we do not need to rely on evidence related to a direct association between added sugars and risk of disease for a DRV. It also suggests that a DRV for added sugars of 10 percent of total calories is not an unrealistic reference value. We note that the 2015–2020 DGA also bases the recommendation to limit intake of calories from added sugars to less than 10 percent per day on food pattern modeling and national intake data on intakes of calories from added sugars that demonstrate the public health need to limit calories from added sugars to meet food group and nutrient needs within calorie limits. The 2015–2020 DGA states that, for most calorie levels in the USDA Food Patterns, there are not enough calories available after meeting food group needs to consume 10 percent of calories from added sugars and 10 percent of calories from saturated fats and still stay within calorie limits.

(Comment 239) One comment said that our scientific justification for proposing a DRV for added sugars of 10 percent of total energy is not clear because it is based on menu-modeling and is not included in the meta-analysis conducted by Te Morenga et al.

(Response) We proposed to establish a DRV for added sugars of 10 percent of total calories (50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age). We said that the 2015 DGAC Report recommended that Americans keep added sugars intake below 10 percent of total energy intake, and that recommendation was based on modeling of dietary patterns, current consumption data, and a published meta-analysis on sugars intake and body weight (80 FR 44303 at 44308). We concluded that the scientific information from the 2015 DGAC report provides a basis for FDA to establish a DRV for added sugars. The 2015 DGAC relied on both food pattern modeling information from the USDA Food Patterns as well as information from the Te Morenga et al. paper for its recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake.

After further consideration, we are establishing a DRV for added sugars of 10 percent of total calories, and are relying on information from the USDA Food Patterns as well as current consumption data for this determination.

(Comment 240) Some comments said it would be inappropriate to base a DRV for added sugars on recommendations from the WHO. The comments said that the WHO recommendation to limit intake of free sugars to 10 percent of energy intake was based on evidence for dental caries and not body weight or CVD risk. In reference to the Te Morenga et al. paper, the comments said that there was no effect of sugar and measures of weight found in children based on the reviews of randomized controlled trials and only a minor effect was found in cohort studies with intake of sugar-sweetened beverages but no other sugar-containing foods.

Other comments referred to the new WHO conditional recommendation to further reduce free sugars intake to 5 percent of total calories and said that this recommendation appears to be based solely on data from several studies that are more than 50 years old. The comments noted that the findings of the evidence-based review are described by the review authors as of ''very low quality'' (Ref. 126).

(Response) Although the WHO commissioned a systematic literature review to answer a series of questions relating to the effects of sugars on excess adiposity that resulted in the Te Morenga et al. paper, the 2015 DGAC considered the evidence discussed to the Te Morenga et al. paper and concluded that the evidence reviewed by Te Morenga et al., as well as food pattern modeling analysis conducted by the 2015 DGAC and consumption data supported a recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake. We did not propose to establish a DRV based on recommendations from the WHO, nor are we finalizing a DRV for added sugars based on recommendations from the WHO.

(v) The Iom Suggested Maximum Intake Level of 25 Percent or Less of Energy From Added Sugars

(Comment 241) Some comments noted that the 2005 IOM Macronutrient Committee concluded that ''based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a UL for total or added sugars. Although a UL is not set for sugars, a maximum intake level of 25 percent or less of energy from added sugars is suggested based on the decreased intake of some micronutrients of American subpopulations exceeding this level'' (Ref. 75). The comments asked why we did not use this 25 percent level as the basis for a DRV for added sugars because it was determined using an evidence-based approach.

(Response) We have concluded that using the IOM suggested maximum intake level of 25 percent or less of energy from added sugars to set a DRV for added sugars would be inappropriate. As noted in the IOM macronutrient report, the IOM could not establish a UL for total or added sugars based on the evidence, and the less than 25 percent of total energy recommendation should not be viewed as a UL. Setting a DRV for added sugars that is one quarter of a 2,000 calorie diet would result in a DRV for added sugars of 125 grams ($2{,}000 \times 0.25 = 500$ calories and $500 \div 4 = 125$ grams). Such a DRV for added sugars would be greater than the DRV for protein and fat, and would be approximately 42 percent of the DRV for total carbohydrate. Although DRVs are reference values rather than precise recommended intake levels, the percent DV declaration, which is calculated based on the DRV, gives the consumer a general idea of how much of a nutrient should be consumed (79 FR 11879 at 11926). A DRV of 25 percent of calories would indicate to consumers that foods containing a significant amount of added sugars are relatively low in added sugars. Such a DRV also would send the message to the American public that consuming one fourth of one's calories in the form of added sugars is appropriate. If a consumer chooses to eat those added sugars in the form of foods that contain few or little other nutrients, it would be very difficult, if

not impossible, to consume a healthful dietary pattern that includes adequate amounts from food groups, meets nutrient needs, and is within calorie limits. As such, a DRV for added sugars that is 25 percent of total calories could have negative public health implications. Therefore, we are not setting a DRV for added sugars based on the IOM suggested maximum level of 25 percent of total calories.

(vi) DRV of 10 Percent of Total Calories

Many comments to the supplemental proposed rule discussed whether a DRV of 10 percent of total energy intake is appropriate or whether another number should be chosen.

(Comment 242) Many comments suggested that the DRV for added sugars should be lower than 10 percent of calories. The comments referred to the 2015 WHO Guideline for Sugars intake for adults and children which recommends reducing the intake of free sugars to less than 10 percent of total energy intake. In the report, the WHO also suggested a further reduction of the intake of free sugars below 5 percent of total energy intake as a ''conditional recommendation.'' The comments also recommended that we follow the recommendation of the Scientific Advisory Committee on Nutrition in the United Kingdom that added sugars should account for no more than 5 percent of daily energy intake. The comments said that the American Heart Association (AHA) also recommends limiting added sugars consumption to no more than 5 percent of total energy intake. The comments also said that a DRV of 5 percent of total energy intake would align with AHA's recommendation that no more than one-half of discretionary calories should come from added sugars. The AHA recommends that most women consume no more than 100 calories (6 teaspoons) from added sugars per day and no more than 150 calories (9 teaspoons) per day for most men. The comments suggested that a DRV of 5 percent of total energy intake would be more appropriate than a DRV of 10 percent of total energy intake because the 2,000-calorie ''Healthy U.S.-Style,'' ''Healthy Mediterranean-Style,'' and ''Healthy Vegetarian'' dietary patterns developed for the DGAC Report included only 6 or 7 percent of calories from added sugars.

(Response) We disagree that the DRV for added sugars should be lower than 10 percent of calories or that there is adequate evidence at this time to set a DRV for added sugars of less than 5 percent of calories. While the WHO and other health organizations have recommended that individuals should consume 5 percent or less of total calories from added sugars, those recommendations are not consistent with those of U.S. consensus reports. Furthermore, current consumption data shows that Americans, on average, are consuming 13.4 percent of calories from added sugars, and the USDA Food Patterns show that it is possible to construct a healthful dietary pattern that includes more than 5 percent of calories from added sugars. The USDA Food Patterns were developed using representative foods with very little or no added sugars or solid fats. Even with using representative foods with little or no added sugars, the amount of calories left over that consumers can use to incorporate added sugars into their diet was 5 percent or more for all but two calorie levels (Ref. 19). A DRV of 10 percent of total calories provides a value that is more realistic considering current consumption of added sugars in the United States as well added sugars in the food supply.

(Comment 243) Several comments recommended lowering the added sugars DRV for children. The comments said that a DRV of 50 grams of added sugars for children 4 years of age and older which is based on the 2,000 reference value is too high. The comments said that according to USDA, 4 year olds should be consuming 1,400 calories per day, assuming moderate activity. The comments said that under our proposal, a 4 year old could consume more than 14 percent of calories from added sugars and still be within the guidelines. The comments noted that this disparity does not align with the 2015 DGAC's or WHO's recommendations for added sugars accounting for no more than 10 percent of total calories until age 11 for boys and age 12 for girls. The comments suggested changing the DRV to 25 grams of added sugars for children aged 1 to 11years, and no more than 50 grams of added sugars for individuals 12 and older. The comments said that this change would bring our recommendations more in line with the stated goal of consuming less than 10 percent of total calories from added sugars. The comments also said that for products marketed to children between the ages of 1 to 11 years old, we should require the use of a DRV of 25 grams for added sugars. The comments suggested criteria that could be used to identify products marketed to children.

One comment noted that in the United Kingdom health authorities further stratify recommendations for children to include no more than 19 grams for children ages 4 to 6 and no more than 24 grams for children ages 7 to 10.

(Response) We decline to revise the rule as suggested by the comments. DRVs should be viewed as reference amounts that consumers can use to determine how a serving of a food fits within their total daily diet. A DRV for children between the ages of 4 through 11 or 7 through 10, as the comments suggested, could clutter the label, cause confusion, and draw attention to the added sugars declaration because more space would be required for two separate percent DV declarations on the label. In addition, the approach we have taken for setting a DRV for added sugars for children and adults 4 years of age and older is consistent with that of total and saturated fat where the DRVs are based on an amount not to exceed.

(vii) Education

(Comment 244) Many comments discussed the need for consumer education to help consumers understand the addition of an added sugars disclosure to the Nutrition Facts label and to help consumers use this information to make healthy food choices. Other comments suggested that education should focus on total calories, total sugars, and the ingredient list—information which can already be found on the current Nutrition Facts label. One comment suggested that we educate consumers about the fact that sugars are included in total carbohydrates, instead of requiring an added sugars declaration on the label. Many comments also said that Nutrition Facts labels that declare added sugars in addition to total sugars will be confusing to consumers, suggest to consumers that added sugars are more harmful than naturally occurring sugars, or suggest that consumers should focus on added sugars more than on other nutrients.

One comment argued that consumer responses to added sugars declarations could lead to unintended consequences, citing studies that have found that ''low-fat'' labels may reduce consumers' experience of guilt associated with excess consumption of foods bearing such labels or may increase what consumers perceive to be an appropriate serving size of such foods. Many comments said that requiring a new line for added sugars could suggest to consumers that they should give increased attention to added sugars whereas current U.S. dietary guidelines do not support an overemphasis on added sugars. One comment said that an added sugars declaration could call undue attention to added sugars as a source of calories when it is no different from other caloric sources. This

comment said that emphasis on reducing individual macronutrients, in lieu of reducing total energy intake defeats the primary goals of our Calories Count report (Ref. 127). Another comment said that the addition of added sugars declarations to the label may lead consumers to opt for foods of equal total sugar content but lesser nutrition, and to overlook health benefits that some foods have to offer.

In contrast, some comments said that listing added sugars on the Nutrition Facts label would provide vital information on the amount of added sugars in a food and help consumers eat less added sugars.

Some comments also said that public education on the food sources and health consequences of excessive added sugars intake is needed. One comment suggested that we develop materials to explain that consuming foods high in added sugars makes it difficult to meet nutritional needs and stay within calorie limits. The comment also suggested that we emphasize that naturally occurring sugars in fruits, vegetables, and dairy products do not pose any health problem, and that people should consume more fruits, vegetables, and low-fat dairy products.

One comment said that an industry-sponsored reanalysis of FDA's added sugars consumer study and a consumer study commissioned by a group of national food and beverage associations showed that the ''% DV/Added Sugars'' information will create consumer confusion that does not exist today. The comment said that we would face education campaign challenges such as confusion related to the concept of percent DV, possible misinterpretation of the new term ''Added Sugars,'' and ''unintended effects'' of placing a percent DV next to ''Added Sugars'' and not ''Total Sugars.'' The comment also said that when misperceptions of ''% DV/Added Sugars'' arise in the marketplace, it will be difficult to correct those misperceptions, particularly given that the new rule and label changes would be interpreted and defined by many other communicators outside FDA. The comment cited examples of other campaigns that faced similar obstacles, and concluded that any campaign FDA undertook related to added sugars would not succeed. Some comments said that some segments of the population may be more susceptible to misunderstanding added sugars information than the general population. Another comment suggested explaining ''daily values'' better and to clarify that the daily value for added sugars does not represent a suggested amount one should eat, but rather, represents a ''conservative estimate'' of the highest amount one should consume of added sugar. The comment also said that if subsequent research were to show that the current daily value for added sugars is too high or too low, the ''incorrect'' value may remain in the public mind long after it has been proven to be incorrect.

One comment included information from a consumer study that sampled 1,088 participants aged 18 years and older from an online respondent panel. The comment described results including, but not limited to, participants' understanding of the term ''Added Sugars'' as displayed on Nutrition Facts labels used in the study. Respondents' answers reflected a range of interpretations, including, but not limited to, beliefs that added sugars refer to specific types of sugars (*e.g.,* ''white sugar'') or artificial sweeteners. The comment said that 30 percent of participants said they ''don't know'' what added sugars are or provided no answer. The comment said that the study findings indicated that there is confusion among consumers regarding what added sugars are and that ''consistent, coordinated communication efforts'' will be needed to educate consumers about the Nutrition Facts label and added sugars.

(Response) Increased consumer education about nutrition and healthy dietary practices would likely benefit a number of consumers in the United States. The updated Nutrition Facts label promulgated by this rule is an important foundational tool for that consumer education. As noted in part II.B.1, we are committed to increasing understanding and use of the Nutrition Facts label to improve healthy dietary patterns through consumer education, in collaboration with key Federal partners such as USDA and CDC, health professionals, and the broader public health community, as well as with industry partners. One aspect of those education and outreach activities will be increasing understanding of new components to the label including added sugars (*e.g.,* definition, relationship to total sugars), considerations for how to interpret the information on added sugars in the context of a healthy diet, and how all of the information provided on the Nutrition Facts label is important to consider when constructing a healthy dietary pattern—not only information on added sugars, but the nutrients declared, the percent Daily Value, and the importance of being mindful of total caloric intake. Attention to calories is highlighted by the substantially increased font size of the calorie declaration per serving of a product discussed in part II.Q. Focusing on the totality of nutrition information on the label in education activities will enable consumers to identify foods that are nutrient rich and may contain some added sugars, and reinforces the recommendations of the 2015 DGAC Report and 2015–2020 DGA to increase fruit and vegetable consumption, decrease saturated fat and sodium, and to limit added sugar intake to less than 10 percent of total calories.

With regard to the comment stating that no education initiative can be successful in helping consumers understand added sugars, and therefore implying that added sugars should not be on the Nutrition Facts label, we disagree. The requirement to declare added sugars on the label is important public health information based on the latest science. Not requiring this important information to be declared would be detrimental to public health and run counter to our mandate to promote healthy dietary practices, even if not all consumers understand and use the information immediately.

With regard to the comments questioning the addition of added sugars to the label, we have determined that there is a public health need for this declaration and that it is necessary to assist consumers in maintaining healthy dietary practices (see part II.H.3.a). We have the legal authority to require this declaration (see part II.C.3). Moreover, we are not aware of any data or information suggests that consumers will focus undue attention on added sugars as a source of calories any more than other nutrients on the label that are a source of calories. Our determination that added sugars should be declared on the label is consistent with the intent of our Calories Count report because the information an assist consumers in limiting their total energy intake.

With regard to the comments questioning the confusion about a percent DV relating to added sugars and not total sugars, we address the need for a percent DV for added sugars and why it is not appropriate for total sugars (see part II.H.3).

Regarding the question about consumer confusion about the concept of the percent DV, we have updated the footnote explaining the percent DV (see part II.Q.11).

With regard to the question about consumer confusion on the relationship between total and added sugars, as described in our response to comment 188, we have modified the format of the added sugars declaration to appear indented under total sugars using the phrasing: ''Includes X g Added Sugars.''

p. Records. When a mixture of naturally occurring and added sugars is present in a food, the proposed rule, at § 101.9(g)(10)(iv), would require manufacturers to make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) to verify the amount of added sugars present in the food. We also proposed specific recordkeeping requirements specific to yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, or beer that does not meet the definition of a ''malt beverage,'' as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)), if the amount of added sugars in those products is reduced through the process of fermentation.

Several comments addressed the proposed recordkeeping requirements for added sugars. We discuss those comments in part II.R.3.

As discussed in part II.H.3.n, we are requiring manufacturers of products containing fruit and vegetable juice concentrates as an ingredient that have not been reconstituted to 100 percent juice in the finished food to provide documentation that shows how they determined how much of the sugars provided by the juice concentrate should be declared as added sugars.

Also, as discussed in part II.H.3.k, when the amount of added sugars in a product is reduced through non-enzymatic browning and/or fermentation, we are requiring manufacturers to make and keep records to demonstrate the amount of amount of added sugars after non-enzymatic browning and/or fermentation, make and keep records of the amount of sugars added to the food before and during the processing of the food, or the submission of a citizen petition requesting an alternative means of compliance if the manufacturer has reason to believe that the amount of added sugars in the finished product is significantly less than the amount added prior to non-enzymatic browning and fermentation but they have no way to determine a reasonable approximation of the amount in the finished food.

4. Sugar Alcohols

Our preexisting regulations, at § 101.9(c)(6)(iii), define sugar alcohols, in part, as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group (*e.g.,* mannitol or sorbitol).

a. Voluntary declaration. Our preexisting regulations, at § 101.9(c)(6)(iii), permit the voluntary declaration of sugar alcohols on the Nutrition Facts label. The preamble to the proposed rule (79 FR 11879 at 11908) discussed how, in reaction to a citizen petition and in the 2007 ANPRM, we considered whether to make the declaration of sugar alcohols on the Nutrition Facts label mandatory. We tentatively concluded that the declaration of sugar alcohols should remain voluntary, and so the proposed rule would not revise the requirement but would, because of other changes, renumber the provision as § 101.9(c)(6)(iv).

We did not receive any comments regarding the voluntary declaration of sugar alcohols, and so the final rule continues to provide for their voluntary declaration.

b. Use of the term ''sugar alcohols''. In the preamble to the proposed rule (79 FR 11879 at 11908), we discussed our consideration of a citizen petition and comments to the 2007 ANPRM regarding the use of the term ''polyols'' (a contraction of the term ''polyalcohol'' instead of ''sugar alcohols''). We determined that ''polyols'' could be potentially more confusing to consumers than the term ''sugar alcohol,'' but acknowledged that consumers also may not be familiar with the term ''sugar alcohol.'' Nevertheless, we continued to support the term ''sugar alcohols'' rather than ''polyols'' because we stated that ''sugar alcohols'' more accurately describes the group of substances encompassed in the definition in § 101.9(c)(6)(iii) (79 FR 11879 at 11908). We explained that ''polyols'' includes non-carbohydrate polyalcohols, such as polyesters, whereas ''sugar alcohols,'' as defined by FDA, includes only carbohydrates, and so the proposed rule would not change the term ''sugar alcohols'' when used on the Nutrition Facts label.

(Comment 245) Several comments supported using the term ''polyols'' instead of ''sugar alcohols.''

Some comments said that sugars are mono- and disaccharides, whereas most sugar alcohols are pentoses and hexoses. The comments said that the chemical structures of sugars are rings, and the chemical structure of sugar alcohols are chains. The comments also said that sugars and sugar alcohols have different calorie contributions. Therefore, the comments said that the term ''polyols'' is more appropriate in reference to carbohydrate-based polyalcohols.

(Response) We disagree with the comments. Both sugars and sugar alcohols contain saccharides. Sugars are defined as mono- and disaccharides (§ 101.9(c)(6)(ii)). Sugars alcohols are defined as the ''sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group'' (§ 101.9(c)(6)(iv)). The presence of the hydroxyl group is the basis for these modified sugars being called ''sugar alcohols.'' The term ''sugar alcohols'' more accurately reflects the chemical composition of these compounds than ''polyols.'' Because of the difference in chemical composition, they are metabolized differently and have different caloric contributions. Analytical methods are available to measure sugar alcohols based on their chemical composition and structure (79 FR 11879 at 11901), and they are listed separately in the Nutrition Facts label. ''Sugar alcohols'' more accurately describes the group of substances encompassed in the definition in § 101.9(c)(6)(iii). ''Polyols'' includes non-carbohydrate polyalcohols, such as polyesters, whereas ''sugar alcohols,'' as defined by FDA, includes only carbohydrates (see 79 FR 11879 at 11908). Thus, we decline to revise § 101.9(c)(6)(iii) to use the term ''polyols.''

(Comment 246) One comment supporting use of the term polyols noted that our explanation in the preamble to the proposed rule, that polyols only cover non-carbohydrate polymers while sugar alcohols include only carbohydrates, is not supported. The comment said that polyols are low-digestible carbohydrates and the only sugar alcohols used in foods are also considered polyols.

(Response) We disagree that polyols only pertain to non-digestible carbohydrate polymers. We consider polyols to include low-digestible carbohydrates (*i.e.,* sugar alcohols) that are used in foods, as well as non-carbohydrate polyalcohols (see 79 FR 11879 at 11908). Therefore, ''sugar alcohols'' is a more specific description of the listing of these ingredients in the Nutrition Facts label.

(Comment 247) One comment said that ''sugar alcohol'' may be confusing to consumers and that ''polyols'' is less likely to cause confusion. The comment said that ''sugar alcohol'' may mislead the consumer regarding health effects, given the negative health connotations of the terms ''sugar'' and ''alcohol'' separately. The comment said that we, at the very least, should conduct consumer testing of the term ''polyols'' and ''sugar alcohols.''

Another comment cited a 1995 survey provided to FDA in a citizen petition in 1995, stating that there is strong evidence that ''sugar alcohols'' is a term widely misunderstood by consumers, with most consumers mistakenly

believing that foods containing sugar alcohols contain both sugar and alcohol. Another comment cited a 2012 survey, ''Adults Remain Confused about 'Sugar Alcohol'—and Whether It Contains Sugar and/or Alcohol,'' which observed that a majority of the 1,000 adults polled believed that ''sugar-free'' products containing ''sugar alcohols'' contained sugar (74 percent) or alcohol (64 percent).

(Response) We previously considered the use of the term ''polyol'' and determined that it could be potentially more confusing to consumers than ''sugar alcohols.'' However, we acknowledge that consumers may not be familiar with the term ''sugar alcohol'' (see 79 FR 11879 at 11908). Therefore, we allow for the listing of the name of the specific sugar alcohol instead of ''sugar alcohols,'' provided that only one sugar alcohol is present in the food, because many sugar alcohols are listed as ingredients (*e.g.,* sorbitol, mannitol, and xylitol) and therefore may be more recognizable to consumers.

(Comment 248) One comment supporting use of the term ''polyols'' said that the EU has introduced optional declaration for ''polyols'' (Ref. 128) (''on the provision of food information to consumers'').

(Response) We acknowledge that the EU provides for the option to declare ''polyols'' which is defined as ''alcohols containing more than two hydroxyl groups.'' The EU, however, does not allow for the optional listing of specific sugar alcohols. ''Sugar alcohols'' more accurately reflects the chemical composition of these ingredients than ''polyols.'' Furthermore, unlike the EU, we allow for the listing of specific sugar alcohols because consumers may not be familiar with the term ''sugar alcohol.''

c. DRV. Our preexisting regulations do not provide a DRV for total sugar alcohols or for individual sugar alcohols. The preamble to the proposed rule (79 FR 11879 at 11908) explained that a quantitative reference intake recommendation for sugar alcohols is not available from current consensus reports, so we have no basis on which to consider setting an appropriate DRV. Therefore, we did not propose to set a DRV for sugar alcohols.

(Comment 249) One comment agreed that there was no scientific basis to establish a DRV for ''sugar alcohols.''

(Response) Because we continue to lack a basis to set an appropriate DRV for sugar alcohols, the final rule does not establish a DRV for sugar alcohols.

d. Caloric value. The caloric value for carbohydrates, other than insoluble fiber, is 4 kcal/gram (§ 101.9(c)(1)(i)(C)). Sugar alcohols have been shown to have a caloric value lower than 4 kcal/gram (Refs. 129–130). In the preamble to the proposed rule (79 FR 11879 at 11908 through 11909), we explained that we considered revising the energy contribution of sugar alcohols and also considered relevant caloric values recommended by the Life Sciences Research Office (LSRO). The LSRO expert panel reports provided the following caloric values for individual sugar alcohols: Isomalt (2.0 kcal/gram), lactitol (2.0 kcal/gram), xylitol (2.4 kcal/gram), maltitol (2.1 kcal/gram), sorbitol (2.6 kcal/gram), hydrogenated starch hydrolysates (3.0 kcal/gram), and mannitol (1.6 kcal/gram). Consequently, we proposed to amend § 101.9(c)(1)(i)(F) to establish the following general factors for caloric values of sugar alcohols, using the values recommended by LSRO: Isomalt—2.0 kcal/gram, lactitol—2.0 kcal/gram, xylitol—2.4 kcal/gram, maltitol—2.1 kcal/gram, sorbitol—2.6 kcal/gram, hydrogenated starch hydrolysates—3.0 kcal/gram, and mannitol—1.6 kcal/gram. We also proposed to amend § 101.9(c)(1)(i)(C) such that the 4 kcal/gram value is not applied to sugar alcohols.

(Comment 250) Several comments supported the proposed caloric values. Some comments, however, noted that we did not identify a caloric value for erythritol. Some comments noted that a caloric value of 0.2 kcal/gram was consistent with the EU and Health Canada, while other comments supported 0 kcal/gram as a value consisted with the EU. One comment provided a review of the evidence, including a publication by Livesey (1992) (Ref. 131) and more recent evidence from human (Ref. 132) and rat studies to support of a caloric value of 0 kcal/gram for erythritol.

(Response) We agree that a caloric value for erythritol should be considered. We generally do not consider animal studies for determining the caloric contribution of nutrients. Livesey (1992) determined that the caloric value for erythritol was 0.2 kcal/gram in humans. Applying the factors that Livesey (1992) used for determining the caloric value for erythritol and considering the newer evidence using radiolabelled erythritol in humans (Ref. 132), the review submitted as part of the comment concluded that erythritol is a substrate that is readily absorbed, and undergoes no metabolism, therefore providing 0 calories. These methods are consistent with those used for establishing caloric values for the other sugars alcohols determined by LSRO (79 FR 11879 at 11909). Therefore, the final rule provides a caloric value of 0 kcal/gram for erythritol.

5. Dietary Fiber

a. Dietary fiber.

(i) Definition

Our preexisting regulations do not establish a definition for dietary fiber. Dietary fiber represents a heterogeneous group of compounds that vary in their carbohydrate composition, linkages between carbohydrates, and molecular weight. Therefore, there is no specific chemical definition for dietary fiber. The amount of dietary fiber that is currently declared is based on analytical methods such as the AOAC analytical methods.

In the preamble to the proposed rule (79 FR 11879 at 11909), we explained how the IOM had issued a report defining ''total fiber'' as the sum of ''dietary fiber'' and ''added fiber,'' where ''dietary fiber'' consists of non-digestible carbohydrates and lignin that are intrinsic and intact in plants, and ''added fiber'' (referred to as ''functional fiber'' in the IOM Macronutrient Report) consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans. We proposed to adopt a definition for dietary fiber that is equivalent to the IOM's definition of ''total fiber'' and therefore would include fibers that the IOM defines as ''dietary fiber'' and ''functional fiber.'' Both ''dietary fiber'' and ''functional fiber,'' as defined by the IOM, are considered to have beneficial health effects, so there is little benefit for consumers in distinguishing between these two types of fiber on the Nutrition Facts label. In addition, the IOM recognized analytical limitations in distinguishing between ''dietary fiber'' and ''functional fiber'' and noted that the labeling of ''total fiber'' would be more practical than labeling ''dietary fiber'' and ''functional fiber'' separately (79 FR 11879 at 11909). Specifically, the proposed rule would amend § 101.9(c)(6)(i) to include the definition for dietary fiber. The proposed definition would include: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; (2) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that we have granted be included in the definition of dietary fiber, in response to a citizen petition we received demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or (3) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim. Our

proposed definition for total fiber also would include a minimum degree of polymerization (DP) greater or equal to 3 monomeric units.

In the preamble to the proposed rule (79 FR 11879 at 11909 through 11910), we proposed to list isolated and synthetic non-digestible carbohydrates with beneficial physiological effect(s) in the definition of dietary fiber. In the proposed codified language, we identified two ways the list of dietary fibers could be amended to include new fibers in the definition. Specifically, we identified the existing citizen petition process in § 10.30 that a manufacturer could use to request an amendment to the definition of dietary fiber and the petition process for the authorization of a health claim (21 CFR 101.70) where a fiber that is the subject of an authorized claim would be considered a dietary fiber that we could add to the list of fibers in the definition. We would consider an isolated or synthetic non-digestible carbohydrate that meets the significant scientific agreement standard in section 403(r)(3) of the FD&C Act, for which a health claim is authorized, to be a dietary fiber with a beneficial physiological effect to human health. Two dietary fibers, for which an authorized health claim exists, *i.e.,* β-glucan soluble fiber and barley β-fiber, were included in the proposed definition. The two types dietary fibers, for which an authorized health claim exists (*i.e.,* β-glucan soluble fiber and psyllium husk), are included in the codified definition for dietary fiber in this final rule.

(Comment 251) Some comments stated that it would be a burden to us to maintain and update an approved list of dietary fibers.

(Response) We consider a listing of dietary fibers that provide a beneficial physiological effect to be an efficient way to ensure the use of a common definition on which all manufacturers can rely to evaluate the fiber content of their products for purposes of the dietary fiber declaration and that we can use to evaluate compliance. Therefore, we decline to revise the rule in response to this comment.

(Comment 252) Some comments expressed concern about using the citizen petition process in § 10.30 to amend the listing of isolated and synthetic non-digestible carbohydrates in the definition of dietary fiber. Some comments considered this aspect of the definition as creating an approval process for dietary fiber and stated that we did not have legal authority for such a process. The comments said our pre-approval authority is limited to the premarket review of food additives, color additives, and health and nutrient/content claims and that section 403(q) of the FD&C Act does not provide a legal basis to support premarket approval. The comments also asserted that, under the Administrative Procedure Act, our actions must be consistent with the authority given to us under the FD&C Act and cannot be arbitrary or capricious.

(Response) We disagree that defining the term ''dietary fiber'' to include the identification of specific isolated and synthetic non-digestible carbohydrates is a pre-approval process for dietary fibers like that for food additives, color additives, and health or nutrient content claims. First, the listing of isolated and synthetic dietary fibers in the definition of dietary fiber does not constitute a pre-approval process related to the safety of the food as an ingredient. We are defining dietary fiber under our authorities in sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act and not under the food additive approval provisions in section 409 of the FD&C Act (21 U.S.C. 348). Moreover, the definition of dietary fiber does not prevent the use of an isolated or synthetic non-digestible carbohydrate to be used as an ingredient in the manufacture of a food. The use of such an added fiber as an ingredient must be lawful under the relevant provisions in the FD&C Act. Second, our definition of dietary fiber for a label declaration does not constitute a health claim or a nutrient content claim under the provisions to authorize such claims in section 403(r) of the FD&C Act. By defining the term dietary fiber, based on beneficial physiological effects in human health rather than by chemical definition, we will ensure that the dietary fiber declared amount will assist consumers to maintain healthy dietary practices, consistent with our labeling authorities under section 403(q) the FD&C Act.

To avoid confusion in the final rule about the citizen petition process at § 10.30, we removed the language that referred to dietary fibers ''that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 demonstrating that such carbohydrates have a physiological effect that is beneficial to health.'' The language is not necessary. Any interested person may seek to amend the listing of added fibers through the existing citizen petition process in § 10.30. We do not need to cite to that process within the codified definition of dietary fiber for that process to be available or used to amend the definition of dietary fiber.

(Comment 253) Some comments expressed concern about the citizen petition process with respect to the time for FDA to respond and about the priority of review. Several comments said that, if we did not respond to a citizen petition after 180 days, the dietary fiber should be considered to be officially recognized. One comment would change the deadline for responding to a petition to 30 days or to 90 days.

(Response) Under § 10.30(e)(2), the Commissioner is to provide a response to a petitioner within 180 days of receipt of the petition to approve the petition, deny the petition, or provide a tentative response. In addition, under § 10.30(e)(3), the Commissioner may grant such other relief or take other action as the petition warrants. The comment that requests a shorter time period for review under § 10.30 would require a substantive amendment to the existing regulation in § 10.30 and is outside the scope of this rule. Therefore, we decline to revise the rule in response to this comment.

(Comment 254) Several comments asked how we would handle more than one petition on the same added non-digestible carbohydrate. For example, if two petitions were submitted on the same added non-digestible carbohydrate, but for different endpoints, and the added non-digestible carbohydrate meets the dietary fiber definition based on one endpoint, but not the other endpoint, would the added non-digestible carbohydrate meet the dietary fiber definition? Another comment stated that it is unlikely that a single dietary fiber source will produce all of the potential health outcomes anticipated for dietary fiber consumption. Some comments questioned whether all manufacturers would have to submit a citizen petition for the same fiber.

(Response) We recognize that different isolated or synthetic non-digestible carbohydrates can have different beneficial physiological effects. An isolated or synthetic non-digestible carbohydrate only needs to demonstrate one beneficial physiological effect. Therefore, for example, if the non-digestible carbohydrate attenuates blood glucose levels, but not blood cholesterol levels, it would meet the definition of dietary fiber. As long as one of the petitions provided sufficient evidence for a beneficial physiological effect, we could add the dietary fiber to the regulation. After an isolated or synthetic non-digestible carbohydrate is included in the list of such fibers in the definition of dietary fiber in § 101.9(c)(6)(i), all manufacturers must list the dietary fiber

as part of the total dietary fiber declaration if it is present in their product. Manufacturers would not have to individually submit a citizen petition for the same fiber already listed before being subject to the mandatory declaration for that fiber.

(Comment 255) One comment said we should authorize only specific formulations of an isolated or synthetic non-digestible carbohydrate. The comment said that generic approval of many added fibers would be inappropriate because companies produce a wide variety of each fiber.

(Response) We recognize that companies may produce a wide variety of specific formulations of isolated or synthetic non-digestible carbohydrates, and we would, as appropriate, provide the needed specificity in a list of isolated or synthetic non-digestible carbohydrates in the definition, including their source and chemical structure to ensure clarity in what fibers must be declared as ''dietary fiber'' if present as an ingredient in food. We intend to issue a guidance document on the information we recommend be provided to us for scientific review, the approach we intend to use to evaluate the studies, including the approach for our evaluation of the strength of the scientific evidence, if a company petitions us to amend the definition of dietary fiber to include an additional fiber in the definition.

(Comment 256) One comment suggested that we use a voluntary pre-notification process, such as that used for FDAMA health claims, to substantiate an added non-digestible carbohydrate. Other comments suggested the use of a voluntary GRAS notification process that involves submitting a detailed summary of a determination for safety or, for companies that have self-determined their ingredient as GRAS, their self-determination process. Other comments said that added non-digestible carbohydrates that are GRAS should meet the dietary fiber definition. Many comments suggested that we use a pre-market notification process, such as that used for structure/functions claims, where the evidence is on file and the evidence is publically available.

(Response) We decline to revise the rule as suggested by the comments. A voluntary process, such as the GRAS notification program, is not consistent with ensuring that there is a singular definition of dietary fiber for purposes of the declaration in the Nutrition Facts label. Furthermore, the GRAS review system evaluates ingredients for their safety, rather than beneficial physiological effects. A dietary fiber that is GRAS does not necessarily meet the definition of dietary fiber for purposes of a nutrient declaration. A non-digestible carbohydrate that is added to a food by a manufacturer must be approved as a food additive under section 409 of the FD&C Act or be GRAS under the conditions of its intended use (see sections 201(s) and 409 of the FD&C Act). The lawfulness of the use of various fibers added to food is outside the scope of this rule.

Moreover, a process whereby a firm retains the evidence that its fiber meets the definition of dietary fiber would not ensure that there is a singular definition of dietary fiber for purposes of the declaration in the Nutrition Facts label. By including a list of all isolated or synthetic dietary fibers that meet the definition of dietary fiber, manufacturers will know that, when they use those fibers as an ingredient in their product, they must include the fibers in the declaration of dietary fiber. Consumers will have a consistent basis on which the declared values for dietary fiber are derived and can use that information in making healthy dietary choices and for comparing products. We are establishing a definition for dietary fiber that includes isolated or synthetic non-digestible carbohydrates that have a beneficial physiological effect to human health and are to be included in the declaration for dietary fibers on the Nutrition Facts label. Without a consistent regulatory definition, we would not be able to determine the veracity of a dietary fiber declaration on the Nutrition Facts label for purposes of compliance, and consumers would not be assured that the fibers declared as dietary fiber on the label are those that will assist them in maintaining healthy dietary practices.

Furthermore, although we consider an isolated or synthetic fiber that is the subject of an authorized health claim to meet the definition of dietary fiber, we are not able to make the same determination for such a fiber if subject of a health claim notification submitted under section 403(r)(3)(C) of the FD&C Act. (We refer to this health claim as a ''FDAMA health claim'' based on the statutory language enacted as part of the Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, 111 Stat. 2296 (1997).) A FDAMA health claim relates to an authoritative statement made by a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition (section 343(r)(3)(C)(i)) of the FD&C Act). A FDAMA health claim may be used on food in the market within 120 days of a submission; however, there are certain circumstances under which we may object to the content of the submission. For FDAMA health claims in use, for which the 120-day period has passed, we must issue a regulation to prohibit or modify the claim or make other findings to prevent the use of the claim (section 343(r)(3)(D) of the FD&C Act). There are a number of factors we must evaluate during the 120-day period of review that could raise questions about the use of the claim. For example, we may have questions about the source of the statement and whether the statement is a health claim, whether the notification contains a balanced representation of the scientific literature about the health claim and whether the claim is misleading. Thus, unlike the 540-day period available to publish a final rule to authorize a health claim (section 403(r)(4)(A)(i) of the FD&C Act), we may not have adequate time during a FDAMA health claim review period to address additional questions about the fiber as it relates to our authority in section 403(q) of the FD&C Act for purposes of nutrient declaration. Therefore, we plan to consider, on a case-by-case basis, whether the scientific evidence for a fiber that is the subject of a FDAMA health claim notification is sufficient to amend the list of dietary fibers in the dietary fiber definition for nutrient declaration.

(Comment 257) One comment asked us to clarify that, when a company makes a structure/function claim (*e.g.,* fiber helps maintain healthy digestive function), the substantiation for that claim would need to be based on a physiological effect. The comment said that companies already must substantiate all claims on the label and said we could issue a guidance document to clarify how substantiation of a claim should be done.

(Response) Structure or function claims are outside the scope of this rule. Therefore, we are making no clarifying statements with respect to structure or function claims in this final rule.

(Comment 258) One comment that objected to the proposed rule's mention of citizen petitions stated that the evidence for meeting the dietary fiber definition should meet the significant scientific agreement (SSA) standard for health claims and that small, short-term studies of varying quality with conflicting results would not suffice. The comment also said that a health claim authorization would require us to consider whether levels of an added non-digestible carbohydrate in foods are sufficient to cause the physiological effect. Other comments said we should only require evidence needed to

demonstrate the physiological effect of the added non-digestible carbohydrate, regardless of the amount in the finished food.

Another comment said that we should not expect the evidence to be equivalent to the significant scientific agreement (SSA) standard required for an authorized health claim. Instead, the comment said the evidence considered could include animal and in vitro studies or else the evidentiary standard would be the same as for structure function and health claims. The comment said we should provide the evidentiary standard in the final rule.

(Response) The comments express concern about the level and sufficiency of the scientific evidence necessary to demonstrate a fiber provides a beneficial physiological benefit to health and whether a certain level of such a fiber in food is needed in order to be considered a ''dietary fiber'' for purposes of a Nutrition Facts label declaration. A health claim and a nutrient declaration are distinct from each other. A health claim is a statement about the relationship between a food or a food component and risk of chronic disease or a health-related condition. A nutrient declaration on a food label is a statement of the amount of the nutrient in a serving of a food that is necessary to assist consumers to maintain healthy dietary practices. A beneficial physiological effect to human health for purposes of nutrition labeling may be based on a relationship between the nutrient (*e.g.,* dietary fiber) and a risk of chronic disease or a health-related condition, but that is not a prerequisite. Not all beneficial physiological effects are specific to chronic disease risk (*e.g.,* attenuation of postprandial blood glucose, improved bowel function). Thus, for purposes of the Nutrition Facts label, the evidence to support a beneficial physiological effect on human health may differ from that required for a health claim that relates to a relationship between an isolated or synthetic non-digestible carbohydrate and a risk of chronic disease. As part of the factors for mandatory declaration, the evidence for a relationship between the nutrient and a health-related physiological endpoint should be ''well-established'' which includes conclusive or strong evidence (79 FR 11879 at 11890). For evidence submitted as part of a citizen petition, we consider that the strength of the total evidence should demonstrate a specific beneficial physiological effect and that the beneficial effect should be replicated (Ref. 133), consistent with generally accepted scientific evidence to competent authorities in the Codex definition of dietary fiber in 2010 (79 FR 11879 at 11909). Accordingly, we do not consider animal or in vitro data to be sufficient. The physiology of animals is different than that of humans. In vitro studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to the consumption of foods and dietary substances (Ref. 134). Animal and in vitro studies can be used to generate hypotheses, investigate biological plausibility of hypotheses, or explore a mechanism of action of a specific food component through controlled animal diets; however, these studies do not provide information from which scientific conclusions can be drawn regarding the beneficial physiological effects of a food component, such as added non-digestible carbohydrates.

If a dietary fiber is the subject of an authorized health claim, we would consider the relationship between the fiber and the chronic disease risk or health-related condition, to provide a beneficial physiological benefit to health. In fact, we proposed, and include in this final rule, two dietary fibers in the definition of dietary fiber that are the subject of an authorized health claim. Prospectively, if we issue a final rule authorizing a health claim for a dietary fiber, we intend to modify the dietary fiber definition accordingly.

Moreover, we are not including a requirement that an isolated or synthetic non-digestible carbohydrate that has beneficial physiological benefit be included at or above a certain level in food in order to be declared as dietary fiber on the Nutrition Facts label. The dietary fiber declaration is not a health claim. We do not consider it necessary to titrate an amount of a dietary fiber in a food with the beneficial physiological effect of the fiber for purposes of a nutrient declaration. We recognize that dose-response relationships may exist between certain isolated or synthetic non-digestible carbohydrates and a beneficial physiological endpoint. We also recognize that the amount of an isolated or synthetic non-digestible carbohydrate will vary in similar and different marketed food products. The scientific evidence from a clinical study to support a beneficial physiological effect should provide an amount of the fiber that is a reasonable level to be expected in a food and relevant based on typical consumption of dietary fiber.

(Comment 259) Several comments said we should accept functional fibers (*i.e.,* isolated or synthetic non-digestible carbohydrates) identified in the IOM macronutrient report (Ref. 5) that summarizes the scientific evidence and where sufficient data documents their beneficial physiological effect. The comments said that the 2002 IOM report already included inulin and oligofructose as dietary fibers in table 7–1 and pages 345 through 346.

(Response) We disagree with the comments. The IOM (Ref. 5) did not consider whether the scientific evidence is sufficient to support a beneficial physiological effect to human health for specific isolated or synthetic non-digestible carbohydrates, but rather identified or classified which non-digestible carbohydrates would be considered to be a functional fiber and, therefore, would need to demonstrate a beneficial physiological effect to fall within the dietary fiber definition. For example, the IOM report states that inulin, oligofructose, and fructooligosaccharides ''could be classified as functional fibers where there are sufficient data to show positive physiological effects in humans'' (Ref. 135). Table 7–1 of the IOM report simply provides the general characteristics of what could qualify as a dietary fiber. The IOM did not evaluate the beneficial physiological effects of the individual non-digestible carbohydrates for the purpose of identifying those that meet the dietary fiber definition. Instead, the IOM provided a brief science review rather than an indepth review for the various physiological endpoints. The IOM stated that it is important to note that the discussions on the potential benefits of what might eventually be classified as functional fibers should not be construed as endorsements of those fibers.

(Comment 260) One comment said our consideration of physiological effects was arbitrarily limited to three endpoints. Many comments said we should use and incorporate into a guidance document the endpoints identified at the Vahouny Fiber Symposium, besides the three endpoints listed in the IOM report (and the proposed rule).

(Response) We disagree that we limited the physiological effects to three endpoints. In the preamble to the proposed rule (79 FR 11879 at 11910), we identified examples of physiological effects that are beneficial to human health, such as attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation. The terms ''such as'' indicate that the subsequent list of items is merely an illustration rather than an exhaustive list.

As for the comments' reference to Vahouny endpoints, at the 9th Vahouny Fiber Symposium, nine physiological health effects were identified: (1) Total/LDL cholesterol; (2) post-prandial glucose and insulin; (3) increased fecal bulk and laxation; (4) colonic transit time; (5) blood pressure; (6) colonic fermentation and short chain fatty acid production; (7) modulation of the colonic microflora; (8) weight loss, weight maintenance, and reduction in satiety; and (9) increased satiety (Ref. 136). We agree that lowering total/LDL levels, lowering post-prandial glucose levels, reducing gut transit time and improving laxation (fecal output), reduced blood pressure, and increased satiety associated with reduced energy intake and with possible associated outcomes on body weight are beneficial to human health. We consider colonic fermentation and short chain fatty acid production and modulation of the colonic microflora to be processes that may be associated with a physiological endpoint, rather than physiological endpoints themselves.

(Comment 261) One comment said that requiring added non-digestible carbohydrates to have a beneficial physiological effect will require research, and funds to support such research, to demonstrate such an effect. The comment said this would be a burden to firms who seek to develop new fibers. Another comment said we should accept the existing body of evidence as an appropriate demonstration of benefit, in many cases, without requiring new substantiation for a beneficial ingredient already in common use.

(Response) The final rule does not require a firm to demonstrate that there is a beneficial physiological effect before it can add an isolated or synthetic non-digestible carbohydrate to a food and declare it as part of the Total Carbohydrate declaration. We recognize that firms may develop new fibers and that we may not be aware of all of the added fibers that a manufacturer may be using as an ingredient in its products. For example, there may be some fibers that a manufacturer has self-determined to be GRAS for which we did not receive a GRAS notification. In addition, isolated or synthetic added fibers may be approved for use as a food additive. Moreover, even if a manufacturer self-determines that a fiber is GRAS, or there is a food additive approval for the fiber, whether the fiber has a beneficial physiological effect to health is a separate question. Therefore, given the potential uncertainties and possible inconsistencies in what fibers may be declared as dietary fiber, we define dietary fiber to include a listing of isolated or synthetic non-digestible carbohydrate that will provide a beneficial physiological effect. In this way, there is transparency in what added fibers are included in the definition that will assist consumers in maintaining healthy dietary practices and certainty in what must be declared for compliance purposes.

Numerous studies have already been conducted on many different types of isolated or synthetic non-digestible carbohydrates. We reviewed the publically available studies for various non-digestible carbohydrates. Based on our review, we found that a number of isolated or synthetic fibers have a demonstrated beneficial physiological effect to health (Ref. 137), and we include such fibers in the definition for dietary fiber (§ 101.9(c)(6)(i)). We consider the totality of the evidence when evaluating the beneficial physiological effect(s) of an isolated or synthetic non-digestible carbohydrate. We reviewed several non-digestible carbohydrates for which the publically available scientific evidence indicated mixed results, or appears to be insufficient. 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, we decline to make a determination on whether these non-digestible carbohydrates meet the definition of ''dietary fiber'' without first providing an opportunity for comment on the available scientific evidence for these non-digestible carbohydrates. We intend to publish a separate notice to seek comment on the available scientific data on these non-digestible carbohydrates to determine if we should consider additional non-digestible carbohydrates to be added to the list of dietary fibers. We also intend to publish a guidance document on the type of evidence we recommend be provided and the approach we plan to use to evaluate the beneficial physiological effect of a non-digestible carbohydrate.

If a manufacturer wants to add an isolated or synthetic non-digestible carbohydrate to the listing of fibers in the dietary fiber definition, it can petition us to amend the definition to include that fiber in the dietary fiber listing for these types of carbohydrates. Under § 10.30(b), the citizen petition must include all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position. Thus, any petition to request an amendment to the definition to include an additional dietary fiber should include all publically available evidence relevant to the review about a beneficial effect of the isolated or synthetic added non-digestible carbohydrate.

(Comment 262) The proposed definition of dietary fiber would mention citizen petitions submitted to us pursuant to § 10.30. One comment said that requiring a citizen petition to seek approval of currently used fibers will cause disruption in the food supply. The comment said there could be a backlog of petitions.

Several comments raised concerns that a review of new fibers that manufacturers want to include as part of a listing of fibers within the definition of dietary fiber will result in lag time resulting in manufacturers dropping the extrinsic fiber they use in products. With a label compliance period of 2 years, the comments questioned whether we could review and respond to citizen petitions within this time period and allow manufacturers to design and secure new packaging. Some comments said that, once we begin implementing the final rule, the time for review of subsequent petitions may be unreasonable and that some added non-digestible carbohydrates that are currently declared as dietary fiber may have to come off the Nutrition Facts label. The comments said that a lengthy petition process undermines the overall purpose to promote the healthful consumption of dietary fibers and that industry would have to make the other label changes in response to the final rule without knowing the amount of dietary fiber to declare and could lose dietary fiber health claims. Some comments said that premarket review should only apply to those fibers that we did not identify as dietary fiber. One comment said that we should issue the guidance document along with the listing of the dietary fibers, including the commonly used added non-digestible carbohydrates that we have determined to have a beneficial effect without submission of formal petitions.

(Response) We recognize that there may be uncertainty about whether certain isolated or synthetic non-digestible carbohydrates, currently in use by manufacturers and declared as dietary fiber, meet the dietary fiber definition. We proposed to list isolated or synthetic non-digestible carbohydrates that we have been determined to have a physiological effect that is beneficial to human health in § 101.9(c)(6)(i), and the final rule includes additional dietary fibers in the definition based on the review of

publically available evidence (Ref. 137). These reviews identify a number of isolated or synthetic non-digestible carbohydrates for which the publically available scientific evidence supports a beneficial physiological effect to human health.

With respect to the concern about a possible backlog in petitions, we did not receive any comment about numbers of specific isolated or synthetic fibers used as an ingredient in food that would not otherwise have been included in our review of publically available evidence. Our review was necessarily limited to the publically available evidence on such fibers. Therefore, to the extent there are uses of isolated or synthetic fibers that are specific to a particular manufacturer, we will need to consider those case-by-case in the context of petition submitted under § 10.30 and consider the resources needed to evaluate such requests as we receive them.

(Comment 263) Several comments said that certain added non-digestible carbohydrates meet the dietary fiber definition. Some comments would add psyllium husk to the list of approved fibers and said that there is a wealth of clinical trial data on inulin which met the dietary fiber definition based on the 2002 IOM report and that there were data to support galactooligosaccharides (GOS) as a dietary fiber.

Other comments supported the inclusion of bamboo fiber, soy fiber, pea fiber, wheat fiber, cellulose, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber. One comment said that cellulose is GRAS under a ''prior sanctioned category.''

(Response) We agree that psyllium husk meets the dietary fiber definition (§ 101.81(c)(2)(B)) and have revised the definition accordingly. We have reviewed the publicly available scientific evidence for some of the isolated or synthetic non-digestible carbohydrates, including cellulose (Ref. 137). Based on our review, we determined that the scientific evidence supports a showing of a beneficial physiological effect to human health from the following fibers: Cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. Cellulose was determined to improve bowel function. Guar gum, pectin, locust bean gum and hydroxypropylmethylcellulose were determined to lower blood total and/or LDL cholesterol levels. Therefore, we include these isolated or synthetic dietary fibers in the final rule's definition of dietary fiber.

As for the other carbohydrates mentioned in the comments, the comments did not provide data on beneficial physiological effects, so we are unable to conduct a scientific review. However, we intend to publish a separate notice to seek comment on the available scientific data on non-digestible carbohydrates to assist us in the review of the scientific evidence. Publically available clinical trial data will be identified and summarized for non-digestible carbohydrates, including inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber.

(Comment 264) Several comments stated that we should provide guidance to industry on submissions to demonstrate physiological effects that are beneficial to humans before we issue the final rule so that meaningful comments can be provided on the process. The comments said that our failure to provide notice and an opportunity to comment on a guidance document would violate the Administrative Procedure Act. Other comments stated that, once we have identified the dietary fibers, we should reopen the dietary fiber section of the proposed rule for public comment, including the requirements for defining dietary fiber.

(Response) We intend to issue guidance concerning the evidence to submit and our approach to reviewing the science in a request to amend the dietary fiber definition to support a fiber's beneficial physiological effect to human health. We do not consider it necessary to publish the draft guidance before the final rule is published. There will be an opportunity to submit comments to the guidance, consistent with our good guidance practices regulation at 21 CFR 10.115.

To the extent the comment asserts a failure to receive comment on the draft guidance before the publication of the final rule violates the Administrative Procedure Act (APA), we disagree. The publication of a draft guidance document is not a general notice of proposed rulemaking to which the APA requirements under 5 U.S.C. 553 would otherwise apply. Furthermore, we provided adequate notice and opportunity to comment on our proposed definition of dietary fiber and provided the Codex definition that includes isolated or synthetic non-digestible carbohydrates that have been shown to have a beneficial physiological effect to health as demonstrated by generally accepted scientific evidence to competent authorities (79 FR 11879 at 11909). We provided examples of beneficial physiological effects (*e.g.,* attenuation of blood glucose and cholesterol levels and improved laxation) and the reference to the IOM reports (Ref. 138) (id.). We also asked for comment on the IOM definition of dietary and functional fibers dating back to the 2007 ANPRM (id.). Therefore, we decline to delay issuance of the final rule as suggested by the comments. Furthermore, the administrative process for submitting a request to amend the definition of dietary fiber is in § 10.30. We have not proposed changes to that regulation in the context of this rulemaking, and, therefore, comments to § 10.30 are outside the scope of this rule.

(Comment 265) Many comments supported the proposed definition of dietary fiber, but for different reasons. Some comments supported the proposed definition because, according to the comments, dietary fibers should show a physiological benefit, and the proposed definition would facilitate the development of healthier products. Other comments said the proposed definition aligns with the IOM and Codex definitions for dietary fiber.

Several comments, however, asked us for clarification. Some comments asked us to clarify what we meant by ''intact and intrinsic in plants'' and ''isolated and synthetic.''

(Response) Consistent with the IOM fiber report (Ref. 138), we consider ''intact'' as having no relevant component removed or destroyed and ''intrinsic'' as originating and included wholly within a food. Intact and intrinsic fibers are naturally present such that they are integrated within the plant matrix and contain other nutrients naturally present in proportions that exist in the plant cell. For example, brans, which are obtained by grinding, are anatomical layers of the grain consisting of intact cells and substantial amounts of starch, protein and other nutrients. Non-digestible carbohydrates that are created during normal food processing (*e.g.,* cooking, rolling, or milling) are intrinsic and intact (*e.g.,* non-digestible (resistant) starch in flaked corn cereal). However, a resistant starch that has been extracted and isolated from the flaked corn cereal, such that it is no longer part of the food matrix (intrinsic) and no longer consists of relevant food components (intact), often with an increased concentration of non-digestible carbohydrates, would be considered an isolated non-digestible carbohydrate. The term ''isolated'' is used to describe isolated non-digestible carbohydrates that are isolated from plant sources such that they are no longer intrinsic or intact. Some of these isolated fibers can be further modified. The term ''synthetic'' is used to describe

synthetic non-digestible carbohydrates that are not isolated from plant sources, but rather chemically synthesized.

We note that the distinction between ''intrinsic and intact'' and ''isolated or synthetic'' is important because foods that contain intrinsic and intact fibers include naturally occurring dietary fibers that contain other nutrients normally found in foods that may be associated with beneficial physiological effects. Such beneficial physiological effects, associated with natural dietary fibers, cannot be assumed to exist when non-digestible carbohydrates are isolated from foods, and especially when synthesized. We note that the IOM (2002) cited an earlier IOM report (Ref. 139), which stated that, while dietary fiber intake is associated with decreased risk or improvements in several chronic diseases, there is no conclusive evidence that dietary fiber, rather than the other components of vegetables, fruits, and cereal products, reduces the risk of those diseases. Furthermore, the IOM stated that there are many constituents of whole grains, in addition to dietary fiber, that may reduce the risk of CHD. These statements emphasize the inherent benefits of intact and intrinsic non-digestible carbohydrates.

(Comment 266) Several comments would change ''intact and intrinsic in plants'' to ''intact or intrinsic.'' The comments said that, without this change, the definition would exclude almost all fiber ingredients.

(Response) We disagree with the comment. These two terms collectively require that the non-digestible carbohydrate is naturally present such that it is integrated within the plant matrix and contains other nutrients naturally present in proportions that exist in the plant cell. These conditions (integration in the plant matrix and providing proportional nutrients that are present naturally in the plant cell) are considered to be inherent in the health benefits associated with naturally occurring dietary fibers. The definition of dietary fiber includes these intact and intrinsic fibers in addition to isolated or synthetic fibers that have a beneficial physiological effect. Therefore, we disagree that the definition of dietary fiber would ''exclude almost all fiber ingredients'' if we retained ''intrinsic and intact in plants'' in the definition. We decline to revise the definition as suggested by the comment.

(Comment 267) One comment suggested changing ''isolated and synthetic'' to ''isolated or synthetic.''

(Response) We agree with the comment. Non-digestible carbohydrates that are added to foods are either isolated from foods or synthesized, and so we have revised the rule as suggested by the comment.

(Comment 268) One comment stated that brans, obtained by mechanical action (grinding), are a layer of grains and therefore should be a dietary fiber.

(Response) We agree that brans that are obtained by mechanical actions are unique and, unlike other fibers subject to mechanical actions, are intact and intrinsic and therefore meet the dietary fiber definition. Bran is the hard outer layer of cereal grain and is obtained by mechanical processing. Bran is rich in dietary fiber, as well as other nutrients including starch, protein, vitamins, and minerals. Furthermore, naturally occurring dietary fiber is part of the matrix in bran. Therefore, dietary fiber in bran is intact and intrinsic.

(Comment 269) One comment opposed to the proposed definition of dietary fiber stated that, as is the case for most dietary components, the health benefits of dietary fiber have only been studied in clinical trials in isolated forms rather than in their intrinsic and intact forms. The comment said it is nearly impossible to separate out any associated health outcome from other bioactive components within the food matrix.

(Response) We agree that the health benefits of non-digestible carbohydrates have been studied in numerous clinical trials in isolated forms. These clinical trials have been used to identify those added non-digestible carbohydrates that meet the dietary fiber definition (Ref. 137). Fiber-containing fruits, vegetable, and grain products have been shown to have beneficial health effects via such clinical trials, as well as observational studies on chronic disease risk (*e.g.,* CHD). The collective information from such studies has been used to substantiate the evidence for the relationship between soluble fibers and CHD risk (*e.g.,* §§ 101.77 and 101.81), as well as the establishment of an AI for dietary fiber (Ref. 36). Thus, the health benefits of foods that contain naturally occurring dietary fibers have already been substantiated.

(Comment 270) Several comments asked us to clarify the meaning of a ''physiological effect that is beneficial to human health.''

(Response) In the preamble of the proposed rule (79 FR 11879 at 11909), we explained that a regulatory definition for dietary fiber, such as those consistent with the IOM and Codex, should be one that emphasizes its physiological effect that is beneficial to human health to assist consumers in maintaining healthy dietary practices. We also identified, in the preamble to the proposed rule (id. at 11910), physiological effects that are beneficial, such as attenuation of blood glucose and cholesterol levels (*i.e.,* total or LDL). We also would consider the lowering of blood pressure to be a beneficial physiological effect. The attenuation/lowering of these biomarkers (lowering of blood glucose and cholesterol levels and lowering of blood pressure) are associated with reduced risk of type 2 diabetes or CVD. Another outcome we consider a beneficial physiological effect is increased satiety, where an isolated or synthetic non-digestible carbohydrate is associated with a reduced energy intake. A reduced energy intake can reduce the risk of being overweight or obese. In addition, improved laxation and bowel function is a beneficial physiological effect where an isolated or synthetic non-digestible carbohydrate shows a reduced intestinal transit time or an increase in the passage of stools. These outcomes result in an increased rate of defecation to improve bowel function. Increased absorption of minerals, such as calcium, are considered to provide beneficial physiological effects because increased absorption of calcium is associated with increased bone mineral density which may reduce osteoporosis. For the purposes of Nutrition Facts labeling, we do not consider processes and mechanisms (*e.g.,* fermentation) per se as beneficial physiological effects for determining whether an isolated or synthetic non-digestible carbohydrate meets the definition of dietary fiber. Fermentation is not a physiological benefit; rather, it is a process associated with the digestion of the non-digestible carbohydrate itself. Unless there is information to support a beneficial physiological effect, such non-digestible carbohydrates would not assist consumers in maintaining healthy dietary practices. As stated in the IOM Diet and Health report (Ref. 139), while dietary fiber intake is associated with decreased risk or improvements in several chronic diseases, there is no conclusive evidence that it is dietary fiber, rather than the other components of vegetables, fruits, and cereal products, that reduces the risk of those diseases. There are many constituents in whole grains, in addition to dietary fiber, that may reduce the risk of CHD. Therefore, unlike the inherent benefits of intact non-digestible carbohydrates, isolated or synthetic non-digestible carbohydrates must be independently shown to have physiological health benefits, and not all such fibers have these types of benefits. One example of a process that is not considered to be a

beneficial physiological effect is fermentation. Another example is changes in the microbiota in the large intestine as a result of the consumption of non-digestible carbohydrates. Physiological effects that are beneficial (*e.g.,* satiety) may be an outcome of a process, such as fermentation and changes in the colonic microbiota.

(Comment 271) One comment said that the food industry will be able to demonstrate at least one physiological effect for each type of isolated or synthetic non-digestible carbohydrate and those effects may be less significant than the benefits from intact fiber. For example, the comment said, referring to EFSA, reduced post-prandial glycemic response would apply for all isolated or synthetic non-digestible carbohydrates (compared to sugar). The comment also said that the evidence showing that isolated or synthetic non-digestible carbohydrates are beneficial is often inconsistent and based on poorly established biomarkers. Thus, according to the comment, added fiber may have less benefit than its intact counterpart.

(Response) Without reviewing the evidence on the beneficial physiological effects of non-digestible carbohydrates, it is premature for us to state whether or not at least one physiological effect for each type of isolated or synthetic non-digestible carbohydrate can be demonstrated. We disagree with the comment, referring to EFSA, that reduced post-prandial glycemic response would apply for all isolated or synthetic non-digestible carbohydrates. As an example, EFSA concluded that a relationship has not been established between acacia gum and reduced postprandial glycemic response (Ref. 140). While some studies may have used poorly established biomarkers, our science reviews have included endpoints that are reliable measurements of physiological effects (*e.g.,* total and LDL cholesterol levels, and intestinal transit time and frequency of bowel movements as a measure of laxation) (Ref. 137).

(Comment 272) One comment said there is an insufficient understanding of the complex interactions among and between gut microbiota and the human host. The comment said these interactions are affected by total fiber intake, but the effects of specific fiber components can be difficult to define. Another comment said that we should indicate that the list of beneficial physiological effects is not exhaustive and is evolving.

(Response) We agree that scientific knowledge of beneficial physiological effects to human health is evolving. The physiological endpoints that we have considered in our science reviews include those that are supported by the current scientific evidence (Ref. 137). We recognize that, as the science evolves, the list of dietary fibers in the definition may change. Thus, our list is not exhaustive.

(Comment 273) One comment presumed that, based on the proposed factor of 2 kcal/gram, ''non-digestible carbohydrates'' includes partially and totally digested carbohydrates. The comment said that, for this reason, we should define ''non-digestible carbohydrate'' to mean ''carbohydrates that are partially or totally fermentable by colonic microflora.''

(Response) As provided in the IOM fiber report (Ref. 138), ''non-digestible'' is an adjective that implies a substance is not broken down to simpler chemical compounds in the living body chiefly through the action of secretion-containing enzymes such as the saliva and the gastric, pancreatic, and intestinal juices in the alimentary canal. Thus, non-digestible carbohydrates are not digested by human enzymes and pass into the colon where they may or not be fermented by colonic microflora, and so we decline to revise the rule as suggested by the comment.

(Comment 274) Many comments disagreed with the proposed definition of dietary fiber. Several comments said that the amount of dietary fiber declared in the Nutrition Facts label should continue to be based on AOAC methods because the measured amount aligns more closely to the chemical composition and structure and is more feasible and practical. The comments also said that natural and isolated fibers are chemically identical.

Other comments argued that using the more recently developed methods (*e.g.,* AOAC 2011.25) allows for a comprehensive isolation and quantitation of all dietary fiber ingredients, without relying on a definition. The comments said that the newer AOAC methods capture the more highly soluble non-digestible carbohydrates (*i.e.,* non-digestible oligosaccharides) that were not captured in the methods available at the time when the IOM considered the definitions for dietary fiber and therefore not considered in the 2002 IOM report.

(Response) We disagree with the comments. While the AOAC methods may be more feasible, practical, and inclusive in measuring non-digestible carbohydrate compared to the amount of non-digestible carbohydrates that meets the dietary fiber definition, these methods are not able to distinguish and measure non-digestible carbohydrates that do not provide a beneficial physiological effect. Therefore, relying on AOAC methods can overestimate the amount of non-digestible carbohydrates that can assist consumers in maintaining healthy dietary practices.

We agree that the newer methods that can measure lower molecular weight non-digestible carbohydrates were not available when the IOM was developing the dietary fiber definitions. However, the availability of analytical methods had no bearing on the IOM's definitions, and the IOM definition included the lower molecular weight non-digestible oligosaccharides as part of the definition of dietary fiber. The focus was on ensuring that all added non-digestible carbohydrates that meet the dietary fiber definition have a beneficial physiological effect. Even though natural and isolated fibers can be identical chemically, they may not provide the same beneficial physiological effect.

(Comment 275) Several comments supported using the American Association of Cereal Chemist International (AACCI) definition because the AACCI definition was consistent with the Codex definition and would support global harmonization. The AACCI definition is:

> Dietary fiber is the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin, and associated plant substances. Dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation.

(Response) We decline to revise the rule as suggested by the comment. While the AACCI definition distinguishes between natural and isolated or synthetic non-digestible carbohydrates, it does not specify the need for isolated or synthetic non-digestible carbohydrates to demonstrate a beneficial physiological effect. Foods that contain naturally occurring dietary fibers are usually a mixture of polysaccharides that are integral components of the plant cell wall or intercellular structure. Naturally occurring dietary fibers have the three-dimensional plant matrix that is responsible for some of the physicochemical properties attributed to dietary fiber (Ref. 138). Furthermore, foods that contain naturally occurring dietary fibers contain other nutrients normally found in foods that may be associated with beneficial physiological effects. Such beneficial physiological

effects, associated with natural dietary fibers, cannot be assumed to exist when non-digestible carbohydrates are isolated from foods, and especially when synthesized.

We also disagree that the AACCI definition is consistent with the Codex definition. The Codex definition includes the need for isolated or synthetic fibers to have been shown to have a physiological effect of benefit to health.

(Comment 276) One comment said we should establish a definition that is consistent with other long-recognized definitions regardless of whether that definition is based on clinical evidence or to include greater than DP >3. The comment, however, did not identify any other definitions.

(Response) To the extent the comment suggests that we should not consider clinical evidence of beneficial physiological effect or length of monomeric units in the dietary fiber definition, we disagree. Consistent with the IOM, we recognize that those non-digestible carbohydrates that have been isolated from foods or synthesized need to demonstrate a physiological benefit in humans and may include a DP of ≥3. Evidence of such a benefit is obtained primarily through human clinical studies that have evaluated the effect of isolated or synthetic non-digestible carbohydrates on individual physiological effects.

(Comment 277) Several comments stated that, for the sake of harmonization, we should adopt the Codex definition, but without footnote 2. Footnote 2 states that the decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

(Response) We decline to revise the rule as suggested by the comments. Codex defines dietary fiber to mean carbohydrate polymers with ten or more monomeric units, which are not hydrolyzed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed;
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic, or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities; and
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

The Codex and IOM definitions are consistent with our definition in that they specify that isolated or synthetic non-digestible carbohydrates that are added to foods need to show a beneficial physiological effect. The footnote is left up to competent authorities, such as FDA, and we have chosen to include non-digestible oligosaccharides with a DP of 3 to 9 monomeric units as part of the dietary fiber definition to include fibers with beneficial physiologic effects regardless of size.

(Comment 278) One comment stated that the dietary fiber definition should include non-digestible carbohydrates with a DP = 2 (*e.g.,* non-digestible disaccharides such as galacto-oligosaccharides (GOS)) to capture all added non-digestible carbohydrates that have a beneficial physiological effect.

(Response) Non-digestible oligosaccharides, such as GOS, vary in size. GOS is a mixture of β-linked polymers in various configurations and the DP ranges from 2 to 8 (Ref. 141). The currently available AOAC methods measure non-digestible carbohydrates at a DP ≥3. Furthermore, non-digestible monosaccharides and disaccharides meet the definition of sugar (see part II.H.3.n). Therefore, we disagree that non-digestible mono- and disaccharides should be considered as dietary fiber.

(Comment 279) One comment said that the IOM definition could be enhanced by including other minor substances that are intrinsic in plant fibers to make it more compatible with a variety of other definitions, such as those issued by Codex and AACCI.

(Response) The IOM (and Codex) definition did not address minor components such as waxes, cutin, and suberin, that are intrinsic in plant fibers. However, like lignin, waxes, cutin, and suberin are not carbohydrates that are closely associated with non-digestible carbohydrates within plants. Therefore, like lignin, these minor components are included in the amount of intact and intrinsic fibers that would be declared as dietary fiber. Newer methods, such as AOAC 2011.25, include waxes, cutin, and suberin in the measurement of non-digestible carbohydrates.

(Comment 280) Several comments said that the proposed requirement to demonstrate a physiological benefit is a drastic shift from the analytical-based approach and dietary fiber would be the only nutrient listed in the Nutrition Facts label that requires a physiological benefit. The comments said our approach contradicts with the rationale (chemical composition) for not excluding certain fatty acids (*i.e.,* stearic acid) from the definition of total fat.

(Response) We disagree with the comments. The definition for saturated fat in § 101.9(c)(2)(i) includes all fatty acids without double bonds, and the accepted analytical methods capture all of the saturated fatty acids, including stearic acid. In adopting this definition, we addressed the issue of the inclusion or exclusion of individual saturated fatty acids and determined that a chemical definition which includes all fatty acids containing no double bonds was the appropriate approach to define saturated fat (see 79 FR 11879 at 11894). The scientific evidence to recommend that saturated fatty acids provide no more than 10 percent of total calories does not exclude stearic acid. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11894), the scientific evidence in the 2010 DGA to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid and, instead, relates to the intake of total saturated fatty acids. Therefore, the DRV that is based on 10 percent of calories includes stearic acid. The DV of 28 grams for dietary fiber is based on the AI set by the IOM for total fiber (Ref. 36). The DV reflects the IOM definition for dietary fiber which excludes those isolated or synthetic non-digestible carbohydrates that do not provide a beneficial physiological effect. Furthermore, the listing of individual nutrients based on physiological effect is not new. Soluble and insoluble dietary fibers can be voluntarily listed separately because of their distinct physiological effects.

(Comment 281) One comment that objected to the proposed definition said that the criteria for listing dietary fiber differ from the criteria used for protein. The comment said there are many sources of protein (soy protein) that are used as ingredients, but they are not reviewed individually for their health benefits.

(Response) Protein is listed because it is a major macronutrient category, as is the case for total carbohydrate. Protein contains amino acids that are essential in the diet. Dietary fiber is not essential in the diet and is listed because of its beneficial physiological effects, rather than essentiality. The DV for protein is based on providing a certain percent of calories, relative to total fat and carbohydrate, whereas the DV for dietary fiber is based chronic disease risk. Therefore, the basis for declaring protein, including protein ingredients, is not comparable to dietary fiber.

As for the comment's mention of soy protein, soy protein that is naturally

present in a food is an intact and intrinsic protein, and thus, is a protein for purposes of nutrient declaration.

(Comment 282) One comment that objected to the proposed definition of dietary fiber said that vitamins naturally present in food and those added through fortification can work effectively together to fulfill nutrient needs in the same manner that added fibers can interact with intrinsic fibers to meet the requirement.

(Response) We agree that different forms of naturally occurring and isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition can work together to assist consumers in maintaining healthy dietary practices, but this fact does not necessitate a change to the definition. The comparison of different sources of fibers to different sources of the same vitamin, as the comment suggests, is not accurate. Fibers represent a heterogeneous group of compounds, and not all isolated or synthetic non-digestible carbohydrates may provide a beneficial physiological effect.

(Comment 283) One comment said that we should base the listing of dietary fiber on physicochemical properties instead of physiological benefit. The comment would define dietary fiber as ''non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin.'' The comment said this definition would allow any review or consideration of dietary fiber to be predicated on its physicochemical characteristics.

(Response) We disagree that the declaration of dietary fiber should be based on physicochemical properties. Although a physiochemical property, such as viscosity (degree of thickness and resistance to flow), is linked to health benefits, it is not known at what level of viscosity a dietary fiber begins to have a physiological effect (see 79 FR 11879 at 11911). Moreover, there are no scientifically valid methods available that we could use to measure the amount of various dietary fibers defined by their physicochemical properties in various food matrices, whereas scientifically valid methods to measure soluble and insoluble fiber are available.

(Comment 284) One comment stated that, instead of using the proposed dietary fiber definition, we should require the listing of soluble and insoluble fiber and conduct an education campaign to understand the difference which might prove to be more beneficial for consumers.

(Response) We disagree that soluble and insoluble fiber should be listed instead of the dietary fiber definition. Both soluble and insoluble fibers should provide a beneficial physiological effect to assist consumers in maintaining healthy dietary practices. Under § 101.9(c)(6)(i) of the final rule, soluble fiber and insoluble fiber that meet the dietary fiber definition may be declared voluntarily.

As for education campaigns, we address such issues in part II.B.1.

(Comment 285) One comment said that all insoluble non-digestible carbohydrates should meet the proposed fiber definition. The comment said that cellulose and lignin do not dissolve in water and are not digested by bacteria in the colon adding bulk to the stool for improved laxation. Furthermore, the comment said that the IOM noted that the body of evidence indicates that non-fermentable fiber sources (often isolated as insoluble fiber) promote laxation and that improved laxation is an established physiological effect that is beneficial to human health.

(Response) We agree that if the scientific evidence for a particular isolated or synthetic non-digestible carbohydrate demonstrates improved laxation, the fiber would meet the dietary fiber definition because improved laxation is a beneficial physiological effect. However, we are not able to conclude that all isolated or synthetic non-digestible carbohydrates improve laxation and therefore meet the dietary fiber definition. Cellulose is a fiber for which the science supports its role in improved laxation (Ref. 138). Therefore, we are listing cellulose in the definition of dietary fiber.

With respect to lignin, and as we stated in the preamble to the proposed rule (79 FR 11879 at 11900), all dietary fibers, with the exception of lignin, are carbohydrate polymers. Although lignin is not a carbohydrate, it is tightly bound to other dietary fibers and cannot be easily isolated using AOAC or other reliable and appropriate analytical procedures. It is, therefore, included in the declaration of dietary fiber.

(Comment 286) One comment stated that fiber-containing ingredients can have a variety of physiological effects that do not depend on whether they are characterized as intrinsic and intact or isolated and synthetic. The comment said that requiring added non-digestible carbohydrates demonstrate a physiological benefit falsely implies a nutritional superiority of fibers that have not been separated from their natural source. The comment added that such a distinction that is not factual from a food chemistry or physiological perspective. Other comments noted that the dietary fiber definition has the potential to be exclusionary and limit the benefits that consumers realize from certain fiber sources that may not meet the dietary fiber definition. One comment stated that all non-digestible carbohydrates have a physiological effect by virtue of not being digested and present in the colon. Another comment questioned why there is not a call to demonstrate physiological benefits of natural dietary fibers.

(Response) We agree that some fiber-containing ingredients may have a variety of physiological effects that do not depend on whether they are characterized as intrinsic and intact or isolated or synthetic. The presence of a fiber in the colon alone is not necessarily beneficial. While one comment did not provide an example of how non-digestible carbohydrates have a physiological effect by virtue of not being digested and present in the colon, not all measurements in a study necessarily demonstrate a physiological effect, much less a beneficial physiological effect. For example, fermentation and changes in the colonic microflora is a process rather than a physiological effect.

Moreover, unlike foods that contain only isolated or synthetic non-digestible carbohydrate as a fiber source, foods that contain intrinsic and intact fibers contain other nutrients normally found in foods, and the foods with these fibers are associated with beneficial physiological effects. Such beneficial physiological effects cannot be assumed to exist when non-digestible carbohydrates are isolated from foods and thereby separated from other nutrients found in the food. The same is true for synthetic fibers which do not have other nutrients present that are found in the food.

(Comment 287) One comment stated that isolated plant fibers are chemically identical to intrinsic fibers and have no similarity with synthetic fibers. The comment said that we should not hold isolated fibers to the same standards as synthetic fibers.

(Response) While some isolated non-digestible carbohydrates may be chemically identical or similar to the forms (including molecular weight) that occur naturally in food, the basis for isolated non-digestible carbohydrates showing a beneficial effect is not chemical composition. Isolated or synthetic fibers are similar in that they are not part of the three-dimensional plant matrix that is responsible for some physicochemical properties attributed to dietary fiber (Ref. 138) or in foods that contain other nutrients normally found in foods that may be associated with beneficial physiological effects.

(Comment 288) Some comments objecting to the proposed definition of

dietary fiber stated that consumers will not easily understand our dietary fiber and functional fiber definition, and these definitions will cause consumer confusion. One comment said that changing the declaration of dietary fiber could cause consumer confusion when a product no longer lists dietary fiber.

(Response) The comments may have misinterpreted the rule. The rule does not change the term ''dietary fiber'' on the Nutrition Facts label, nor does it use the term ''functional fiber'' on the Nutrition Facts label. Consumers generally view dietary fiber as being a beneficial nutrient (Ref. 142). Including fibers in the definition of dietary fiber that do not have a beneficial physiological effect would be misleading in that the fiber listed would not assist consumers in maintaining healthy dietary practices. Therefore, ensuring that all non-digestible carbohydrates that are declared as dietary fiber have a beneficial physiological effect will provide a consistent benchmark with respect to the types of fibers included in the declaration so that consumers can understand the relative significance of the amount of dietary fiber declared in a product in the context of a total daily diet. We expect that some dietary fiber label declarations will need to change to comply with the definition of dietary fiber. Consumers may have questions about fiber ingredients based on changes in dietary fiber declarations and will be better informed as to the dietary fiber content of a product that provides a beneficial nutrient.

(Comment 289) One comment said that our rule would prevent consumers from knowing how much fiber in many foods has been linked to a lower risk of disease and how much fiber has some ''physiological benefit'' that may be far less consequential.

(Response) While there can be a distinction between physiological benefit and lower chronic disease risk, a number of the endpoints for a physiological benefit also are surrogate endpoints for chronic disease risk (*e.g.,* fasting blood cholesterol and glucose levels, blood pressure). Furthermore, requiring that an added non-digestible carbohydrate meet the dietary fiber definition will better identify those dietary fibers that have a beneficial role in human health than the current process of declaring dietary fiber solely based on analytical methods. A dietary fiber is not necessarily limited to one physiological health benefit, and there may be multiple types of dietary fibers present in a particular food. Thus, to the extent the comment suggests the Nutrition Facts label needs to list individual dietary fibers so that consumers can match particular beneficial physiological effects with each, we disagree and consider such an approach to be unwieldy.

(Comment 290) One comment said that the proposed definition of dietary fiber, insofar as it states that non-digestible carbohydrates have a physiological effect that is beneficial to human health, will reduce the availability of high fiber products and reduce their use as ingredients. The comment said that regulatory hurdles will discourage manufacturers from innovating fiber containing products and reduce the intake of dietary fiber. Another comment stated that these ingredients are used as thickeners, bulking agents, or anti-caking agents, in addition to fiber fortification.

(Response) We agree that many non-digestible carbohydrates are added to foods for a technical effect other than as a source of dietary fiber. There are numerous non-digestible carbohydrates approved as foods additives and GRAS notifications submitted to FDA about manufacturers' determinations that certain non-digestible carbohydrates added to food provide a technical effect and are safe. The final rule does not prohibit isolated or synthetic non-digestible carbohydrates from being added to foods.

Manufacturers have a responsibility to ensure that the ingredients they use are safe and do not adulterate the food and to obtain FDA pre-market approval as appropriate. Innovative non-digestible carbohydrate-containing products have been shown to provide a variety of technical effects. If the isolated or synthetic non-digestible carbohydrate is included in the listing of fibers in the definition of dietary fiber, then the dietary fiber must be included in the declaration of declared as dietary fiber in addition to the declaration of Total Carbohydrate. If the added fiber is not included in the listing of dietary fibers in the definition, the added fiber is not a dietary fiber and must not be part of the declaration of dietary fiber; instead, the added fiber would only need to be included in the declaration of Total Carbohydrate.

(Comment 291) Some comments said that there may be a need to make significant product changes to maintain current dietary fiber label values. The comments explained that a dietary fiber that is now a significant source may no longer be a significant source if we change the definition of dietary fiber. The comments said that companies would lose their ability to make fiber claims that have been marketed for years and that significant reformulation would be needed to be eligible for claims.

(Response) We recognize that some non-digestible carbohydrates added to foods may not meet the dietary fiber definition in the final rule, resulting in a lower amount of dietary fiber being declared on the Nutrition Facts label. We also recognize that the definition may affect the number of foods that voluntarily make a nutrient content or health claim. However, we disagree that this is a sufficient basis for not requiring added non-digestible carbohydrates to meet the dietary fiber definition; the declaration of dietary fiber should assist consumers in maintaining healthy dietary practices.

(Comment 292) One comment said that the dietary fiber definition would encourage the food industry to market cookies, candies, ice cream, refined grains, and other highly processed and relatively non-nutritious foods that would compete with the fiber-rich fruits, vegetables, beans, and whole grains that are linked to a lower risk of disease.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, evidence to suggest that the dietary fiber definition would encourage the food industry to market cookies, candies, ice cream, refined grains, and other highly processed and relatively non-nutritious foods that would compete with the fiber-rich fruits, vegetables, beans, and whole grains that are linked to a lower risk of disease. Furthermore, the current process of relying solely on analytical methods does not ensure that isolated or synthetic non-digestible carbohydrates provide any beneficial physiological effect. While we do have a fortification policy in place (see § 104.20), manufacturers can and currently do add these non-digestible carbohydrates to a variety of foods that may or may not have a beneficial physiological effect. The final rule's definition of dietary fiber would prevent the declaration of isolated or synthetic non-digestible carbohydrates that have no beneficial physiological effect as dietary fiber. If there were to be a change in the marketing of snack foods, it would more likely result in a reduction of the use of isolated or synthetic non-digestible carbohydrates that do not meet the dietary fiber definition.

(Comment 293) One comment said that the definition could result in unintended consequences (*i.e.,* reduced dietary fiber intake) because only dietary fibers would be based on physiological function.

(Response) We disagree with the comment. Those dietary fibers that

occur naturally in food must be declared as dietary fiber. Information on the amount of isolated or synthetic non-digestible carbohydrates that demonstrate a beneficial physiological effect to human health can assist consumers in maintaining healthy dietary practices. While the dietary fiber declaration may need to be revised to a lower value in some foods based on the definition of dietary fiber, that does mean that consumption of the various carbohydrates will change or that consumers will not seek out other foods to achieve a desired dietary fiber intake.

(Comment 294) One comment stated that some added fibers have adverse effects (flatulence, exacerbation of irritable bowel syndrome) that outweigh their benefits.

(Response) While the comment did not provide information as to which isolated or synthetic non-digestible carbohydrates have adverse effects, the overall health implications of fibers in the context of the daily diet have been considered. While the safety of added fibers is outside the scope of this rule, we have approved many isolated or synthetic non-digestible carbohydrates as food additives, and there have been determinations that certain non-digestible carbohydrates added to food provide a technical effect and are safe. Furthermore, natural dietary fibers also can cause flatulence.

(Comment 295) One comment asked whether dietary fibers that are currently declared in the Nutrition Facts label would have to be removed until approved. The comment said we should allow industry to continue using and labeling fibers already on the market during the authorization process.

(Response) The compliance date for the final rule is 2 years after the effective date, except that the compliance date for manufacturers with less than $10 million in annual food sales is 3 years after the final rule's effective date. After the compliance date, foods must declare dietary fiber in accordance with the requirements of the final rule. Thus, if fibers are included as an ingredient in a food and do not meet the definition of dietary fiber after that date, the declaration of dietary fiber must not include those fibers. We are not aware of how many isolated or synthetic fibers may be used as an ingredient in food that we have not already evaluated and that are not already included in the definition of dietary fiber. Thus, we have no information to suggest that we would receive numerous petitions or that, if we were to receive petitions, our review would extend beyond the compliance dates.

(Comment 296) Several comments said we should allow isolated or synthetic non-digestible carbohydrates identified by other governmental organizations to meet the dietary fiber definition. The comments further stated that our isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition should be harmonized with those approved by Canada (*e.g.,* inulin) or Europe so as to not hinder trade. Some comments noted that EFSA mentions physiological endpoints such as improved bowel function, colonic fermentation, maintenance of cholesterol levels, and lowered glycemic response. Other comments said we should consider Health Canada and EFSA decisions to grandfather in our isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition.

(Response) We decline to revise the rule as suggested by the comments.

Health Canada provides a list novel fibers that are ingredients manufactured to be sources of dietary fiber and consist of carbohydrates with a DP of 3 or more that are not digested and absorbed by the small intestine. Novel fibers are synthetically produced or are obtained from natural sources which have no history of safe use as a dietary fiber or which have been processed so as to modify the properties of the fiber. Health Canada considers the following to be beneficial effects: (1) Improved laxation or regularity by increasing stool bulk; (2) reduced blood total and/or low-density lipoprotein cholesterol levels; (3) reduced post-prandial blood glucose and/or insulin levels; and (4) energy-yielding metabolites through colonic fermentation. There are distinct differences between how novel fibers are identified and our definition of dietary fiber. First, a novel fiber need only show a physiological effect, rather than a beneficial physiological effect. We do not consider energy-yielding metabolites (*e.g.,* short chain fatty acids) to be a beneficial physiological effect but rather an end product of fermentation that may result in a physiological effect that may be beneficial. Second, Health Canada does not require that all added non-digestible carbohydrates demonstrate a physiological effect. Isolated or synthetic non-digestible carbohydrates that have a history of safe use are considered to be traditional fibers rather than novel fibers and do not have to demonstrate a physiological effect. We have determined that a fiber must have beneficial physiological effects to human health to assist consumers in maintaining healthy dietary practices, consistent with section 403(q) of the FD&C Act.

As for the comments' reference to EFSA, in response to evidence submitted in a petition, EFSA conducts premarket reviews of added non-digestible carbohydrates and their role in beneficial physiological effects for health claims (claims that are similar to our structure function claims). Simply adopting isolated or synthetic non-digestible carbohydrates approved by other countries or organizations without determining if they have a beneficial physiological effect would not ensure that there is a consistent basis for an isolated or synthetic non-digestible carbohydrate meeting the definition of dietary fiber for purposes of the declaration in the Nutrition Facts label.

(ii) Mandatory Declaration

Section 403(q)(1)(D) of the FD&C Act specifies, in part, that for each serving size or other unit of measure of a food, the amount of dietary fiber must be provided. Accordingly, our preexisting regulations, at § 101.9(c)(6)(i), require the declaration of dietary fiber on the Nutrition Facts label.

In the preamble to the proposed rule (79 FR 11879 at 11910), we mentioned that the 2007 ANPRM did not ask any questions about the mandatory labeling of dietary fiber and that we received no comments on this subject. Dietary fiber is not an essential nutrient, although it has physiological effects that are beneficial to human health, such as attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation. The consumption of certain dietary fibers, particularly those that are poorly fermented (*i.e.,* insoluble fiber), improve fecal bulk and laxation and ameliorate constipation, and soluble fiber plays a beneficial role in reducing the risk of heart disease (id.). Given the health benefits of dietary fiber, we did not propose any changes to our current requirement for the mandatory declaration of dietary fiber in § 101.9(6)(i).

We received no comments on this topic, and so no changes to the final rule, with respect to mandatory declaration of dietary fiber, are necessary.

With respect to the term used to declare dietary fiber content on the Nutrition Facts label, the preamble to the proposed rule (79 FR 11879 at 11910) said that the term ''dietary fiber'' has been listed on the Nutrition Facts label since 1993. Thus, we did not propose to change the current requirement to declare dietary fiber

using the term ''dietary fiber,'' as specified in § 101.9(f).

(Comment 297) One comment supported the current single disclosure of dietary fiber because, according to the comment, all fibers have a beneficial effect.

(Response) We agree that there should be a single disclosure for dietary fiber. While it is premature to know whether all isolated or synthetic non-digestible carbohydrates have a beneficial physiological effect, and therefore are a ''dietary fiber'' as defined in the final rule, the final rule does not affect the preexisting requirement to use the term ''dietary fiber.''

(Comment 298) Several comments supported a separate disclosure (*e.g.,* subcategory) of added fiber. Some comments said that consumers should know the amount of added (processed) versus natural (unprocessed) non-digestible carbohydrates in a product so that consumers who want to increase their intake of only intact fiber are able to do so. Other comments noted that the 2010 DGA stated that it is unclear whether added fibers provide the same health benefits as naturally occurring dietary fiber. Other comments said that a separate declaration of added non-digestible carbohydrates would exclude non-digestible carbohydrates that do not have a demonstrated health benefit.

One comment supporting a separate listing of added non-digestible carbohydrates stated that, although the IOM concluded that functional (added) fiber should be included in total fiber, the IOM clearly had more confidence in the benefits of foods rich in intact fiber than in the benefits of added fiber. The comment said that, in the years since the IOM report was issued, the evidence that dietary fiber lowers the risk of heart disease, diabetes, and diverticular disease continues to come from studies of people who consume foods rich in intact fiber, especially whole grains and wheat bran. The comment said that allowing labels to combine intact and added fiber misleads consumers into believing that added fiber has the same health benefits as intact fiber. The comment said we have tentatively concluded that there is little benefit for consumers in distinguishing between intact and added fiber on the Nutrition Facts label because ''both have beneficial health effects.'' However, the comment said that the two types of fiber do not necessarily have equivalent health effects, as labels would imply.

(Response) We agree that intact and intrinsic (naturally occurring) dietary fibers may have different health effects than isolated or synthetic non-digestible carbohydrates. For example, some soluble naturally occurring dietary fibers are associated with CVD risk, whereas insoluble naturally occurring dietary fiber, such as some forms of cellulose, is associated with improved laxation. However, we disagree that the differences in health effects warrant separate declarations on the Nutrition Facts label when both categories are composed of a heterogeneous group of compounds with variable health effects, all of which assist consumers to maintain healthy dietary practices. We have no basis on which we could rely, nor has the comment provided one, to separate the dietary fiber declaration in the Nutrition Facts label into two separate listings; one for intact and intrinsic fibers, and the other for isolated or synthetic non-digestible fibers that provide a physiological benefit to human health. Therefore, we disagree that the declaration of dietary fiber, as proposed, would mislead consumers, and we decline to revise the rule in response to this comment.

(iii) Analytical Methods

Under our preexisting regulations, at § 101.9(g)(2), compliance with the requirement for declaration of dietary fiber is determined using appropriate AOAC analytical methods. In the preamble to the proposed rule (79 FR 11879 at 11910), we discussed comments to the 2007 ANPRM regarding the use of analytical methods and our review of other analytical methods. We noted that while some AOAC methods, such as AOAC 985.29, 991.43 and 994.13, measure soluble and insoluble polysaccharides, lignin, higher molecular weight non-digestible oligosaccharides (DP >12), and some measure resistant starch, inulin and low molecular weight non-digestible oligosaccharides (DP <10), they do not measure all non-digestible carbohydrates with a DP <10 (id.). In contrast, newer methods (AOAC 2009.01 and AOAC 2011.25) measure all low molecular weight non-digestible carbohydrates (*i.e.,* non-digestible oligosaccharides) in addition to the higher molecular weight non-digestible carbohydrates, and we said that the newer, more inclusive AOAC methods would be more consistent with our proposed definition of dietary fiber (id.). We acknowledged, however, that there is no analytical method that can distinguish non-digestible carbohydrates that have a beneficial physiological effect from those that do not (id.).

Thus, we proposed to amend § 101.9(c)(6)(i) to indicate that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber (in proposed § 101.9(c)(6)(i)) from the value obtained using AOAC 2009.01, AOAC 2011.25 or an equivalent AOAC method of analysis as given in the ''Official Methods of Analysis of the AOAC International'' 19th Edition. If a product contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber, using AOAC 2009.01, AOAC 2011.25, or an equivalent method would be sufficient to quantify the dietary fiber content of a food. However, if the product contains both dietary fiber that is included in the proposed definition (*e.g.,* naturally occurring fibers) and non-digestible carbohydrates not included in the definition (*e.g.,* synthetic fibers without a physiological effect that is beneficial to human health), neither AOAC 2009.01 or AOAC 2011.25 nor an equivalent AOAC method would accurately quantify the dietary fiber that could be declared on the Nutrition Facts label, because the determination of fiber by these methods would include the non-digestible carbohydrates that do not meet the proposed definition of dietary fiber.

To verify that the quantity of dietary fiber declared on the Nutrition Facts label includes only those fibers that meet the regulatory definition of dietary fiber, when a food contains a mixture of non-digestible carbohydrates that meet the proposed dietary fiber definition and those that do not, we also proposed, in §§ 101.9(c)(6) and (g)(10), to require manufacturers to make and keep written records to verify the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. The amount of non-digestible carbohydrate measured by AOAC 2009.01 or AOAC 2011.25 (or an equivalent AOAC method) minus the amount of added non-digestible carbohydrate which is not included in the definition of ''dietary fiber'' would reflect the amount of dietary fiber lawfully declared on the label. Only those fibers that have been determined by FDA to have a physiological effect that is beneficial to human health would be included in the definition of ''dietary fiber.''

(Comment 299) One comment stated that AOAC 2009.01 is suitable to measure low molecular weight non-digestible oligosaccharides, as well as the higher molecular weight non-digestible carbohydrates and quantitatively cover inulin and oligofructose while the older methods did not. Another comment supported acceptance of the ''all-inclusive'' methods of analysis, AACCI 32–45

(AOAC 2009.01) and AACCI 32–50 (AOAC 2011.25), as well as other equivalent and validated AACCI and AOAC Approved or Official methods. Several comments stated that AOAC 2009.01 and 2011.25 are not the only methods that can be used to measure dietary fiber. Some comments suggested that we allow for other dietary fiber analytical methods, such as AOAC 985.29, AOAC 991.43 and AOAC 2001.03. One comment would revise the rule to allow the use of alternative methods provided they have been sufficiently validated (*e.g.,* if they are noted in USP or CFR citations). The comment said that test methods may evolve to incorporate superior measurement technologies and will better keep pace with the science and understanding of dietary fiber. Several comments stated that we should allow the use of methods that measure specific non-digestible carbohydrates such as GOS, β-glucan, fructans, polydextrose, *trans* galactose oligosaccharides, and resistant starch.

(Response) The proposed rule did not specify the use of AOAC 2009.01 and AOAC 2011.25 for measuring and declaring dietary fiber. We stated that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent method of analysis as given in the ''Official Methods of Analysis of the AOAC International, 19th Ed., 2012 (see 79 FR 11879 at 11968). The methods used must support the dietary fiber definition and therefore must measure lower molecular weight non-digestible oligosaccharides (DP 3–9) if present in a food.

(Comment 300) One comment stated that AOAC 2009.01 and 2011.25 do not capture all types of resistant starch (RS) (*e.g.,* RS4).

(Response) We agree that AOAC 2009.01 and 2011.25 do not measure all forms of RS4, such as cross-linked wheat starch (Ref. 143). In these cases, when submitting a citizen petition or a health claim petition, a more appropriate method can be identified that can measure all of the RS4.

(iv) DRV

The DRV for dietary fiber is 25 grams (§ 101.9(c)(9)). In the preamble to the proposed rule (79 FR 11879 at 11911), we noted that, in 2002, the IOM set an AI of 14 grams/1,000 kcal for ''total fiber'' and that the AI was primarily based on the intake level that was associated with the greatest reduction in the risk of CHD. Therefore, we proposed to use 14 grams/1,000 kcal as the basis for a DRV for dietary fiber and to amend § 101.9(c)(9) to set a DRV of 28 grams (14 grams/1,000 kcal × 2,000 kcal/day) for dietary fiber.

(Comment 301) Some comments supported the proposed DV (also a DRV) of 28 grams based on most recent findings by the IOM and current dietary recommendations. One comment supported increasing the DV from 25 to 28 grams after we have a better understanding of consumer and shopper dynamics.

In contrast, one comment objected to a DV of 28 grams; the comment said that the AI is based on observational data rather than clinical trial data.

(Response) We proposed the DV of 28 grams based on the current scientific evidence evaluated by the IOM. The comments objecting to a DV of 28 grams did not provide a basis on which we could rely that would cause us not to use the current DRIs provided by the IOM. The AI was set by the IOM based on three prospective cohorts that consistently demonstrated that the greatest reduction in CVD risk could be achieved when consuming 14 grams/1,000 kcal of dietary fiber. We agree that observational data alone are insufficient for evaluating the causal relationship between a nutrient and a health endpoint, such as CVD. The IOM noted that there are a large number of intervention trials on blood lipid concentrations that alter the risk of CHD (Ref. 29). In our science review of the evidence to authorize a health claim for dietary fiber-containing fruits, vegetables and grain products and CVD (§ 101.77), numerous intervention studies were cited that showed a cholesterol-lowering effect (58 FR 2552 at 2552 through 2559). Furthermore, our recent review of intervention studies on some added fibers (*e.g.,* pectin, guar gum, hydroxypropylmethylcellulose and locust bean gum) has shown a cholesterol-lowering effect (Ref. 138) Because of the available underlying evidence from intervention studies to support a cholesterol-lowering effect of dietary fibers, we disagree that a quantitative intake recommendation based on observational data related to CVD risk is inadequate for setting a DV, and the final rule sets a DRV of 28 grams for dietary fiber.

(Comment 302) Several comments supported retaining the DV of 25 grams rather than the proposed DV of 28 grams for dietary fiber. One comment stated that 28 grams is based on an AI of 14 grams/1,000 calories and is tied to calories rather than reflecting the energy needs of children and women. The comment said that recommendations to reduce calorie intake will make it more difficult to increase dietary fiber intake and to increase the DV to 28 grams will require consumers to increase their calorie intake.

(Response) We disagree with the comments' assertion that an AI based on calories is not a sufficient basis for setting the DV. There have been a number of DVs based on calories other than dietary fiber (*e.g.,* total fat and saturated fat). Furthermore, the AI was not set based on energy needs but rather on energy intake. While there may be recommendations to reduce calorie intake for some individuals, the 2010 DGA encourages consumption of fruits, vegetables and whole grains which are sources of dietary fiber.

(Comment 303) Several comments opposed a DV of 28 grams because, according to the comments, some foods that are a good source of dietary fiber would no longer qualify if the DV was set at 28 grams.

(Response) We will address, as appropriate, the impact on our other regulations that are outside the scope of this rulemaking, such as the regulations for nutrient-content claims, in separate rulemaking actions. While some foods may no longer qualify as a good source of dietary fiber, the DV is based on evidence linking dietary fiber to reduced risk of chronic disease. Therefore, this DV and nutrient-content claims based on this DV can assist consumers in maintaining healthy dietary practices.

(Comment 304) One comment opposed to setting the DV at 28 grams said that increasing the level of dietary fiber to meet the increased DV will present many technical and economic hurdles to ingredient suppliers and manufacturers. The comment said manufacturers would be deterred from developing products that help consumers close the dietary fiber intake gap.

(Response) While it is unclear how an increased DV would present technical and economic hurdles or deter the development of products, the DV of 28 grams is a quantitative intake recommendation set by the IOM (14 grams/1,000 calories) based on reducing the risk of CVD and therefore should inform the consumer on the contribution of a food to dietary fiber to assist the consumer in maintaining healthy dietary practices. Increasing the DV for dietary fiber (which may result in a corresponding reduction in the percent DV for some foods) tells the consumer how much that food contributes to the overall dietary fiber intake as part of a healthy diet.

Consumers attempting to meet a certain percent DV could increase their dietary fiber intake based on the new DV and based on the dietary fiber definition are assured that the percent DV reflects beneficial physiological effects.

(Comment 305) One comment would keep the DV at 25 grams and noted that WHO/FAO and EFSA recommend 25 grams/day as an amount needed for healthy laxation.

(Response) We disagree that a DV of 25 grams should be set based on laxation. The WHO/FAO (Ref. 144) did not provide a recommendation for dietary fiber, but stated that the recommended intake of fruits and vegetables is likely to provide greater than 25 grams/day of total dietary fiber. This amount would only reflect dietary fiber that is naturally occurring in food.

While EFSA set a Nutrient Reference Value of 25 grams/day based on laxation, EFSA also noted that there is evidence of benefit to health associated with the consumption of dietary fiber intakes greater than 25 grams/day (*e.g.,* reduced risk of CHD) (Ref. 145).

(Comment 306) One comment opposed to a DV of 28 grams stated that this value represents intact dietary fiber only because the IOM relied on evidence from studies of intact fiber to set the AI.

(Response) We disagree with the comment. The AI of 28 grams/day (14 grams/1,000 calories) set by the IOM represents total dietary fiber which includes both naturally occurring and added dietary fiber (IOM).

b. Soluble and insoluble fiber. Dietary fibers can be classified as being soluble or insoluble. Soluble fibers, such as pectin and gums, dissolve in water and are digested by the bacteria in the large intestine. Insoluble fibers, such as some forms of cellulose and lignin, do not dissolve in water and are not digested by bacteria in the large intestine, adding bulk to the stool for improved laxation.

(i) Definition

Our preexisting regulations do not define soluble or insoluble fiber. In the preamble to the proposed rule (79 FR 11879 at 11911), we explained that, because soluble and insoluble fibers are components of dietary fiber, they must meet the proposed definition of dietary fiber. Therefore, we proposed, in § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), that soluble fiber and insoluble fiber, respectively, must meet the definition of dietary fiber in § 101.9(c)(6)(i).

(Comment 307) One comment said that the terms soluble and insoluble fiber did not clearly identify physiological or nutritional functions.

(Response) We agree that the terms soluble and insoluble fiber do not necessarily reflect physiological or nutrition functions. In the preamble to the proposed rule (79 FR 11879 at 11911), we considered physicochemical terms such as ''viscous'' or ''fermentable.'' The standardization of the characterization of such terms, however, has not yet occurred. Furthermore, the viscosity of a fiber does not necessarily predict fermentability, and it is not known at what level of viscosity a fiber begins to have a physiological effect. Therefore, we did not propose to change the terms soluble and insoluble fiber.

The final rule, at § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), requires soluble fiber and insoluble fiber, respectively, to meet the definition of dietary fiber in § 101.9(c)(6)(i).

(ii) Voluntary Declaration

Our preexisting regulations permit, but do not require, the declaration of soluble fiber (§ 101.9(c)(6)(i)(A)) and insoluble fiber (§ 101.9(c)(6)(i)(B)) on the Nutrition Facts label. We did not propose any changes to these provisions with respect to voluntary declaration.

(Comment 308) One comment supported voluntary declaration of soluble and insoluble fiber. The comment said consumers may not know the difference between these two categories of dietary fiber.

In contrast, another comment supported mandatory declaration of soluble and insoluble fiber. The comment said that, while the IOM did not provide DRIs for each category of dietary fiber, there is a recommendation of a 3:1 ratio of insoluble fiber to soluble fiber. Furthermore, the comment said, there is little burden to measure both, consumers may make more informed choices that offer a balance of soluble and insoluble fiber, and the solubility relates to physiological benefit.

(Response) We decline to revise the rule to provide for the mandatory declaration of soluble and insoluble fiber. We are unaware of a recommended ratio for insoluble to soluble fiber intake, and, therefore, we do not know on what basis such a declaration would allow consumers to make more informed choices on an appropriate balance of soluble and insoluble fibers. However, to meet the dietary fiber definition, all non-digestible carbohydrates declared as dietary fiber should assist consumers in maintaining healthy dietary practices, regardless of the ratio of such fibers. While there is evidence to suggest that, in general, solubility relates to physiological benefit, we consider it important to evaluate the physiological benefits of individual isolated or synthetic non-digestible carbohydrates.

(iii) Analytical Methods

Our preexisting regulations, at § 101.9(g)(2), state that compliance with any declaration of soluble or insoluble fibers is to be determined using appropriate AOAC analytical methods. In the preamble to the proposed rule (79 FR 11879 at 11911), we said that there are a number of traditional AOAC methods available for measuring soluble fiber (*e.g.,* AOAC 991.43 and 993.19) and insoluble fiber (*e.g.,* AOAC 991.42 and 991.43), but that, as is the case with dietary fiber, these methods cannot measure all non-digestible carbohydrates with a DP <10. Similarly, a newer method, AOAC 2011.25, can measure low molecular weight non-digestible carbohydrates and separately measure soluble and insoluble non-digestible carbohydrates, but AOAC 2011.25 cannot distinguish soluble and insoluble non-digestible carbohydrates that have a physiological effect that is beneficial to human health from those that do not (id.).

The proposed rule would amend § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to indicate that the soluble and insoluble non-digestible carbohydrate content may be calculated by first using AOAC 2011.25, or an equivalent AOAC method of analysis. If a food contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber (*e.g.,* contains naturally occurring fiber only), then AOAC 2011.25 or an equivalent AOAC method would measure the amount of soluble or insoluble fiber that can be declared on the Nutrition Facts label. If a food contains a mixture of non-digestible carbohydrates that do and do not meet the proposed dietary fiber definition, and the label of the food declares soluble or insoluble fiber content, proposed § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) would require manufacturers to make and keep records to verify the amount of soluble or insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber that have been added to the food product during processing.

(Comment 309) Some comments said that other analytical methods (*e.g.* AOAC 991.43) are cited in a health claim regulation for soluble fiber from certain foods and risk of CHD (§ 101.81). One comment further stated that there is an opportunity to incorporate HPLC analysis to quantify the DP 3–9 fraction which previously has not been detected by the health claim-mandated method for psyllium husk.

(Response) We recognize that § 101.81(c)(G)(2)(ii) states that β-glucan soluble fiber from the whole oat and barley sources will be determined by AOAC 992.28 and that we will determine the amount of soluble fiber provided by psyllium husk by using a modification of AOAC 991.43. We intend to update this regulation in the future such that these soluble fibers would be required to be measured by methods that meet the dietary fiber definition (DP >3). However, the final rule no longer refers to AOAC methods in § 101.9(c)(6)(i), (i)(A), and (i)(B). We discuss the omission of the AOAC methods in these provisions in our response to comment 524.

(iv) DRV

Our preexisting regulations do not establish DRVs for soluble fiber or insoluble fiber. In the preamble to the proposed rule (79 FR 11879 at 11912), we explained that no DRIs were established for soluble or insoluble fiber during the IOM's evaluation of a DRI for dietary fiber, so we have no basis on which to derive an appropriate DRV. Therefore, we did not propose to set a DRV for either soluble fiber or insoluble fiber.

We did not receive any comments on a DRV for soluble or insoluble fiber. The final rule, therefore, does not establish a DRV for soluble or insoluble fiber.

(v) Caloric Value

Under our preexisting regulations, at § 101.9(c)(1)(i)(C), the caloric content of a food may be calculated by, among other methods, using the general factors of 4, 4, and 9 kcal/gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively. Soluble fiber, which is encompassed within ''total carbohydrate,'' is assigned a general factor of 4 kcal/gram. In the preamble to the proposed rule (79 FR 11879 at 11912), we explained how comments to the 2007 ANPRM and a citizen petition supported a caloric value of 2 kcal/gram for soluble fiber, and so we proposed to amend § 101.9(c)(1)(i)(C) to establish a general factor of 2 kcal/gram as the caloric value of soluble non-digestible carbohydrates. Insoluble non-digestible carbohydrates are not included in the caloric calculation.

We also proposed a corresponding change to the introductory text in § 101.9(c)(1)(i)(C) to reflect the caloric value of total carbohydrate based on the new caloric contribution of soluble fiber. We explained that our regulations require that the calories from total carbohydrate be calculated by using the general factor of 4 kcal/gram of carbohydrate less the amount of insoluble dietary fiber (§ 101.9(c)(1)(i)(C)) (79 FR 11879 at 11912). Because the proposed rule would establish a new definition of dietary fiber that only allows for the declaration of dietary fibers that are added to foods that we have determined to have a physiological effect that is beneficial to human health, the proposed definition of dietary fiber would exclude soluble and insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. Thus, to calculate calories from soluble and insoluble non-digestible carbohydrate, the proposed factor of 2 kcal/gram and 0 kcal/gram, respectively, would apply to those soluble and insoluble non-digestible carbohydrates that both do and do not meet the proposed definition of dietary fiber. To ensure that soluble non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber are considered in the caloric contribution of total carbohydrate, such that a general factor of 2 kcal/gram is applied to these non-digestible carbohydrates, we proposed to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 kcal/gram of total carbohydrate less the amount of non-digestible carbohydrates, which includes soluble (2 kcal/gram) and insoluble (0 kcal/gram) non-digestible carbohydrates that do and do not meet the definition of dietary fiber. The calorie contribution of soluble non-digestible carbohydrate would be added to that sum to determine the total carbohydrate calorie contribution.

(Comment 310) Several comments agreed with a caloric value of 2 kcal/gram for soluble, non-digestible carbohydrates. Some comments, however, said the final rule should provide for exceptions when the difference in energy value would be significant and has been established by science.

(Response) We decline to revise the rule to provide for exceptions. We recognize that fermentation of fibers can yield different caloric values and that a fermentable fiber is not equivalent to a soluble fiber. We agree that exceptions could be considered for changing the caloric value of a soluble non-digestible carbohydrate when the difference in energy value is significant and when we determine that the evidence is established by science. We would need to evaluate any requests for exceptions case-by-case in a request to amend § 101.9(c)(1)(i)(C) to include the greater caloric value of the fiber in the total carbohydrate calorie amount. Thus, the final rule retains a general factor of 2 calories per gram for soluble non-digestible carbohydrates.

(Comment 311) One comment supported a caloric value of 1 kcal/gram for polydextrose. The comment said that, in 1981, FDA recognized that polydextrose has a biocalorie value of 1 kcal/gram and that the science supporting this value has been reviewed (Ref. 146).

(Response) The comment is referring to a 1981 letter from the Bureau of Foods, Division of Food and Color Additives that did not object to the caloric value of 1 kcal/gram from polydextrose. This letter was in reference to food additive petition 9A3441. We disagree that the 1981 FDA letter related to polydextrose is a basis for establishing a caloric value for polydextrose for the Nutrition Facts label. Polydextrose is a synthetic, non-digestible carbohydrate. We are establishing, in this final rule, a definition for dietary fiber that does not include polydextrose as a listed dietary fiber. Thus, polydextrose would be considered a component of total carbohydrate subject to the calculation of the value for total carbohydrate in § 101.9(c)(1)(i)(C) and not as a dietary fiber.

As for the comment's reference to a specific scientific article, the publication was a review article on studies that had evaluated the caloric contribution of polydextrose in humans and animals (Ref. 146). We have not considered all of the caloric values of individual components of total carbohydrate as part of this rule, and all are subject to § 101.9(c)(1)(i)(C) for total carbohydrate, unless otherwise specified.

6. Other Carbohydrate

Our preexisting regulations, at § 101.9(c)(6)(iv), define ''other carbohydrate'' as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared, ''other carbohydrate'' is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Examples of ''other carbohydrate'' include starch and oligosaccharides. Our preexisting regulations, at § 101.9(c)(6)(iv), also provide for the voluntary declaration of the amount of ''other carbohydrate'' on the Nutrition Facts label.

The preamble to the proposed rule (79 FR 11879 at 11912) explained that we were reconsidering the voluntary declaration of ''Other carbohydrate'' on the Nutrition Facts label based on the factors we consider for the mandatory

and voluntary declaration. We stated that ''other carbohydrate'' represents different types of carbohydrate, and, unlike sugars and dietary fiber, carbohydrates covered under this category have no shared physiological effects and that there is no well-established evidence to support the role of particular types of carbohydrate that fall within the ''Other carbohydrate'' category, such as starch and oligosaccharides, in human health that is based on reliable and valid physiological or clinical endpoints (id.). We also noted that a quantitative intake recommendation for ''Other carbohydrate'' is not available from relevant consensus reports, and so, given the lack of public health significance or a quantitative intake recommendation for ''other carbohydrate'' as a category, we tentatively concluded that ''Other carbohydrate'' should no longer be permitted to be declared on the Nutrition Facts label (id.). Thus, the proposed rule would remove the provision that allows for the voluntary declaration of ''Other carbohydrate'' on the Nutrition Facts label, and we would make a corresponding revision to § 101.9(g)(4) and (g)(6) to remove references to ''Other carbohydrates.''

(Comment 312) Several comments supporting the removal of ''Other carbohydrate.'' Some comments agreed that there is no quantitative intake recommendation and the scientific evidence does not demonstrate public health significance. Other comments said that retaining ''Other carbohydrate'' may be confusing and that most consumers are not likely to understand what the term ''Other carbohydrate'' represents. One comment said it was not aware of any data or other factual information around consumer understanding of the term.

In contrast, some comments said we should retain the voluntary declaration of ''Other carbohydrate'' because, according to the comments, consumers use the information to determine the carbohydrate content of foods that are not attributable to sugars and dietary fiber or because removing the voluntary declaration could confuse consumers. Some comments said that the ''Other carbohydrate'' declaration allows consumers to better understand the total carbohydrates portion of the Nutrition Facts label because the various components that constitute ''Total carbohydrate'' approximates the sum when ''Other carbohydrate'' is included.

(Response) The comments did not provide data or information, nor are we aware of any, to support their view that consumers use, are confused by, or do not understand the ''Other carbohydrate'' declaration.

In any case, the declaration of ''Other carbohydrate'' was voluntary, so most products did not contain the declaration. The FDA Food Label and Package Survey (FLAPS) (2006–2007) estimated that about 4 percent of products list ''Other carbohydrate.'' As a result, consumers had limited ability to be informed about the components of total carbohydrate on most products. The contribution of ''Other carbohydrate'' can be determined by subtracting dietary fiber and sugars from the ''Total carbohydrate'' declaration. The declaration of ''Total carbohydrate,'' is mandatory, so the total carbohydrate content is available on all products that must bear a Nutrition Facts label. Consequently, the final rule removes the provision that allows for the voluntary declaration of ''Other carbohydrate'' on the Nutrition Facts label, and we also have revised § 101.9(g)(4) and (g)(6) to remove references to ''Other carbohydrates.''

I. Protein

1. Mandatory and Voluntary Declaration

Section 403(q)(1)(D) of the FD&C Act requires food labeling to bear nutrition information about protein, and so our preexisting regulations, at § 101.9(c)(7)(i), require the declaration of the amount of protein by weight and provide for voluntary declaration of the percent DV for protein on the Nutrition Facts label (§ 101.9(c)(7)(i)). In the preamble to the proposed rule, we stated that there is strong evidence, based on valid physiological and clinical endpoints, that protein is an essential nutrient that is necessary for human health and growth and that the declaration of protein content remains necessary to assist consumers in maintaining healthy dietary practices. We also stated that, because protein intake in the U.S. population continues to be adequate when compared to the EAR, absent a mandatory percent DV declaration, the declaration of protein as a percent DV should remain voluntary (id.). Consequently, we did not propose any changes to the requirement for declaration of the quantitative amount of protein and the voluntary declaration of this amount as a percent DV on the Nutrition Facts label.

(Comment 313) Several comments supported the continued mandatory declaration of protein on the label.

(Response) Because we did not propose to change the preexisting requirement to declare the amount of protein by weight, no changes to the final rule are necessary.

2. Analytical Methods

Our preexisting regulations, at § 101.9(c)(7), state that protein may be calculated on the basis of 6.25 times the nitrogen content of the food determined by the appropriate method of analysis as given in the Official Methods of Analysis of AOAC International, 15th ed. (1990), except when the official procedure for a specific food requires another factor. The preamble to the proposed rule discussed a citizen petition that asked us to consider other methods of analysis as set forth in a newer edition of the Official Methods of Analysis of AOAC International, and we agreed that we should update the version of the Official Methods of Analysis of the AOAC International that we use for compliance purposes because newer, and sometimes better, analytical methods for many nutrients are included in new or revised versions of the methods (79 FR 11879 at 11913). The proposed rule, therefore, would amend § 101.9(c)(7) to incorporate by reference the Official Methods of Analysis of the AOAC International, 19th ed. (2012) by removing ''15th Ed. (1990)'' and adding in its place ''19th Ed. (2012).''

We did not receive any comments on the AOAC methods for the determination of protein. The Official Methods of Analysis of AOAC International, 20th Edition was published in 2016. The 20th Edition includes a number of new methods of analysis as well as changes to current methods. We need additional time to consider the additions and changes, and to determine if additional public comment is necessary on the 20th Edition of the AOAC Methods of Analysis. Therefore, we are finalizing the regulation as proposed, and are incorporating the 19th Edition of the Official Methods of Analysis of the AOAC International by reference. Consequently, we have finalized § 101.9(c)(7), insofar as the AOAC methods are concerned, without change.

(Comment 314) Although we did not propose any changes to how the gram amount of protein in a serving of a food product is calculated, several comments addressed this subject. Our preexisting regulations, at § 101.9(c)(7), require that protein content be calculated using a factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis in the ''Official Methods of Analysis of the AOAC International'' (15th Ed.), except when the official procedure for a specific food requires another factor. We also state in § 101.9(c)(7)(ii) that the protein digestibility-corrected amino

acid score (PDCAAS) must be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1990 (which we also proposed changing the publication year to 1991; hereafter referred to as the 1991 FAO/WHO Protein Quality Report), except that when official AOAC procedures described in § 101.9(c)(7) require a specific food factor other than 6.25, that specific factor shall be used.

One comment noted that the language related to use of nitrogen to protein conversion factors in § 101.9(c)(7) and (c)(7)(ii) is inconsistent. The comment suggested that the term ''official procedure'' is vague, and the term ''food'' does not allow for the differentiation between single foods like peas, or a blend like beans and rice. The comment suggested revising both § 101.9(c)(7) and (c)(7)(ii) to say ''or if another scientifically supported factor is generally accepted.'' The comment said that this change would allow for the use of nitrogen to protein conversion factors other than 6.25 that are commonly used throughout industry. The comment noted that a number of sources have suggested that the factor of 6.25 does not reflect an accurate nitrogen level for all foods, particularly non-meat items and that other commodity-specific nitrogen-to-protein conversion factors are included in reports from USDA (Ref. 69).

(Response) We agree, in part, with the comment and disagree, in part, with the comment. We agree that the language in § 101.9(c)(7) and (c)(7)(ii) should be consistent and have revised § 101.9(c)(7) to say ''except that when official AOAC procedures described in paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used'' and have made a corresponding edit to § 101.9(c)(7)(ii). We also agree that the generally accepted factors (*i.e.,* the Jones' factors) should be used when specified in official AOAC procedures. We decline to allow for the use of other factors for the reasons discussed in this response.

For purposes of nutrition labeling, among others, protein is estimated by determining the nitrogen content of an ingredient and multiplying it by a nitrogen-to-protein conversion factor. A number of Jones factors cited in the USDA references provided in the comment have been in use for a wide variety of foods for about 75 years. These conversion factors for calculating protein from nitrogen content for 43 foods were published in 1973 by USDA (Ref. 69). Use of Jones' factors provides a value for ''crude protein'' since the factors are derived by applying the appropriate factor to the total nitrogen present. For groups of foods for which a conversion factor is not provided, a general factor of 6.25 is used. This general conversion factor is derived from observations that many commonly occurring proteins contain about 16 percent nitrogen (*i.e.,* (100/16 = 6.25)) (Ref. 69). A single nitrogen-to-protein conversion factor may be sufficient if the aim is to indicate the amount of nitrogen present and to present it as an average protein content. In contrast, specific conversion factors rather than a single general factor provide a more accurate indication of dietary amino acids in a food (Ref. 147).

As for the comment's assertion that the word ''food'' does not allow for differentiation between single foods or a blend of foods, we disagree. Food is defined in section 201(f) of the FD&C Act as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article. Therefore, ''food'' refers to both single-ingredient foods, such as peas, and blends such as beans and rice. We note, however, that all of the Jones' factors were determined for specific single foods and not for blends of foods as suggested in the comment (Ref. 69). We are not aware of any conversion factors that have been developed for blends of foods (*e.g.* a mixture of beans and rice).

With respect to the comment's assertion regarding other, more accurate food factors, we note that, in the 1993 Final Rule for Mandatory Nutrition Labeling, we responded to a comment requesting that food-specific conversion factors used by AOAC be allowed for calculating the PDCAAS whenever such factors are available (58 FR 2079 at 2102). The PDCAAS is an amino acid scoring procedure that takes into account digestibility of a protein. The PDCAAS provides a reasonable measure of protein quality. We acknowledged that the method for calculating PDCAAS described in the 1991 FAO/WHO Protein Quality Report specifies a conversion factor of 6.25, but agreed to allow for the use of other food-specific conversion factors when the official AOAC procedures require them (58 FR 2079 at 2102). When amending our regulations to allow for use of such conversion factors, we intended to allow for the use of food-specific conversion factors that are specified in official AOAC procedures. The conversion factors specified in official AOAC procedures are commodity-specific Jones' factors.

In recent years, a number of conversion factors have been recalculated based on the best available data, including the amino acid composition of foods rather than the nitrogen content. Conversion factors calculated from the nitrogen content provide a measure of the ''crude protein'' content (Refs. 147–152). However, the amino acid composition rather than the nitrogen content of a protein is increasingly viewed as the more important quality of a protein for nutrition purposes. This is because ''protein'' is increasingly taken to mean ''amino acids,'' which is the focus of greatest concern to those interested in human nutrition (Ref. 147). Theoretically, these newer factors may provide a more nutritionally relevant way to estimate protein quantity and quality. As discussed in our response to comment 317, other comments have raised issues related to the determination of protein for the purposes of nutrition labeling which require additional review and consideration. We need to evaluate the use of methods which include conversion factors other than those specified in official AOAC procedures to determine if they are appropriate and in context with other changes to how protein is determined for the purposes of nutrition labeling before amending the regulation. We therefore decline to allow for the use of conversion factors other than those specified in the official AOAC procedures at this time, but will continue to monitor future developments in the determination of protein and will consider amendments to our requirements for protein labeling, as appropriate.

In the future, it may be possible to accept factors other than Jones' factors if there is a description of methods used for their determination (*e.g.* complete amino acid determination) and a description of the foods to which such new factors are applicable. Because a nitrogen-to-protein conversion factor can be ''calculated'' by simply dividing 100 by the total nitrogen content of a food, it will be critical that newer factors be accompanied by publicly available documentation of the amino acid analyses by which they were developed and the specific foods to which the new factors apply. Continued use of Jones' factors other than 6.25 (*e.g.,* 5.7 for wheat, 6.38 for milk, 5.46 for peanuts and Brazil nuts, 5.18 for almonds) in AOAC Official Methods is appropriate. These factors are used in commodity-specific analytical methods which have been replicated in

numerous laboratories and, as a result, have achieved Official Method status.

(Comment 315) One comment stated that, because the regulation says that ''protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food,'' manufacturers are using various practices in calculating protein for the labeling of foods (*e.g.,* breakfast cereal, meal replacement products, and dietary supplements) that contain protein combined with non-protein sources of nitrogen such as free amino acids and non-proteinogenic nitrogen compounds (*e.g.,* L-carnitine, creatine, D-phenalalanine, adenosine, niacinamide, etc.). Two comments recommended that we revise the rule so that the declared content of protein in grams does not include non-protein nitrogen sources and to define protein as ''a chain of amino acids connected by peptide bonds.'' One comment suggested that, if these changes are made, there are two means by which the appropriate label declaration for protein may be determined. The first is by subtracting the quantity of non-protein nitrogen sources from the total protein calculated based on the nitrogen content. The second is by measuring the total amino acids in the food and subtracting the free amino acids present. The comment acknowledged that methods for various non-protein nitrogen sources may not exist or may not be valid for a given food matrix. The comment recommended that we should give manufacturers greater flexibility to select an appropriate test method or to rely on recordkeeping to determine the quantities of non-protein nitrogen sources.

Another comment noted that § 101.36(b)(2) states that protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids. The comment argued that this requirement does not prevent foods from containing non-amino acid nitrogen compounds as the only source of nitrogen (*e.g.,* a dietary supplement containing vitamins or nucleotides, but no amino acids) from being labeled as containing protein.

(Response) We agree with comments that the term ''may'' in § 101.9(c)(7) could be interpreted to mean that a variety of different practices could be used to determine the amount of protein in a serving of food. However, we decline to replace the term ''may'' with other terms that would require manufacturers to calculate the amount of protein in a serving of a product on the basis of 6.25 times the nitrogen content of the food, except when the official procedure requires another factor. Replacement of the term ''may'' with other terms in § 101.9(c)(7) would prevent the use of all other means of protein determination. Manufacturers are permitted to use other means, such as databases, to determine the amount of protein in a serving of their product, and the suggested change would not permit such practices. Therefore, the final rule does not prohibit the use of values derived from databases or other methods, but the protein value declared in labeling must meet the value that we obtain using our compliance criteria for the product to not be misbranded. Regardless of the means used to determine the amount of protein, a manufacturer is responsible for the accuracy and compliance of the information presented on the label. We will determine whether a product complies with § 101.9(g) by laboratory analysis.

We also agree that methods for the determination of non-protein nitrogen sources may not yet be available or may not be valid for a given food matrix. We are currently aware of such methods for milk, but not for other matrices. For example, a number of AOAC Official Methods are available, including a method for TCA-precipitated protein nitrogen in milk (AOAC Official Methods 991.20, 991.21, and 991.22). These methods have been validated for milk and are considered to be adequate to determine true protein and non-protein nitrogen in milk. It may be possible to extend these methods or to develop analogous methods for other food matrices in the future.

We disagree with the comments that we should define protein as ''a chain of amino acids connected by peptide bonds;'' such a definition is overly simplistic and would not prevent the declaration of compounds, such as di- and tri-peptides, from being declared as protein on the label.

Methods for the determination of such compounds may not be widely available. There is also no definition of protein that is generally accepted by the scientific community that could be applied to a regulatory framework. The development of validated analytical methods for the determination of non-protein nitrogen containing compounds to match a scientifically sound regulatory definition of protein will take time. Therefore, we plan to revisit the determination of protein on the label once validated analytical methods and/or a regulatory definition for protein can be established.

(Comment 316) We did not propose any changes to how the quality of a protein is determined, yet some comments addressed this subject. Our preexisting regulations, at § 101.9(c)(7), require the use of a PDCAAS for determining whether a food contains a significant amount of protein per serving and for calculating the percent DV for protein. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a PDCAAS of less than 40 expressed as a percent, a statement must be placed on the label indicating that the food is not a significant source of protein or the percent DV for protein must be declared.

We also require, in § 101.9(c)(7)(ii), that the PDCAAS be multiplied by the actual amount of protein in grams to determine the ''corrected amount of protein (gram) per serving''. Under our preexisting regulations, at § 101.9(c)(7)(i), the corrected amount of protein per serving must then be used to calculate a percentage of the RDI or DRV for protein, as appropriate. The PDCAAS must be determined by methods given in the 1991 FAO/WHO Protein Quality Report, which is incorporated by reference in § 101.9(c)(7)(ii).

Some comments expressed support for continued use of the PDCAAS for calculation of the percent DV for protein. However, other comments recommended replacing the PDCAAS method with the Digestible Indispensable Amino Acid Score (DIAAS) in § 101.9(c)(7) because the comments believed the DIAAS to be a more accurate method of evaluating protein quality (Ref. 153). DIAAS is defined as: DIAAS percent = 100 × [(mg of digestible dietary indispensable amino acid in 1 g of the dietary protein/(mg of the same dietary indispensable amino acid in 1 g of the reference protein)] (Ref. 154). Indispensable or ''essential'' amino acids are those that the body cannot make and that can only be obtained from the diet. The comments referred to conclusions and recommendations from the FAO Expert Consultation on Dietary Protein Quality Evaluation in Human Nutrition (Ref. 154). The 2013 FAO Protein Quality Report states that for regulatory purposes, DIAAS is the recommended method for dietary protein quality assessment. A key recommendation by the FAO Expert Consultation was to replace PDCAAS with DIAAS because DIAAS more accurately reflects protein digestion and amino acid absorption compared to the single fecal crude

protein values used as part of the PDCAAS calculation. Some comments noted that the 2013 FAO Protein Quality Report states that DIAAS should optimally be based on known values of ileal amino acid digestibility for human foods, and such data are currently lacking. According to the comments, the FAO Expert Consultation suggested that, until such data become available, DIAAS values could be calculated by applying fecal crude protein digestibility values to dietary amino acid contents.

(Response) We agree that the DIAAS is an important new method of evaluating protein quality when true ileal amino acid digestibility data are used. However, we decline to replace the PDCAAS with DIAAS in the final rule because there are insufficient data available to implement the DIAAS. The digestibility of protein has traditionally been determined from fecal digestibility, which does not take into account metabolism of protein in the colon. Unabsorbed amino acids are largely metabolized by bacteria in the colon and then converted into other compounds that can be absorbed; therefore, determination of fecal digestibility may provide inaccurate measurements of amino acids absorbed from the small intestine (Refs. 153, 155–156). Digestibility measured at the terminal ileum (that is, at the end of the intestine) has been suggested by some in the scientific community (Ref. 153) to be more accurate than fecal digestibility for determination of dietary amino acid digestibility. The difference between DIAAS and PDCAAS is that true ileal amino acid digestibility for the dietary indispensable amino acids is used for the calculation of DIAAS rather than a single fecal crude protein digestibility value.

As mentioned in the comments, a key finding of the 2013 FAO Protein Quality Report is that digestibility should be based on the true ileal digestibility of each amino acid, preferably determined in humans. If collection of human data is not possible, the true ileal digestibility can be determined in growing pigs or in growing rats, in that order. However, the report noted that, after assessment of the ileal amino acid digestibility dataset, the FAO Expert Consultation concluded that currently available data are insufficient to implement true ileal amino acid digestibility in the calculation of DIAAS. Furthermore, until such time that a dataset of true ileal amino acid digestibility for human foods becomes available, the report suggested that values for fecal crude protein digestibility should be used in the calculation of DIAAS (Ref. 154).

Notes from the Sub-Committee Report (Ref. 157) express the conclusions of the Sub-Committee members that, while there is a sound scientific case for using ileal digestibility, it derives almost entirely from work with animals. Based on limitations and the nature of data currently available, a case cannot be made for changing from fecal to ileal digestibility. The Sub-Committee also concluded that, ''For an organization like the FAO representing the whole World, a change will produce confusion. Before the change is made, sufficient data on comparisons across animal species and humans are needed'' (Ref. 157). Therefore, we decline to propose to replace PDCAAS with DIAAS until such time that a database of true ileal amino acid digestibility for humans that is widely accepted by the scientific community has been developed. We will continue to monitor future developments in the evaluation of dietary protein quality, and will consider amendments to our requirements for protein labeling based on new information, as appropriate.

(Comment 317) One comment recommended replacing the scoring pattern for PDCAAS found in the 1991 FAO/WHO Protein Quality Report, which is incorporated by reference in § 101.9(c)(7)(ii), with the scoring patterns found in the 2007 WHO/FAO/UNU Report ''Protein and Amino Acid Requirements in Human Nutrition, Report of a Joint WHO/FAO/UNU Expert Consultation'' (Ref. 158). Specifically, the comment would amend § 101.9(c)(7)(ii) by removing the incorporation by reference of the determination of PDCAAS by methods in sections 5.4.1, 7.2.1, and 8.00 of the 1991 Protein Quality Report and incorporating by reference sections 6.2 and 6.3, section 8.3 (including Table 23), section 9.4.2 (including Table 36), and section 14.7 (including Tables 49 and 50) from the 2007 Protein and Amino Acid Requirements Report. Specifically, section 5.4 of the 1991 Protein Quality Report provides recommended procedures for methods for the determination of all amino acids, partial amino acid analysis, and recommendations regarding the use of published amino acid data. Section 7 of the Protein Quality Report identifies digestibility methods and provides a detailed description of the in vivo rat assay for true protein digestibility. This section also describes the composition of experimental diets to be used, rat feeding protocol, collection of food and feces, and calculations to be performed. Section 8.00 of the Protein Quality Report describes how the PDCAAS is determined, describes the analyses needed for test foods, the amino acid scoring pattern, and calculation of amino acid scores. The four sections from the 2007 Protein and Amino Acid Requirements Report include the following information: Current concerns about the PDCAAS approach (sections 6.2 through 6.3), summary of adult indispensable amino acid requirements (section 8.3), summary of indispensable amino acid requirements for older infants and children (section 9.4.2.) and summaries of requirements for various age groups (section 14.7). The comment recommended these changes because it said there have been advances in science since the 1991 FAO/WHO Protein Quality Report was published. The comment said that the 2007 Protein and Amino Acid Requirements Report provides updated adult indispensable amino acid requirements as well as corrections to the calculation of the PDCAAS for food mixtures.

(Response) We decline to amend § 101.9(c)(7)(ii) as suggested by the comment. The amendment sought by the comment would eliminate important information that identifies and describes the methods and procedures for determination of the PDCAAS, would remove the current preschool child scoring pattern used for PDCAAS, and would replace the scoring patterns with newer ones that were developed in a different manner than those in the 1991 FAO/WHO Protein Quality Report.

None of this methods-related and procedural information is included in the 2007 Protein and Amino Acid Requirements Report, including those sections mentioned specifically for inclusion (*i.e.,* sections 6.2 and 6.3, section 8.3, section 9.4.2 and section 14.7).

In addition to removing important methods-related information for the calculation of PDCAAS, replacement of the 1991 FAO/WHO Protein Quality Report with specific sections of the 2007 Protein and Amino Acid Recommendations Report would remove the current preschool child scoring pattern for the PDCAAS and replace it with an adult scoring pattern. The amino acid scoring pattern currently in use by FDA is that for the preschool child (age 2 to 5 years), as recommended in the 1991 FAO/WHO Protein Quality Report. This scoring pattern was established by FAO/WHO/UNU in 1985 for preschool children 2 to 5 years of age (''Energy and protein requirements: Report of a Joint FAO/WHO/UNU Expert Consultation'' (Ref. 159). The 1985 Report suggested separate amino acid scoring patterns for

infants, pre-school children 2 to 5 years of age, and adults, implying that protein quality varies with the age of the individual. The 1985 Report stated that protein and diets containing essential amino acids that met the greater needs of young children were also adequate for older children and adults, whereas the reverse may not be true (Ref. 159).

In 1991, the FAO/WHO Consultation evaluated the 1985 Report and recommended that the FAO/WHO/UNU amino acid scoring pattern for preschool children be used to evaluate protein quality for all age groups except infants (Ref. 160). The FAO Expert Consultation also concluded that the PDCAAS is the most suitable regulatory method for evaluating protein quality of foods (Ref. 160). We reviewed the 1991 FAO/WHO Protein Quality Report, tentatively accepted its conclusions, and proposed to require the use of PDCAAS as the method for determining protein quality for food intended for children over 1 year of age and adults in the 1991 proposed rule for Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision (56 FR 60366 at 60370).

We responded to comments on this subject in the 1993 final rule for Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (58 FR 2079 at 2104) and concluded that the proposed amino acid scoring pattern for preschool age children was the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants.

We also decline to replace the incorporation by reference of information from the 1991 FAO/WHO 1991 Protein Quality Report with the information cited in the comment from the 2007 Protein and Amino Acid Requirements Report. The use of the 2007 Report's scoring pattern for adults would provide significantly lower amounts of specific indispensable amino acids (*i.e.,* histidine, lysine, phenylalanine + tyrosine, and tryptophan) than those provided by use of the scoring pattern in the 1991 FAO/WHO Protein Report. The scoring patterns in the 2007 Protein and Amino Acid Requirements Report were based on amino acid requirement values divided by the mean protein requirement while the scoring patterns provided in the 1991 FAO/WHO Protein Quality Report were estimated by dividing amino acid requirements by what was considered a safe level of protein intake (Refs. 158, 160). Further evaluation of the two approaches used to derive scoring patterns is necessary before we can determine which approach provides a better estimation determination of protein quality. We will continue to monitor future developments in the determination of protein quality and will consider amendments to our requirements for protein labeling based on new information, as appropriate.

(Comment 318) One comment recommended that, in § 101.9(c)(7), when the protein in foods represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children older than 1 but less than 4 years of age has a PDCAAS of less than 40 expressed as a percent, the statement ''not a significant source of protein'' should be changed to ''not a source of complete protein'' for products that supply a non-trivial amount of protein but which have a low PDCAAS. The comment explained that many consumers, especially vegetarians, are familiar with the concept of complete vs. incomplete protein and, even for consumers who are unfamiliar with the concept, the statement ''not a source of complete protein'' provides notice that the food in question cannot be relied upon as the sole source of protein in the diet. (Complete proteins are those that contain all of the ''essential'' amino acids, or those amino acids that cannot be made by the body. An incomplete protein is one that is low in one or more of the essential amino acids (Ref. 161).

The comment stated that the label for a product that contains 10 grams of protein per serving (which would provide 20 percent of the DRV for adults) from low-PDCAAS proteins such as gelatin or collagen as the sole source of amino acids will often have ''10 g of protein'' declared and a ''not a significant source of protein'' declaration as well. The comment suggested that such a situation is confusing and misleading to the consumer.

The comment further stated that amino acids deficient in one food or meal can be supplied by another, so that dietary needs are met over the course of the day. Therefore, according to the comment, foods with a low PDCAAS are a valuable source of protein in the context of the overall diet, and the labeling regulations should not completely discount their value.

(Response) We decline to amend § 101.9(c)(7) to replace the statement ''not a significant source of protein'' with ''not a source of complete protein'' when a product contains protein with a low PDCAAS. We agree that amino acids that are deficient in one food or meal can be supplied by another so that dietary needs are met over the course of the day. However, it is not clear, based on the information provided in the comment, if the general public would understand what a ''complete'' protein is and, even if consumers did understand, whether the statements would be viewed differently. Therefore, we are not replacing the statement ''not a significant source of protein'' with ''not a source of complete protein'' when a product contains protein with a low PDCAAS.

3. DRV

Our preexisting regulations, at § 101.9(c)(9), set the DRV for protein at 50 grams, and this represents 10 percent of the 2,000 reference calorie intake level. The preamble to the proposed rule (79 FR 11879 at 11913 through 11914) discussed scientific recommendations for setting the DV for protein and comments we received in response to the 2007 ANPRM. The preamble to the proposed rule (79 FR 11879 at 11913) explained how using the IOM Labeling Committee's recommended approach for setting the DV for protein would result in no change to the DRV for protein and how the DRV of 50 grams for protein falls within the range of the RDAs calculated using reference weights.

We did not propose to change the DRV of 50 grams for protein.

(Comment 319) Several comments supported maintaining the current DRV of 50 grams for protein. However, other comments recommended increasing the DRV for protein. One comment suggested that the DRV for protein should be 23 percent of calories, which is the median of the IOM's Acceptable Macronutrient Distribution Range (AMDR) range (Ref. 5). Taking into account the average actual weight of people in the United States, which is 195.5 pounds (lbs) for men and 166.2 lbs for women based on data from the Centers for Disease Control and Prevention National Center for Health Statistics (Ref. 162), the comment said an individual would need to eat 66 grams/day of protein to meet the recommended grams/kilogram of protein. The comment suggested that increasing the DRV for protein would help people lose weight because it would allow people to increase their muscle mass. However, the comment did not provide scientific support for this statement.

Other comments recommended increasing the DRV for protein from 10 percent to 15 percent or a minimum 15 percent of calories. The comments suggested that the current DRV of 10

percent of energy from protein is too low considering the IOM's AMDR for protein is 10 to 35 percent of energy intake for adults. One comment stated that Americans typically consume 15 to 17 percent of calories from protein, so increasing the DRV for protein to 15 percent would be consistent with protein intakes in the United States. One comment expressed concern that a DRV of 10 percent of energy from protein could lead to overconsumption of calories from other macronutrients, such as carbohydrates or fats.

Another comment compared the current DRV for protein to the IOM's RDAs. The comment acknowledged that our DRV for protein is not based on the RDA for protein, but said it is less than the RDA for adolescent and adult men. The comment further stated that, because protein is an essential nutrient and because the RDA is set based on grams/kilogram of body weight, protein needs may exceed the RDA for some men, especially for men who are taller than average and/or have increased muscle mass. The comment expressed concern that we are not determining the DRV for protein in a similar manner to that for vitamins and minerals (*i.e.,* the population coverage approach).

One comment suggested that the DRV for protein should reflect dietitian-suggested values (*e.g.,* 60 grams/day), but did not provide any basis for the change.

(Response) We decline to increase the DRV for protein and are not making any changes to the existing DRV for protein of 50 g. The preamble to the proposed rule discussed comments we had received in response to an ANPRM and explained why we declined to change the DRV (79 FR 11879 at 11913). In brief, we considered basing the DRV for protein on the midpoint of the AMDR for protein 22.5 grams (79 FR 11879 at 11913), but declined to base the DRV for protein on the midpoint of the AMDR range because we had no data to show that protein intakes in the United States were inadequate or that setting a higher DRV that is based on the midpoint of the AMDR is needed to reduce the risk of chronic diseases. Furthermore, the DRV of 10 percent of calories from protein falls within the AMDR range of 10 to 35 percent of calories from protein (id.).

We also disagree that the DRV for protein should be increased to 15 percent of calories from protein. The only basis provided in comments for increasing the DRV for protein to 15 percent of calories from protein is consumption data indicating that Americans typically consume 15 to 17 percent of calories from protein. In reference to the concern that the established DRV for protein does not cover the needs of adolescent and adult men, recent consumption data shows that, on average, males 19 years and older are exceeding the RDA for protein, and thus a DRV of 10 percent has not had a negative impact on protein consumption (Ref. 163). The mean protein intake from foods and beverages in males 20 years of age and older is 98.8 grams/day and ranges from 80 grams/day to 110.0 grams/day. Four percent or less of males 19 years of age and older are consuming below the EAR for protein. Therefore, regardless of the current DRV, males 19 years of age and older are consuming well above the RDA for protein.

We also disagree that the DRV should reflect suggested values from a dietitian. There is a range of values that could be recommended by a dietitian depending on the individual or group that a dietitian is counseling. Dietitians work in a variety of settings such as hospitals, long-term care facilities, wellness or rehabilitation centers, food industry, and non-profit organizations. They provide recommendations based on the patient or client's needs. The protein recommendations provided by dietitians vary greatly depending on the audience. Therefore, a DRV based on values suggested by dietitians would not necessarily be reflective of the needs of the general population.

4. Miscellaneous Comments

(Comment 320) One comment recommended reorganizing § 101.9(c)(7) so that the regulated industry can more easily understand its provisions. The comment stated that the regulation is written in a manner that is convoluted and confusing, such that many readers have a hard time understanding its requirements. For example, the comment said that readers are often confused as to when, how, and to what the PDCAAS correction is to be applied in labeling, and when declaration of the percent DV is required, prohibited, or optional. The comment also stated that there is also confusion regarding the most appropriate method to determine the declared quantity of protein.

The comment suggested revisions to the codified text, which included: (1) Removal of the discussion related to protein quality and when the statement ''not a significant source of protein'' must be declared from § 101.9(c)(7); (2) removal of the discussion of how protein content may be determined from § 101.9(c)(7) and placement of this information under§ 101.9(c)(7)(i); (3) addition of ''(The quantity of protein in grams shall not be corrected based on protein quality values as described in paragraph (c)(7)(vii) of this section.)'' to § 101.9(c)(7); (4) addition of the statement ''for foods in which the only significant source of nitrogen is from protein (*i.e.,* chains of amino acids linked by peptide bonds) followed by information related to the calculation of protein content (moved from § 101.9(c)(7)) to § 101.9(c)(7)(i)); (5) addition of a new § 101.9(c)(7)(ii) which includes requirements for foods containing non-protein sources of nitrogen; (6) replacement of the proposed language in § 101.9(c)(7)(iii) related to the DRV and RDI values for protein with information related to the protein quality of foods purported to be for children and adults 4 years of age and older and new requirements for when the statement ''not a source of complete protein'' or a calculated percent DV for protein can be declared; (7) addition of a new § 101.9(c)(7)(iv), which includes requirements for when the statement ''not a significant source of protein'' or the percent DV for protein must be declared on foods represented or purported to be for children greater than 1 but less than 4 years of age; (8) addition of a new § 101.9(c)(7)(v), which includes requirements for when the statement ''not a significant source of protein'' must be declared and the prohibition of the declaration of the percent DV for foods represented or purported to be specifically for infants 7 through 12 months of age; (9) addition of a new § 101.9(c)(7)(vi) which includes information related to the voluntary declaration of a percent DV for protein, except that the percent DV declaration is prohibited if a food is represented or purported to be for infants 7 through 12 months of age; (10) addition of a new § 101.9(c)(7)(vii), which includes all of the information in proposed § 101.9(c)(7)(ii) related to the calculation of the ''corrected amount of protein (gram) per serving''; and (11) addition of a new § 101.9(c)(7)(viii), which includes all of the information in proposed § 101.9(c)(7)(iii) related to the proposed DRVs and RDIs for protein.

The comment also recommended revising § 101.36(b)(2)(iii)(B) to state that the percent DV of all dietary ingredients declared under § 101.36(b)(2)(i) must be listed, except that the percent for protein may ''or shall'' be omitted as provided in § 101.9(c)(7). In addition, the comment recommended clarifying § 101.36(b)(2)(iii)(B) so that the percent DV for protein, when present, be calculated using the corrected amount of protein as specified in § 101.9(c)(7).

(Response) We decline to revise § 101.9(c)(7) based on the comment. It is

not clear that the suggested reorganization of the codified makes it easier for the reader to understand the requirements related to when, how, and to what the PDCAAS correction is to be applied, and when the declaration of the percent DV is required, prohibited, or optional.

We do agree, however, that § 101.36(b)(2)(iii) should be revised for clarity to explicitly state that the percentage of the RDI for protein shall be omitted when a food is purported to be for infants through 12 months of age, and we have revised the rule accordingly. (We explain, in our response to comment 441, our reasons for changing ''infants 7 through 12 months of age'' to ''infants through 12 months of age.'')

We also agree to clarify, in § 101.36(b)(2)(iii), that the percent DV for protein should be calculated using the corrected amount of protein as specified in § 101.9(c)(7). Therefore, we have revised § 101.36(b)(2)(iii) to state that the percent DV for protein, when present, shall be calculated using the corrected amount of protein as specified in § 101.9(c)(7)(ii).

J. Sodium

The preamble to the proposed rule discussed key consensus reports and recommendations that we reviewed in reconsidering the DRV (79 FR 11879 at 11914 through 11915). After we published the proposed rule in March 2014, three new reports were issued that provided corroborative evidence to our proposal to set a DRV of 2,300 mg.

The first report was the ''NHLBI Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group'' (Ref. 17). In 2013, the Lifestyle Work Group evaluated evidence on the role of specific dietary patterns, nutrient intake (*e.g.,* macronutrients, sodium, and potassium), and levels and types of physical activity, through effects on such modifiable CVD risk factors as high BP and lipids, in reducing CVD risk. The results of this systematic review were intended to be used to establish clinical recommendations that are directed at patients with CVD risk factors (*i.e.,* abnormal lipids and/or prehypertension and hypertension). The Lifestyle Work Group evaluated evidence statements on the: (1) Overall effect of dietary intake of sodium on blood pressure; (2) comparison of different levels of dietary intake of sodium on blood pressure; (3) sodium and blood pressure in subpopulations defined by sex, race/ethnicity, age, and hypertension status; (4) sodium intake and blood pressure in the context of dietary pattern changes; (5) sodium and blood pressure in the context of other minerals; and (6) effect of dietary intake of sodium on CVD outcomes. The Lifestyle Workgroup found that the strength of the evidence was high and that, in adults 25 to 80 years of age with blood pressure 120 to 159/80 to 95 mm HG, reducing sodium intake lowers blood pressure. The Lifestyle Work Group found moderate evidence that, in adults 25 to 75 years of age with blood pressure 120 to 159/80 to 95 mm HG, reducing sodium intake that achieves a mean 24-hour urinary sodium excretion of approximately 2,400 mg/day relative to approximately 3,300 mg/day lowers blood pressure by 2/1 mm HG and reducing sodium intake that achieves a mean 24-hour urinary sodium excretion of approximately 1,500 mg/day lowers blood pressure by 7/3 mm Hg. There was low evidence that a reduction in sodium by approximately 1,000 mg/day reduces CVD events by about 30 percent and that higher sodium intake is associated with greater risk for fatal and nonfatal stroke and CVD. The Lifestyle Work Group did not find sufficient evidence to determine the association between sodium intake and the development of heart failure.

The second report was the 2015 DGAC. The DGAC informs the Federal government of current scientific evidence on topics related to diet, nutrition, and health. The 2015 DGAC considered the 2010 DGAC reviews, the 2013 NHLBI Lifestyle Evidence Review, the 2013 IOM Sodium in Populations report, and new evidence released since 2013 for sodium intake and blood pressure and CVD outcomes. The 2015 DGAC recommended that the general population, ages 2 years and older, rely on the recommendations in the 2005 IOM DRI Electrolytes report that set the UL at 2,300 mg/day based on evidence showing associations between high sodium intake, high blood pressure, and subsequent risk of heart disease, stroke, and mortality. The committee also noted that, given the well-documented relationship between sodium intake and high blood pressure, sodium intake should be reduced and combined with a healthful dietary pattern (Ref. 19).

The third report was the 2015–2020 Dietary Guidelines for Americans (Ref. 28). The 2015–2020 DGA made a key recommendation to limit calories from added sugars and saturated fats and reduce sodium intake and to consume an eating pattern low in added sugars, saturated fats, and sodium. Cutting back on foods and beverages higher in these components will help people achieve diets that fit into healthy eating patterns. The 2015–2020 DGA also made a key recommendation to consume less than 2,300 mg of sodium per day. This recommendation was based on the UL for individuals ages 14 years and older set by the IOM (Ref. 28)).

1. Mandatory Declaration

Under section 403(q)(1)(D) of the FD&C Act, nutrition information in food labels or labeling must include, among other things, the amount of sodium, and our preexisting regulations, at § 101.9(c)(4), require the declaration of sodium content on the Nutrition Facts label. The preamble to the proposed rule (79 FR 11879 at 11914) explained that Americans 4 years and older consume an average of approximately 3,650 mg sodium/day, which is more than twice the amount required to meet their adequate intake (1,500 mg/day for individuals 9 to 50 years old). We also noted that evidence continues to support the association between increased sodium consumption and increased blood pressure (id.). Consequently, the preamble to the proposed rule indicated that we would continue to require mandatory declaration of sodium at § 101.9(c)(4).

(Comment 321) Several comments supported the ongoing mandatory declaration of sodium content on the Nutrition Facts label. Some comments noted that providing this information will assist consumers in maintaining healthy dietary practices by helping them identify products with less sodium and to follow the advice of their health care professionals, specifically those consumers who are at higher risk of cardiovascular disease (CVD) (*e.g.,* people with chronic kidney disease, African Americans, people 51 years and older, and those with hypertension). One comment stated that consumer research indicates that sodium is one of the top three food components Americans consider when making decisions about buying packaged foods or beverages (Ref. 164). Another comment suggested that mandatory declaration along with the declaration of potassium would encourage food manufacturers to reduce sodium that is added to foods. However, the comment did not provide data to support these assertions.

(Response) We agree that the declaration of sodium on the food label will provide consumers with information on sodium content that can help them make appropriate food choices to help them maintain healthy dietary practices. However, with respect to the comment suggesting that mandatory declaration of sodium, along

with the declaration of potassium, would encourage food manufacturers to reduce sodium addition to foods, the extent that mandatory declaration of sodium and potassium will encourage reformulation is unknown.

The final rule also requires disclosure of potassium. We discuss comments regarding the mandatory declaration of potassium at part II.L.3.b.

(Comment 322) One comment opposed mandatory declaration of sodium and asked us to look critically at the science behind the dietary sodium recommendations and to consider removing sodium from the list of mandatory nutrients. However, the comment recognized that, given the 2010 DGA (Ref. 30) and the 2010 IOM Sodium Strategies Report (Ref. 165), FDA may feel that eliminating sodium as a mandatory nutrient is not possible at the current time.

(Response) We decline to remove sodium from the list of mandatory nutrients. We note that section 403(q) of the FD&C Act expressly lists sodium as one of the nutrients to appear on the Nutrition Facts label. While the FD&C Act also provides a mechanism for us to remove nutrients from the label or labeling of food, we would have to determine that the information related to that nutrient is not necessary to assist consumers in maintaining healthy dietary practices. In the case of sodium, evidence continues to support the association between increased sodium consumption and blood pressure. In 2005, the IOM DRI Electrolytes Report noted a direct relationship between sodium intake and increased blood pressure (Ref. 166). The 2010 DGAC (Ref. 30) and the 2013 IOM report on Sodium Intake in Populations, Assessment of the Evidence (Ref. 167) concluded that a strong body of evidence has been documented in adults that blood pressure decreases as sodium intake decreases. The 2015 DGAC Report corroborates our position in the proposed rule because it also concluded that there is a strong body of evidence linking increased sodium intake to increased blood pressure (Ref. 19). Thus, the evidence continues to support mandatory declaration of sodium on the Nutrition Facts label.

2. DRV

We proposed to revise § 101.9(c)(9) to reduce the DRV for sodium from 2,400 mg to 2,300 mg. The preamble to the proposed rule (79 FR 11879 at 11914 through 11915) explained that new scientific data and consensus reports on sodium highlighted the need to reconsider the DRV.

(Comment 323) Several comments supported a DRV of 2,300 mg and agreed that the UL established by the IOM in 2005 is an appropriate basis for setting a DRV. The comments also noted that the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence report (Ref. 167) concluded that evidence on direct health outcomes is not consistent and insufficient to conclude that lowering sodium intakes below 2,300 mg/day either increases or decreases risk of CVD outcomes or all-cause mortality for the general population. The comments also noted that the IOM concluded there was no evidence on health outcomes to support treating subpopulation groups differently from the general U.S. population. A few comments noted that a recent meta-analysis by Graudal et. al (2014) showed that there is a U-shaped relationship between sodium intake and health outcomes (Ref. 168). (A U-shaped curve indicates that, at low levels of intake, there is a risk of inadequacy and, at high levels of intake, there is a risk of adverse events.) The comments noted that the Graudal et al. study extends the IOM report by identifying a specific range of sodium intake, 2,645 to 4,945 mg, associated with the most favorable health outcomes, within which variation in sodium intake is not associated with variation in mortality. The comments stated that this analysis underscores the conclusions of the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence report (Ref. 167) and supports setting a DRV of 2,300 mg and does not support reducing the DV to 1,500 mg.

Other comments supporting a DRV of 2,300 mg argued that a DRV based on a UL (rather than an RDI based on an AI) is consistent with our current and proposed approach for other nutrients (*e.g.,* saturated fat and cholesterol) that should be limited in the diet and for which there are concerns of excess intake and risk of chronic-disease or health-related conditions.

Some comments supporting a DRV of 2,300 mg said that this value is consistent with the 2010 DGA recommendation for the general population. Another comment stated that scientific evidence and Federal nutrition policy do not support recommending that the general public reduce their daily intake of sodium to 1,500 mg/day. The comment noted that 2005 DGA report's statement for specific population groups to ''consume no more than 1,500 mg'' inadvertently implied that the 2005 DGA had defined a new UL for these groups. Furthermore, the comments said that the NHLBI's Lifestyles Evidence Review recommended no more than 2,400 mg/day and that a further reduction to 1,500 mg/day would be even more beneficial for adults with pre-hypertension and hypertension who could benefit from blood pressure lowering. While the NHLBI report found strong evidence for reducing sodium intake and lower blood pressure, the comment said that the evidence for specifying an optimal intake level for sodium intake was moderate, and the evidence for sodium intake and CVD events was low.

(Response) We agree with the comments supporting a DRV of 2,300 mg for sodium. The DRV is consistent with the scientific evidence from consensus reports, such as the 2005 IOM DRI Electrolytes report (Ref. 166) and the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence (Ref. 167), as well as our approach for other nutrients (such as saturated fat and cholesterol) that should be limited in the diet. The final rule, therefore, establishes a DRV of 2,300 mg for sodium.

To the extent the comment suggests that the 2005 DGA implied that 1,500 mg was the new UL for specific subgroups, we disagree. While the 2010 DGA recommended reducing sodium intake to the AI of 1,500 mg/day for certain subpopulations at increased risk of the blood-pressure raising effects of sodium (*e.g.,* older persons, African-Americans, and individuals with hypertension, diabetes or chronic kidney disease), the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set a separate UL for these groups (see 79 FR 11879 at 11914 through 11915). The AI for sodium of 1,500 mg/day was based on meeting essential needs of sodium (*e.g.,* replacing sweat losses) and not blood pressure. We note that the NHLBI Lifestyles Evidence Review recommendations apply to adults with pre-hypertension and hypertension who would benefit from blood pressure lowering.

(Comment 324) Some comments stated that, while intake below 2,300 mg/day of sodium is desirable for some individuals, particularly those at risk of hypertension, the 2,300 mg/day recommendation seems most achievable given the current food supply and intake levels in the general U.S. population. The comments said that sodium targets below 2,300 mg/day would make it hard to meet other nutrient needs, particularly potassium. In addition, one comment said that substantially lowering the current DV to 1,500 mg would reduce the palatability of foods that can be labeled as ''low sodium'' (*e.g.,* assuming, as FDA

recognized, the eligibility criteria of 140 mg/RACC) used to define low sodium would likely be adjusted to remain consistent with current cut points for ''low'' nutrient content claims which are set at levels around 5 percent DV or less).

(Response) The DRV of 2,300 mg is based on clinical data on sodium and blood pressure that is applicable to the general U.S. population and represents an amount not to exceed. The DRV for sodium is not based on the levels of sodium in the food supply or eligibility requirements for nutrient content claims. However, we recognize that revisions of other regulatory requirements, such as nutrient content claims (*e.g.,* low sodium), would be less likely if the DV were updated to 2,300 mg (see 79 FR 11879 at 11916) and that there may be fewer technological barriers and product acceptance issues (*e.g.,* palatability) for products that meet the current definition of ''low'' sodium.

(Comment 325) A few comments supported establishing a DRV of 2,300 mg, but suggested that we should consider the 2015–2020 DGA before issuing a final rule. Other comments suggested that we ask the IOM to re-evaluate the DRI for sodium or conduct our own re-evaluation to determine a sodium intake range. The comments stated that a new reevaluation should consider data on biomarkers, clinical outcomes as well as the sodium and potassium ratio.

(Response) Given the extensive reviews already conducted by the IOM, the 2010 DGA, and the 2015 DGAC, we decline to ask the IOM to re-evaluate the existing evidence for sodium or to conduct our own re-evaluation. The UL set by the IOM in 2005 was based on clinical studies on sodium intake and blood pressure. Additionally, the 2005 IOM Electrolytes report evaluated the data on the sodium and potassium ratio and concluded that the data were insufficient to be used to set requirements. The 2013 IOM report, Sodium Intake in Populations, evaluated the evidence on sodium intake and CVD outcomes, and the report's conclusions support the UL of 2,300 mg/day. Furthermore, the 2015 DGAC reviewed the evidence for blood pressure and clinical outcomes and recommended that the general population, 2 years and older, should rely on the UL of 2,300 mg/day based on evidence showing associations between increased sodium intake, increased blood pressure, and subsequent risk of heart disease, stroke, and mortality (Ref. 166). Therefore, we continue to consider the UL of 2,300 mg/day to be appropriate for the DRV for sodium. However, if significant changes in the science occur in the future, we would re-evaluate the evidence. We also note that the 2015–2020 DGA also supported a UL of 2,300 mg/day for individuals ages 14 years and older.

(Comment 326) Some comments stated that consumers recognize that sodium is a nutrient to limit and that it is appropriate to use the UL of 2,300 mg/day to establish a DRV because the UL is the dietary intake level of a nutrient that is recommended not to exceed during any given day. Some comments noted that setting a DRV of 2,300 would result in less consumer confusion than changing to an RDI of 1,500 mg because consumers already understand that sodium is a nutrient to limit (Ref. 164).

(Response) Results from the FDA Health and Diet Surveys (Refs. 169–171) have shown that consumers are aware that sodium is a nutrient to limit in the diet. As we noted in the preamble to the proposed rule (79 FR 11879 at 11916), this awareness would suggest that consumer acceptance of a DV based on a level not to exceed would be consistent with a DRV of 2,300 mg.

(Comment 327) Several comments objected to a DRV of 2,300 mg and supported a different level instead. Some comments supported using 1,500 mg and said that lowering the DV for sodium from 2,400 mg to 1,500 mg/day would align with the 2010 DGA recommendation for the majority of Americans, including persons who are 51 years or over, African-Americans, or individuals who have hypertension, diabetes, or chronic kidney disease.

(Response) We decline to establish an RDI for sodium of 1,500 mg. We note that the 2010 DGA recommended 2,300 mg/day for the general population. While the 2010 DGA recommended reducing sodium intake to the AI of 1,500 mg/day for certain subpopulations at increased risk of the blood-pressure raising effects of sodium (*e.g.,* older persons, African-Americans, and individuals with hypertension, diabetes or chronic kidney disease), the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set separate UL for these groups (see 79 FR 11879 at 11914 through 11915). The AI for sodium of 1,500 mg/day was based on meeting essential needs of sodium (*e.g.,* replacing sweat losses) and not blood pressure. The UL of 2,300 mg/day applies to the majority of the U.S. population (persons aged 14 years and older) and is the highest daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population (79 FR 11879 at 11914). More recently, the 2013 IOM Sodium Intake in Populations (Ref. 167) report concluded that evidence was insufficient and inconsistent to recommend sodium intake levels below 2,300 mg/day for the general U.S. population based on the direct outcomes of CVD or all-cause mortality. In addition, the IOM concluded that the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day (see 79 FR 11879 at 11915). We also note that the 2015–2020 DGA recommended limiting sodium intake to less than 2,300 mg/day for individuals ages 14 years and older.

(Comment 328) Some comments supporting a DV of 1,500 mg noted that the 2010 IOM Strategies to Reduce Sodium Intake in the U.S. report recommended that we lower the DV for sodium to 1,500 mg based on the AI.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11916, 11917), we recognized that the 2010 IOM report recommended that we base the DV for sodium on the AI of 1,500 mg/day, and we invited comment on whether an RDI of 1,500 mg would be more appropriate and why. We also noted that the IOM said that using the AI would be consistent with the approach used for all other essential nutrients, where the DV is based on a reference value of adequacy rather than a reference value of safety (79 FR 11879 at 11916). However, the 2010 IOM report did not focus on reviewing the scientific evidence between sodium intake and health or with reevaluating the dietary guidance levels of sodium that should be consumed. The AI is a level to achieve in the diet to meet essential needs and is not an UL. Thus, we continue to consider that the 2005 IOM DRI Electrolytes report and 2013 IOM Sodium in Populations report, which conducted extensive reviews of the literature on sodium intake and blood pressure and/or CVD outcomes, are the most appropriate basis for a DRV of 2,300 mg.

(Comment 329) Some comments stated that a DV of 1,500 mg would be consistent with recommendations of the 2010 DGAC, CDC, the American Public Health Association, and the American Heart Association.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11890), we explained the factors we consider for nutrients of this type: (1) Existence of

quantitative intake recommendations, particularly reference intake levels provided in consensus reports that can be used to set a DRV or RDI; and (2) public health significance, as demonstrated by either well-established evidence or evidence of a problem with the intake of the nutrient in the general U.S. population and evidence of the prevalence of the chronic disease, health-related condition, or health-related physiological endpoint that is linked to that nutrient in the general U.S. population. While the 2010 DGAC Report recommended that sodium be reduced over time to 1,500 mg/day, the 2010 DGA did not recommend 1,500 mg/day for the general population. The CDC recommendations are consistent with the 2010 DGA. The recommendations of the American Heart Association and the American Public Health Association of 1,500 mg/day did not persuade us to adopt a lower value as the DRV for sodium for the general U.S. population. We determined that the data and information on sodium intake and health from U.S. consensus reports that support a quantitative intake recommendation for sodium of 2,300 mg/day provide an adequate basis on which we can rely to establish 2,300 mg/day as the DRV for sodium.

(Comment 330) Several comments said we should not use the ''flawed'' 2013 IOM Sodium Intake in Populations report to set dietary policy. According to the comments, the IOM did not consider hypertension itself as a health outcome despite the relationship between blood pressure and cardiovascular disease. The comments also said that there are methodological concerns with some studies that the IOM considered, such as unreliable measures of sodium intake and results that are not generalizable to the general population. The comments also said that the IOM based its conclusions, in part, on a study with suspect evidence that focused on people with heart failure who received an aggressive treatment that is not used in the United States. The comments said that these methodological issues limit the IOM report's usefulness in setting dietary recommendations that are applicable to the general population and that we should base the DV for sodium on a robust body of evidence linking sodium intake with elevated blood pressure and on the few existing trials of sodium reduction and CVD. One comment stated that among those population trials is the Trials of Hypertension Prevention Study (TOHP I and II). The comment noted that the observational followup study showed a 30 percent reduction in the risk of CVD even among those in the reduced sodium group that decreased sodium intake by 20 to 30 percent (Refs. 172–173). The followup study found a continued decrease in CVD events among those with sodium levels as low as 1,500 mg/day with no evidence of a J-shaped curve (increased risk of CVD at upper and lower levels of sodium intake) (Ref. 174). Those who excreted less than 2,300 mg/day had a 32 percent reduction in risk; however, this reduction was not statistically significant (Ref. 174).

(Response) We based the DRV of 2,300 mg primarily on the UL established in the 2005 IOM DRI Electrolytes report. The UL is, itself, based on clinical studies on sodium intake and blood pressure. Moreover, the 2013 IOM Sodium Intake in Populations report conclusions that are based mostly on observational studies on intake of sodium and outcomes for CVD and all-cause mortality are consistent with a DRV of 2,300 mg. While the IOM included studies in patients with Congestive Heart Failure (CHF), it did consider the other subgroups separately. The IOM concluded that, while the current literature provides some evidence for adverse health effects of low sodium intake among individuals with diabetes, chronic kidney disease (CKD), or preexisting CVD, the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the IOM concluded that the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day.

As for the comment regarding the use of a ''robust body of evidence,'' our decision to use the DRV of 2,300 mg is based on a robust body of evidence. Both IOM consensus reports were comprehensive reviews on the evidence between sodium intake and blood pressure and/or CVD outcomes. Additionally, the TOHP I and TOHP II trials and the followup observational study (Ref. 172) cited by the comment were included in the IOM's comprehensive review in 2013. The 2013 IOM report noted that Cook et al. 2007 (Ref. 172), an observational followup of the TOHP I and II sodium reduction trials, found a 25 percent reduction in CVD incidence (RR = 0.75, [Confidence Interval [CI]: 0.57 to 0.99], P = 0.04) when average sodium intake decreased from approximately 3,600 to 2,300 mg/day in the intervention group in TOHP I and from 4,200 to 3,200 mg/day in TOHP II (Refs. 167, 172). Further adjustment for baseline sodium excretion and body weight found a 30 percent lower risk (RR = 0.70 [CI: 0.53, 0.94], P = 0.02). The recent additional analysis conducted by Cook et al., 2014 (Ref. 174) on a subset of the TOHP participants not in the sodium reduction intervention group and stratified based on sodium intake (<2,300 mg, 2,300 to <3600 mg, 3,600 to <4,800 mg, and 4,800 mg and higher) was published after the 2013 IOM report. This additional analysis showed a significant P for trend; however, CIs for CVD risk were not statistically significant between the lower daily intake levels (<2,300 mg; 2,300 to <3,600 mg) and the reference intake level (of 3,600 mg to <4,800 mg) for the three models used in the analysis. Many studies analyze for the statistical significance of the linear relationship (P for trend) between the substance and the disease. While this trend may be significant (P <0.05), the difference in risk between subjects at the various levels of intake (*e.g.,* tertiles, quartiles or quintiles of intake) may not be significant (Ref. 85). In this case, because the CIs are not significant, the Cooke et al., 2014 study shows no effect for the association of sodium intake and risk of CVD when stratified by intake levels. When establishing a DRV, we consider the totality of the scientific evidence and do not consider it appropriate to rely on one observational study in lieu of a larger body of evidence that includes intervention studies on sodium and blood pressure and other observational studies on sodium and CVD outcomes. Therefore, we consider the UL of 2,300 mg/day appropriate for establishing a DRV.

(Comment 331) Some comments supporting a DRV of 1,500 mg stated that this value would be consistent with what we had proposed for other nutrients (*e.g.,* vitamin K, biotin, pantothenic acid, manganese) where the IOM had established an AI, but not an RDA.

(Response) We disagree that the DRV for sodium should be consistent with vitamins and other minerals. Unlike vitamins and other minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL. There is not a concern with overconsumption of these vitamins and other minerals. This makes sodium unique in comparison to other vitamins and minerals for which people generally strive to meet their daily needs.

(Comment 332) Some comments opposed to a DRV of 2,300 mg stated that using the UL might confuse consumers into thinking that it is a recommended intake level.

(Response) The comment provided no data to support its position, and we are not aware of data indicating that consumers would be confused with using a DRV based on an intake level not to exceed. The current DRV for sodium has been listed on food labels for the past 20 years and represents an amount not to exceed. Additionally, the FDA Health and Diet Surveys (Refs. 169–171) have shown that consumers are aware that sodium is a nutrient to limit in the diet. Furthermore, our approach for sodium is consistent with the approach we use for other nutrients, such as saturated fat and cholesterol, that should be limited in the diet (see 79 FR 11879 at 11915 through 11916).

(Comment 333) One comment said that we had indicated that consumers would find it difficult to reduce their sodium consumption to 1,500 mg/day because of the high-sodium content in the food supply and because of taste preferences. The comment said that tastes can change as sodium levels are reduced and that lowering the DV for sodium would give manufacturers greater incentive to reduce the sodium content of their foods.

(Response) We are establishing a DRV of 2,300 mg/day for reasons unrelated to the sodium content in the food supply and taste preferences. Therefore, the issues the comment raises are no longer relevant, and we are not making changes in response to this comment. We note that we are considering other ways to support the reduction of sodium in the food supply that take into account technological challenges to sodium reduction (see 76 FR 57050, September 15, 2011).

(Comment 334) One comment said that not setting the DV at 1,500 mg would be arbitrary and capricious. The comment said that Agency action is arbitrary and capricious if the action departs from prior Agency policy without explanation or with disregard for factual determinations that we made in the past. The comment acknowledged that we had presented several alternatives to the DV of 2,300 mg, including alternative DVs of 1,500 and 1,900 mg and a ''tiered approach,'' but said that our proposal ''lacks an adequate basis in the record'' and that a DV of 2,300 mg is not protective of vulnerable populations. The comment cited the preamble to the proposed rule to indicate that most DRVs have been based on a quantitative intake recommendation associated with chronic disease risk of a health-related condition (79 FR 11879 at 11892) and that, in the case of iron, we set a DV to protect population subgroups that require more iron, such as young children (1 to 4 years of age), women of childbearing age (12 to 49 years old), and pregnant women. It contrasted the DV for sodium as being a ''UL for all of the population over 14 years of age and substantially in excess of that for younger children.'' The comment said that we acknowledged that roughly one-half of the adult population, namely African Americans, individuals ages 51 years or older, and individuals with hypertension, chronic kidney disease, or diabetes, should be consuming lower levels of sodium (Ref. 175). For those subgroups, 1,500 mg/day is the recommended maximum intake for sodium (Ref. 30). The comment claimed that the DV ''will affirmatively mislead the most affected but suggesting a much higher target for their consumption than is healthy or medically appropriate.''

The comment referred to the preamble to the proposed rule where we discussed using 1,500 mg as a possible DV for sodium (79 FR 11879 at 11914 through 11915) and said we focused inappropriately on a ''flawed'' 2013 IOM report to arrive at a DV of 2,300 mg for sodium.

(Response) We disagree with the comment. The preamble to the proposed rule discussed, at some length, the options we considered for updating the DV for sodium and why we proposed to set a DRV of 2,300 mg for sodium based on the UL for individuals aged 4 years and older and how a DRV of 2,300 mg for sodium is the most appropriate DV (79 FR 11879 at 11914 through 11917). For example, we stated that:

- A DRV of 2,300 mg represents the UL for the majority of the population (persons 14 years of age and older) and is consistent with both the 2005 and 2010 DGA recommendations for sodium intake in the general population as the 2013 IOM report on Sodium Intake in Populations (id. at 11914);
- Setting the DV at 2,300 mg would classify the level as a DRV (rather than an RDI) and represent a reference intake level not to exceed. This would be consistent with our approaches to using DRVs for other nutrients that should be limited in the diet and for which there are concerns of excess intake and risk of chronic or health-related conditions (id.). Thus, although the comment claimed that a DV of 2,300 mg would mislead consumers into believing they should consume more sodium, we reiterate that, as a DRV, it is a reference intake level not to exceed. Moreover, as we stated in the preamble to the proposed rule, if we were to adopt a DV of 1,500 mg, we anticipate that consumer education efforts would be needed to help consumers understand that the updated DV for sodium is a level to achieve rather than a level to consume less than and also that consuming in excess of this level would not be helpful (id. at 11916);
- Although the comment said we used a different approach for iron, the comment's comparison is misplaced. As the preamble to the proposed rule noted, iron *deficiency* is a concern (see id. at 11919), so the DV for iron represents a level that is to be achieved. Sodium, in contrast, is a concern due to overconsumption, so the DV for sodium is based on a reference intake level that should not be exceeded. As we stated in the preamble to the proposed rule, unlike the consumption of other vitamins and minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL, and this makes sodium unique in comparison to the other vitamins and minerals for which people generally must strive to meet their daily needs (id. at 11916);
- As for the comment's depiction of the 2013 IOM report as ''flawed,'' as discussed in our response to comment 330, we disagree. Furthermore, we stated, in the preamble to the proposed rule, that a DRV of 2,300 mg, which represents the UL, would be consistent with the 2005 and 2010 DGA recommendations for sodium intake in the general population (id. at 11915). (We also note that it is consistent with the 2015–2020 DGA and that the ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee'' maintains a goal of less than 2,300 mg dietary sodium per day for the general population);
- We disagree that the UL is ''substantially in excess of that for younger children.'' The UL for children 4 to 8 years is 1,900 mg/day and 2,200 mg/day for adolescents 9 to 13 years. (We note that these values are the same in the 2015–2020 DGA.) The IOM derived these ULs for these age groups by extrapolating downward from the adult UL of 2,300 mg/day based on mean energy intakes because the evidence for sodium reduction on blood pressure in children is limited and inconsistent and was therefore insufficient to directly set a UL. We reiterate that the DRV for sodium is an amount not to exceed and not a recommended intake level. Therefore, it is appropriate to use the UL that represents the majority of the population as the basis for setting the DRV; and
- We also disagree with the comment's assertion that for subgroups the DV ''will affirmatively mislead the most affected by suggesting a much higher target for their consumption than

is healthy or medically appropriate.'' The 2013 IOM Sodium in Populations report concluded that the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day (see 79 FR 11879 at 11915). Additionally, the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set a separate UL for these groups (see 79 FR 11879 at 11914 through 11915). Furthermore, consumers in these subgroups may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions (see 79 FR 11879 at 11887).

Thus, we disagree that a DV of 2,300 mg for sodium is ''arbitrary and capricious,'' departs from our past practice, or lacks an adequate basis in the record.

(Comment 335) Several comments supported retaining a DV of 2,400 mg. Some comments said experts disagree what the recommended daily amount for sodium should be and said that the 2013 IOM report on Sodium Intake in Populations did not recommend an intake level. Some comments cited a meta-analysis by Graudal et al. (Ref. 168) that included over 250,000 participants; the comment said that there is a u-shaped relationship between sodium intake and health outcomes (Ref. 168). One comment noted that this relationship could enable a more precise determination of intake levels to be achieved rather than relying on dietary modeling and a somewhat arbitrary cutoff on a continuous scale. Therefore, the comment said we should convene a panel to review the evidence, examine the scientific evidence associating sodium intake to measurable health outcomes, or wait for the publication of the 2015–2020 DGA report to be published for consideration.

(Response) We disagree that there is not agreement on a sodium intake level among experts. The 2005 IOM DRI Electrolytes report, a U.S. consensus report, set a UL of 2,300 mg/day based on clinical trials that evaluated the dose-response relationship between sodium intake and blood pressure. Retaining the existing DRV of 2,400 mg would exceed the UL for sodium for the majority of the population (persons 14 years of age and older) (see 79 FR 11879 at 11915). While the 2013 IOM Report on Sodium Intake in Populations Assessment of the Evidence was not given the task to set a target intake level, the conclusions of this review that examined the benefits and adverse outcomes of reducing sodium intake primarily in observational studies are consistent with the UL of 2,300 mg/day. Furthermore, all of the individual studies in the Graudal meta-analysis (2014) cited by the comments have been considered in the IOM reports (Refs. 166–168). In addition, this meta-analysis does not represent the totality of the scientific evidence. Given the extensive reviews already conducted by the IOM, we do not agree that it is necessary to convene a panel to re-review the existing evidence at this time. The scientific evidence from the 2005 IOM DRI Electrolytes report, the 2013 IOM Sodium in Populations report, and the 2010 DGA report that we relied on in the proposed rule are a sufficient basis to establish a DRV of 2,300 mg. Furthermore, the 2015–2020 DGA conclusions corroborate a DRV of 2,300 mg.

(Comment 336) The preamble to the proposed rule discussed the possibility of using a ''tiered approach'' whereby we would set an interim DRV of 2,300 mg and lower to an RDI of 1,500 mg over time (79 FR 11879 at 11916 through 11917). We explained that a tiered approach would give companies more time to manufacture new foods or reformulate existing products, would help gradually achieve an adequate intake level of 1,500 mg/day, and would be consistent with the 2010 DGAC recommendation, but we stated that there was inadequate justification for proposing a tiered approach.

A few comments agreed with our conclusion that there is inadequate justification in consensus reports to use a tiered approach. The comments noted that a tiered approach would be an unprecedented process and inconsistent to the approach used for other nutrients, such as saturated fat and cholesterol, to limit in the diet. Another comment noted that a tiered approach may not help consumers adjust their taste preferences for sodium (Ref. 176).

Other comments, however, recommended that we consider the tiered option if an RDI of 1,500 mg is not used. The comments said a tiered approach would provide food manufacturers with more time to reformulate, allow consumer taste preferences to adjust, and be consistent with the 2010 DGAC recommendation to reduce sodium intake to 1,500 mg/day over time. Some comments said a phased-in approach also would be consistent with the 2010 IOM Strategies to Reduce Sodium Intake in Populations report which recommended reducing sodium content in a stepwise manner (Ref. 165).

(Response) We decline to amend the rule to adopt a tiered approach. As we explain in our response to comment 325, we have set a DV of 2,300 mg based on a UL. We also maintain that DVs are based on scientific data supporting healthy dietary practices rather than the levels of a nutrient present in the food supply (see 79 FR 11879 at 11914). However, we are working on efforts to reduce sodium content in various foods and encourage manufacturers to take steps towards reducing sodium content.

(Comment 337) One comment suggested that reference to any daily nutritional intake or requirement for sodium is misleading and that we should halt any further consideration of regulations on the sodium content of food. The comment said that neither the AI nor the UL established by the IOM should be used to recommend intake levels of sodium because they are inconsistent with results from populations studies on sodium intake (Refs. 177–178). The comment also said that using the AI and UL would violate the National Nutrition Monitoring and Related Research Act, 7 U.S.C 5301 *et seq.* The comment added that the 2013 IOM report concluded that there is no consistent evidence supporting any association between sodium intake and health outcomes and the Dietary Guideline of 1,500 mg sodium per day and could increase health risk for certain population groups. The comment asserted that the range of sodium intake at which there is the least negative health outcomes based on mortality and measureable feedback responses (renin, aldosterone, catecholamines, cholesterol and triglycerides) is above 130 mmol (approximately 3,000 mg/day) and that this is the level that most people around the world already consume (Ref. 179). The comment stated that restriction of sodium intake stimulates the renin-angiotensin-aldosterone (RAS) response and may lead to insulin resistance, increased mortality from diabetes, increased congestive heart failure risk, negative blood chemistry and increased overall mortality (Refs. 179–182). The comment also stated that the IOM had agreed to re-evaluate the DRIs for sodium.

(Response) We disagree that any reference to any daily intake is misleading, that there should be no reference to an intake recommendation for sodium, and that we should stop working on ways to reduce the sodium content of food. While we agree that the AI for sodium, which was based on

meeting essential needs, is not a suitable basis for establishing a DRV, we disagree that the UL should not be used to establish a DRV for sodium. There is well-established evidence from consensus reports on the relationship between sodium intake and blood pressure (Ref. 166). The UL of 2,300 mg/day was based on clinical trials that evaluated the dose-response relationship between sodium intake and blood pressure (Ref. 166). In addition, the 2013 IOM Sodium Intake in Populations report concluded that clinical outcomes primarily from observational studies are consistent with the UL of 2,300 mg/day. One observational population study cited by the comment (Ref. 177) was reviewed by the IOM in 2005 and 2013 and another study done by Powles et al., 2013 (Ref. 178) did not evaluate sodium intake to CVD outcomes or blood pressure and only estimated sodium intakes around the world.

We also disagree with the comment that suggests there should be no restriction of sodium below current intake levels of 3,000 mg/day because of concerns of negative health outcomes. The 2005 IOM Electrolytes report reviewed the evidence on low sodium intake and blood lipid concentrations and insulin resistance and noted that the Al of 1,500 mg/day exceeds the levels of sodium intake (typically less than 700 mg/day) that have been associated in some studies with adverse effects of blood lipid concentrations and insulin resistance (Ref. 166). The 2005 IOM Electrolytes report reviewed the evidence for plasma renin and concluded that, in contrast to blood pressure, there is no consensus on the interpretation of plasma renin activity and its role in guiding therapy for high blood pressure (Ref. 166). Similar to plasma renin activity, the evidence for the role of sympathetic nerve activity (*e.g.,* release of catecholamines) and aldosterone is limited, and neither catecholamines, aldosterone, plasma renin, or triglycerides are recognized as validated surrogate endpoints for predicting CVD risk (see 79 FR 11879 at 11916). Furthermore, while consumers with acute or chronic disease, such as obesity, CVD (including CHF), or diabetes, may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions, the nutrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and are not intended for the clinical management of an existing disease (see 79 FR 11879 at 11887 and part II.B.2). In addition, while sodium was nominated as part of the DRI nomination process that was developed to help Federal Agencies prioritize which nutrients are reviewed, the IOM has not been asked to undertake a re-evaluation of the DRI for sodium as asserted by the comment (Ref. 183). To our knowledge, the IOM also has not agreed to reevaluate the DRI for sodium as asserted by the comment.

Lastly, in response to the comment asserting that using the AI and UL would violate the National Nutrition Monitoring and Related Research Act (NNMRRA), to the extent the comment suggests our establishment of a DRV of 2,300 mg/day for sodium for purposes of labeling is somehow not consistent with nutritional monitoring and related research activities related to the NNMRRA, we disagree. We are requiring a DRV of 2,300 mg/day for sodium consistent with our authority in section 403(q) of the FD&C Act to assist consumers to maintain healthy dietary practices and to enable consumers to observe and comprehend the information and to understand the relative significance of the information in the context of a total daily diet. We also note that the NNMRRA was enacted on October 22, 1990 and that the NLEA was enacted on November 8, 1990. Nothing in the NLEA states or even suggests that the NNMRRA imposes limits or conditions on the declaration of nutrients on food labeling or on our statutory obligations under the NLEA.

(Comment 338) A few comments said that food labels should distinguish the amount of sodium that is added to food from the amount that is naturally occurring. The comments said we proposed a similar result for added sugar and that both sodium and added sugar cause serious health problems.

(Response) We decline to require the amount of added sodium to be declared separately from the amount that occurs naturally in food. The comment did not explain why we should consider a distinction between naturally occurring and added sodium for purposes of the sodium declaration or provide a scientific rationale for that distinction. (In contrast, the preamble to the proposed rule (79 FR 11879 at 11902 through 11905) discussed why we were proposing to require the declaration of added sugars, and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309) explained why we were proposing to establish a DRV of 10 percent of total energy intake from added sugars and to require a percent DV for added sugars.) We are not aware of any scientific evidence to support a distinction for added sodium in labeling. Therefore, we are not making changes in response to this comment.

(Comment 339) One comment said we should require disclosure of ''salt'' instead of ''sodium.'' The comment said that consumers understand ''salt,'' but may not know what ''sodium'' means. The comment also noted that most sodium we consume is in the form of salt and that other countries use the term ''salt.'' The comment stated that requiring use of the term ''salt'' would mean that consumers would see a larger number on food labels and that could deter consumers from eating high sodium foods.

(Response) We decline to revise the rule to replace ''sodium'' with ''salt.'' We note that section 403(q)(1)(D) of the FD&C Act expressly refers to ''sodium'' (rather than a specific form of sodium) as a nutrient and that ''sodium'' has been in the Nutrition Facts label since 1993 (see 58 FR 2079). We also note that our surveys suggest that consumers are aware that too much sodium is unhealthy (see 79 FR 11879 at 11916 (referring to results from the FDA Health and Diet Surveys)).

Furthermore, while most sodium consumed in the diet comes from sodium chloride (which is the compound associated most with ''salt''), other forms of sodium, such as sodium bicarbonate (*e.g.* baking soda) and monosodium glutamate (MSG), used in foods contribute to the intake of sodium and can also raise blood pressure.

K. Fluoride

1. Voluntary Declaration

Our preexisting regulations do not require or permit the declaration of fluoride on the Nutrition Facts label. Fluoride is a nonessential nutrient, but there is well-established evidence for the role of fluoride in reducing the risk of dental caries. As we said in the preamble to the proposed rule (79 FR 11879 at 11917), the declaration of fluoride content of a food can provide consumers with information to assist them in maintaining healthy dietary practices. However, because the evidence available to us did not allow us to establish a DRV for fluoride, we proposed to amend § 101.9(c)(5) to provide for voluntary declaration of fluoride. In addition, consistent with existing provisions for voluntary declaration of other nutrients, we proposed that the declaration of fluoride would be mandatory when a claim about fluoride is made on the label or in labeling of foods and that, when fluoride content is declared, it must be expressed as zero when a serving

contains less than 0.1 mg of fluoride, to the nearest 0.1 mg increment when a serving contains less than or equal to 0.8 mg of fluoride, and the nearest 0.2 mg when a serving contains more than 0.8 mg of fluoride, consistent with how we have approached incremental values for other nutrients that are present in food in small amounts.

(Comment 340) Several comments supported voluntary fluoride labeling and agreed that there is well-established evidence for the role of fluoride in reducing the risk of dental caries.

One comment suggested that manufacturers of foodstuffs/beverages voluntarily label fluoride content if levels do not exceed 0.2 ppm from fluoride-contaminated materials during product preparation or are less than 2 ppm if fluoride is present naturally. The comment would require foodstuffs/beverages to be labeled if fluoride is intentionally added to the product.

(Response) Under the final rule, declaration of a product's fluoride levels is voluntary whether intentionally added or present naturally. As we stated in the preamble to the proposed rule (79 FR 11879 at 11917), a DRV cannot be established for fluoride based on the available quantitative intake recommendations. Therefore, while fluoride is a nutrient with public health significance, consistent with the factors we considered for declaration of non-statutory nutrients such as this, fluoride declaration is voluntary in the Nutrition Facts label. The final rule also states how fluoride content must be expressed, depending on the amount of fluoride in a specified serving.

As for the comment suggesting that the declaration of fluoride be mandatory if it is added intentionally to a product, we disagree. The comment did not provide, nor do we have, a basis to require labeling of fluoride content when intentionally added. The addition of fluorine compounds to foods that would be subject to a voluntary fluoride declaration in the Nutrition Facts label includes fluoride in water that is used as an ingredient in food from fluoridation of public water supplies and fluoridation of bottled water within the limitations set forth in § 165.110(b)(4)(ii) (see § 170.45). We are not aware of added fluorinated compounds to other foods and would consider such an addition to be subject to a food additive approval under section 409 of the FD&C Act. Moreover, mandatory declaration is required if a claim about fluoride content is made on the label or in the labeling of foods (see § 101.9(c)(5)). Thus, we decline to revise the rule as suggested by the comment.

(Comment 341) One comment stated that declaration of fluoride should be mandatory because fluoride consumption is one of the safest and most effective ways to help prevent tooth decay. The comment said that most bottled waters contain negligible amounts of fluoride or are fluoride-free, so displaying the fluoride content of bottled water on Nutrition and Supplement Facts labels will help consumers make informed decisions about their choice of drinking water. The comment noted that, without such labeling, individuals who use bottled water as their primary water source could unknowingly be missing the decay preventive effects of optimally fluoridated water available from their community water supply.

(Response) We decline to amend the rule as suggested by the comment. There are already quantitative limits for fluoride with respect to bottled water. Furthermore, labeling of fluoride on bottled water would not be sufficient to inform a consumer about whether to consume water from the local municipal water supply. The consumer would need to understand the fluoride content of the local municipal water supply (or well water, if applicable) to understand the relative contribution of fluoride from each. Therefore, we do not consider it necessary to require labeling on the fluoride content of bottled water.

We also do not expect fluorination of food. To the extent fluoride is approved for use as an ingredient in a food, its form must be listed in the ingredient list, and so one can determine if there is fluoride in food by checking the ingredient list (§ 101.4(a)(1)).

(Comment 342) One comment agreed with the proposed requirements for voluntary declaration of fluoride and for mandatory declaration of fluoride if a claim is made about fluoride content or the label includes a FDA health claim for fluoride and dental caries. However, the comment objected to the need for a fluoride nutrient content declaration on bottled water when the product bears a statement of ''added fluoride'' as part of the statement of identity with an accompanying quantitative declaration elsewhere on the label. The comment said that declaring fluoride in the Nutrition Facts label in such a situation would not help consumers. The comment stated that including a statement about fluoride in the statement of identity (*e.g.,* spring water with fluoride added) under the bottled water standard should not be treated as a fluoride claim that triggers mandatory nutrition labeling as long as the amount of fluoride is otherwise declared on the label. The comment said that the proposed rule would impose a burden without any consumer benefit because fluoride is already declared and all other nutrients would be declared as zero. The comment added that, if we required Nutrition Facts labels on all foods that are otherwise exempt from nutrition labeling, labels on these foods would have to increase in size.

(Response) We agree that a declaration of fluoride would not be required on the label for bottled water if statements such as ''fluoridated,'' fluoride added,'' or ''with added fluoride,'' consistent with § 101.13(q)(8), are included. The use of these statements would, however, require use of a simplified format for nutrition labeling. In the preamble to the final rule establishing the standard of identity and standard of quality for bottled water (60 FR 57076 at 57079; November 13, 1995), we recognized that bottled water may be used by some consumers as an alternative to community drinking water and that the Surgeon General's Report on Nutrition and Health recommends that community water systems contain fluoride at optimal levels to prevent tooth decay. Therefore, we included, as part of the standard of identity for bottled water (§ 165.110(a)(1)), the optional addition of fluoride to bottled water within the limitations established in the quality standard (§ 165.110(b)(4)(ii)). We stated that a bottled water with added fluoride would be a multi-ingredient food and, as such, its label must bear ingredient labeling (21 CFR 101.4(a)(1)) (id.). We also stated that we provided for the use of terms ''fluoridated,'' ''fluoride added,'' or ''with added fluoride'' on the label or in labeling of bottled water that contains added fluoride in 21 CFR 101.13(q)(8) (id.). By doing so, we did not define a nutrient content claim for fluoride, and, instead, provided that a statement indicating the presence of added fluoride could be used, but that the claim cannot include a description of the level of fluoride present (*e.g.,* ''good source'' or ''high'') (58 FR 2302 at 2314). We also stated, in the preamble to another final rule (58 FR 2079 at 2149), that we considered the identity statement ''fluoridated water'' to be misleading if the product is derived from a source naturally containing fluoride. We concluded that the term ''fluoridated'' should be used to describe only products to which fluoride has been added in the manufacturing process and that such products must bear nutrition labeling that complies with the simplified format (id.). Thus, fluoride that is added to bottled water consistent with the

standard of quality in § 165.119(b)(4)(ii) and that bears a statement consistent with § 101.13(q)(8) must comply with the simplified format for labeling in § 101.9(f). However, we did not require any inclusion or declaration of fluoride in the simplified format for Nutrition Facts label because of the regulatory status of fluoride declarations and fluoride claims at the time. The terms ''fluoridated,'' ''fluoride added,'' or ''with added fluoride'' were not provided for use as nutrient content claims (which would require declaration of fluoride if defined as such), but rather as statements regarding the presence of added fluoride, which were declared exempt from the nutrient content claim general requirements (§ 101.13(q)). Moreover, even if the terms ''fluoridated,'' ''fluoride added,'' or ''with added fluoride'' were defined as nutrient content claims at that time, fluoride had not been included in § 101.9 as a nutrient for inclusion in Nutrition Facts label and would not have been able to be included in the simplified format for Nutrition Facts label even if those claims were used.

Through this final rule, we provide for the voluntary declaration of fluoride in the Nutrition Facts label, but, under the preexisting regulations, statements on the presence of added fluoride remain exempt from the nutrient content claim general requirements. We may evaluate our regulations for nutrient content claims (and health claims) for any necessary changes after publication of this final rule and the final rule on serving sizes. To be clear, with respect to labeling requirements when statements are made on the label about added fluoride in bottled water consistent with § 101.13(q)(8), we are not requiring the mandatory declaration of fluoride for bottled water that bears a statement about added fluoride. We are, however, including additional language in § 101.9(c)(5) to make clear that bottled water that bears a statement about added fluoride, as permitted by § 101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in § 101.9(f). If any other fluoride claim is used on the label (*e.g.,* the FDAMA health claim for fluoride or an amount statement under § 101.13(i)(3)), the declaration of fluoride would be mandatory on the Nutrition Facts label.

(Comment 343) One comment would revise the rule to require the declaration of fluoride if the amount of fluoride exceeds 0.5 mg per serving. The comment said that fluoride is a dangerous neurotoxin and that consumption of over 2 mg/day of fluoride in drinking water would cause widespread, significant dental fluorosis. The comment said that athletes or others who drink twice the average intake of water could easily consume more than 2 mg of fluoride per day.

(Response) The level of fluoride in public drinking water is outside the scope of this rulemaking.

With respect to community water sources, we note that, on April 27, 2015, the U.S. Public Health Service (PHS) recommended an optimal fluoride concentration of 0.7 mg/L for community water systems that add fluoride (see Department of Health and Human Services, ''HHS Issues Final Recommendation for Community Water Fluoridation,'' dated April 27, 2015; ''U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries,'' *Public Health Reports,* vol. 130, pages 1 through 14 (July–August 2015) (''PHS Recommendation'') (accessed on the Internet at *http://www.publichealthreports.org/documents/PHS_2015_Fluoride_Guidelines.pdf*). PHS indicated that this fluoride concentration, which replaces the previous recommended range of 0.7 to 1.2 mg/L, would maintain caries prevention benefits while reducing the risk of dental fluorosis (PHS Recommendation at 2). It also noted that the Environmental Protection Agency (EPA) is in the process of reviewing the maximum amount of fluoride allowed in drinking water (id.).

As for bottled water, although we have regulations establishing a quality standard for bottled water (§ 165.110), we issued a letter on April 27, 2015, based on the PHS recommendation, advising manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L (see Letter from Susan T. Mayne, Ph.D., F.A.C.E., Director, Center for Food Safety and Applied Nutrition, to Manufacturer, Distributor, or Importer of Bottled Water, dated April 27, 2015 (available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/BottledWaterCarbonatedSoftDrinks/ucm444373.htm*)). We intend to revise our quality standard for fluoride added to bottled water (at § 165.110(b)(4)(ii)) to be consistent with the PHS recommendation.

As for the comment's mention of dental fluorosis, the majority of dental fluorosis in the United States is the very mild form, and severe dental fluorosis is not common in the United States (Ref. 184). The prevalence of severe dental fluorosis could not be estimated in U.S. adolescents due to few cases in the participants in a national survey (Ref. 184). The PHS stated that ''to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation (birth through 8 years of age) for most permanent teeth, and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water'' (Ref. 184). The PHS and FDA recommendations or advice should reduce the risk of dental fluorosis while still preserving the benefit of caries prevention.

2. DRV

Our preexisting regulations do not provide an RDI or DRV for fluoride, and, in the preamble to the proposed rule (79 FR 11879 at 11917), we stated that we were not proposing to establish a DRV for fluoride.

(Comment 344) Some comments agreed with our decision to not establish a DRV for fluoride.

(Response) The final rule does not establish a DRV for fluoride.

3. Miscellaneous Comments

Several comments raised additional issues regarding fluoride.

(Comment 345) One comment said the fluoride declaration should be in units of mg per liter (mg/L) rather than mg/serving. The comment stated that that the FDAMA health claim is in mg/L, that we mandated the amount of fluoride in bottled water in mg/L, and that consumers are accustomed to seeing fluoride as mg/L on bottles. Therefore, according to the comment, to facilitate consumer understanding and comparisons between the amount of fluoride in bottled water or other products and the recommended intake levels, we should adopt mg/L as the unit for fluoride declarations. The comment further stated that if mg/serving were to be used as the unit, some servings of bottled water would need to be declared as 0 mg fluoride, despite containing a meaningful amount of fluoride from a public health perspective on a mg/L basis and that consumers may be confused if the label said ''with fluoride added'' but the Nutrition Facts label declared 0 mg of fluoride.

(Response) We decline to require the declaration of fluoride in the Nutrition Facts label to be in units of mg/L. The declaration of fluoride in the Nutrition Facts label is comparable to the other nutrients which are declared in absolute amounts per serving. Reporting mg per serving gives consumers an accurate amount of fluoride in a serving of the

product. Providing the amount of fluoride per liter may confuse consumers because the consumer may not be aware how much fluoride will be in the amount per serving (*e.g.,* 12 ounces of bottled water which is equal to about 360 mL).

As for the comment's mention of the FDAMA health claim and our bottled water regulation, the FDAMA health claim language did not mention a specific quantity of fluoride nor did it use a specific unit of measure; the claim language is ''Drinking fluoridated water may reduce the risk of [dental caries or tooth decay].'' We acknowledge that the bottled water regulation uses units in mg/L, yet we also note that the bottled water regulation is directed at manufacturers, distributors, and importers of bottled water and establishes a standard of identity and standard of quality for bottled water and includes maximum levels of fluoride in bottled water. In contrast, the Nutrition Facts label information declares nutrient content in a serving of a product to assist consumers in maintaining healthy dietary practices. Thus, we decline to amend the rule to require the declaration of fluoride to be in mg/L.

Finally, regarding the comment's claim that consumers would be confused if the label said ''with fluoride added'' and the Nutrition Facts label declared fluoride content as 0 mg, we note that the use of a statement, consistent with § 101.13(q)(8) would not require fluoride be declared on the label as ''0 mg.'' We are not aware of, and think it would be unlikely for, a manufacturer to voluntarily declare ''0 mg'' for fluoride if the level of added fluoride is at a level that must be declared as zero when making statements on its product consistent with § 101.13(q)(8). Any labeling must be truthful and not misleading, within the meaning of sections 403(a) and 201(n) of the FD&C Act.

(Comment 346) One comment interpreted the proposed rule as allowing fluoride claims for dental caries on all food labels. The comment asked if these health claims will be permissible, beyond fluoride in bottled water products, for conventional foods and dietary supplements of any matrix because we have evidence acknowledging fluoride's health benefits and whether we will update the current qualified health claim for fluoridated water and reduced risk of dental caries. Alternatively, the comment asked if claims for the reduction in dental caries in the labels for conventional food products (other than bottled water) and dietary supplements would lead us to regulate those products under a different category (such as an unapproved drug). The comment said that, if our evidence suggests benefits of dietary fluoride exposure in preventing dental caries, it is reasonable to conclude that the qualified health claim should be expanded to allow the claim in conventional foods and dietary supplements, labeled with dietary fluoride, and in all forms (capsule, tablet, liquid).

(Response) The proposed rule did not set forth a qualified claim with respect to fluoride. In the preamble to the proposed rule (79 FR 11879 at 11917), we explained that we received a FDAMA notification in 2006 for a health claim for fluoride in bottled water and that we did not object to the claim. The FDAMA health claim is limited to bottled water and does not extend to other foods. Under the FDAMA health claim, the food eligible to bear the claim is bottled water meeting the standards of identity and quality set forth in § 165.110, and general requirements for health claims in § 101.14 with the exception of the minimum nutrient contribution (§ 101.14 (e)(6)). For a health claim to be expanded to more foods, a health claim petition (§ 101.70) or a FDAMA notification must be submitted for our review (section 403(r)(3)(C) of the FD&C Act).

(Comment 347) One comment suggested that, when fluoride is intentionally added to foods/beverages for ingestion by consumers, the following disclaimer/label appear before the listed amount: ''Fluoride is not a mineral nutrient, has no daily allowance, and is not FDA approved for ingestion particularly for women who are pregnant. Fluoride is recognized by U.S. EPA as a water contaminant.'' One comment stated that voluntary labeling could help because those who add fluoride and claim it as a ''dietary ingredient'' will show fluoride content. The comment noted that consumers who understand that fluoride is unsafe to add to food can avoid buying the product.

(Response) We decline to revise the rule to include the comment's suggested language. While we agree that fluoride is a non-essential nutrient, there is well-established evidence for the role of fluoride in reducing the risk of dental caries, and the IOM set a quantitative intake recommendation (AI) based on its role in the reduction of risk of dental caries, but a DRV for fluoride has not been established. Furthermore, we have a standard of identity and a standard for quality for bottled water that allows voluntary addition of fluoride within the limitation established in § 165.110, and, as we stated in our response to comment 343, the PHS recently recommended an optimal fluoride concentration of 0.7 mg/L for community water systems that add fluoride. Based on the PHS recommendation, we advised manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L.

As for the comment's suggestion to include language that the EPA has recognized fluoride as a water ''contaminant,'' the fact that EPA has a maximum contaminant level for fluoride in public drinking water does not mean bottled water or other products containing fluoride should state that fluoride is recognized by U.S. EPA as a water contaminant. Fluoride, as a contaminant to public drinking water, is outside the scope of this rule.

(Comment 348) One comment stated that labeling could promote the false notion that fluoride is a nutrient and said that any accompanying claim that fluoride has ''nutritional value'' or is a ''dietary ingredient'' would constitute false labeling and would violate the FD&C Act.

(Response) We disagree with the comment. We consider fluoride to be a nutrient (specifically, a mineral) (Ref. 185) for purposes of nutrition labeling in section 403(q) of the FD&C Act. We consider a nutrient that is subject to nutrition labeling under section 403(q)(1) or (q)(2) of the FD&C Act also to be a dietary ingredient in section 201(ff) of the FD&C Act.

(Comment 349) One comment suggested that, when fluoride is declared over 0.5 grams per serving, the manufacturer declare the form of fluoride present. The comment said that this information is highly relevant given the well-known differences between the bioavailability and pharmacokinetic profiles of artificial fluorides (*e.g.* hydrosilicic acid, sodium monofluorophosphate) as compared with naturally occurring ones (principally calcium fluoride).

(Response) If a nutrient is added to a food, the form that is added must be declared in the ingredients list (§ 101.4(a)(1)). Moreover, under § 101.4(a)(1), if the ingredient is a dietary ingredient, the form would be in the ingredient list, unless already labeled in accordance with § 101.36. Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified within the nutrition label in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word ''as'' or

''from''. Therefore, we decline to revise the rule as suggested by the comment.

(Comment 350) One comment rejected the notion that fluoride is a safe ingredient that only provides benefit and no harm. The comment said that ingested fluoride is toxic and that we should cite references that address the harm of ingested fluoride. Another comment stated that all synthetic industrial fluorides (*e.g.,* hydrosilic acid, sodium monofluorophosphate) are toxic calcium chelators that are assimilated well. The comment said that fluoride is incorporated permanently in the bone during lifelong consumption, contributes to osteoporosis, accentuates hypothyroidism and dysfunctional kidneys, and can cause dental fluorosis in children and other effects. The comment said that natural calcium fluoride is not well assimilated and is the fluoride source for which labeling could be voluntary. The comment added that EPA's maximum contaminant level (MCL) for fluoride in drinking water (2 ppm) is derived for calcium fluoride in natural sources in public water supplies and that there is no established MCL for synthetic fluoride where toxicity can vary under differing environmental conditions and disease conditions of the consumers.

(Response) The preamble to the proposed rule highlighted the adverse impacts of high fluoride consumption set by IOM (Ref. 185) and U.S. EPA report (Ref. 186) (see 79 FR 11879 at 11917 through 11918). We also stated that other FDA regulations (§§ 165.110 and 170.45) have limited what foods contain added fluoride. We reiterate that we recently advised manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L.

As for the comment regarding synthetic and natural forms of fluoride, the final rule does not restrict itself to a specific source of fluoride. Absent data or information, we do not have a sufficient basis in the administrative record on which to distinguish ''natural'' forms of fluoride from ''synthetic'' forms and to base the fluoride declaration in the Nutrition Facts label on a particular form of fluoride.

We have not made any changes to the rule in response to these comments.

L. Essential Vitamins and Minerals of Public Health Significance

In addition to sodium, a statutorily required nutrient, our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of four essential vitamins and minerals, namely, vitamin A, vitamin C, calcium, and iron. Vitamins and minerals that may be declared voluntarily are vitamin D, vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium.

1. General Comments

(Comment 351) One comment opposed the mandatory declaration of any vitamins or minerals other than sodium and potassium. The comment noted that all vitamins and minerals are required in the diet and said that singling out a few nutrients on the label encourages unnecessary fortification and overconsumption. The comment stated that labeling potassium would encourage food manufacturers to reduce sodium to achieve a better balance.

(Response) The comment did not provide data or information to support its argument that the inclusion of a vitamin or a mineral on the Nutrition Facts label will encourage fortification or overconsumption. With respect to fortification, we encourage manufacturers to follow the principles in our fortification policy at § 104.20 if they add nutrients to food. We issued the fortification policy to promote the rational addition of nutrients to foods and to preserve a balance of nutrients in the U.S. diet. In addition, our food additive regulations or GRAS status of some nutrients (*e.g.,* vitamin D and folic acid) may limit which foods may be fortified and at what level. For example, the food additive regulations on folic acid (21 CFR 172.345) and vitamin D (§ 172.379 (21 CFR 172.379); § 172.380) stipulate which foods may be fortified and at what level.

As for the mandatory declaration of vitamins and minerals, as we stated in the preamble to the proposed rule (79 FR 11879 at 11918 through 11922), we determined that iron, calcium, vitamin D, and potassium are nutrients of public health significance and their mandatory declaration on the label can help consumers maintain healthy dietary practices. We mentioned how we considered several factors, such as intake and/or biomarker data, IOM setting a quantitative intake recommendation for a nutrient based on its relationship to a chronic disease, or a health-related condition to determine whether a particular nutrient was of public health significance for the general U.S. population (id.). The comment did not dispute our assessment of the data or provide information that would cause us to reconsider our analysis of the factors supporting mandatory declaration. Thus, we decline to revise the rule as suggested by the comment.

(Comment 352) Some comments said that our nutrients of public health significance (*e.g.,* calcium and vitamin D) are similar to nutrients of public health concern as determined by the 2010 DGA recommendations. The comments suggested that we wait for the 2015–2020 DGA decision on nutrients of public health concern, so we can be consistent with the 2015–2020 DGA.

(Response) We note that our nutrients of public health significance are the same as the 2010 DGA and the 2015 DGAC recommendations. The 2015 DGAC used a three pronged approach similar to our factors for determining whether nutrients that have a specific relationship to chronic disease risk or a health-related condition are nutrients of public health concern, including an analysis of intake data, available valid biochemical indices from NHANES dietary survey, and data on the prevalence of health condition in the U.S. population. Based on the 2015 DGAC approach, vitamin D, calcium, potassium, iron, and fiber were considered as nutrients of public health concern for under-consumption.

We also note that the 2015–2020 DGA identifies calcium, potassium, dietary fiber, vitamin D, and iron as nutrients of public health concern.

2. Essential Vitamins and Minerals That Are Mandatory

a. Calcium. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of calcium content as a percent DV on the Nutrition Facts label. We require the declaration of calcium in nutrition labeling because: (1) There were a limited number of calcium-rich foods in the food supply; (2) calcium intakes in the United States were generally marginal; (3) adequate calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood; and (4) calcium was identified as a nutrient of public health significance in the 1990 IOM report and in other consensus reports (58 FR 2079 at 2106).

In the preamble to the proposed rule (79 FR 11879 at 11918 through 11919), we discussed the benefits of adequate calcium intake on bone health, the relatively low intakes of calcium, and the high prevalence of osteoporosis and osteopenia among the U.S. population. We decided to continue requiring the declaration of calcium on the Nutrition Facts label, and so the proposed rule would not change § 101.9(c)(8)(ii).

(Comment 353) Most comments supported mandatory declaration of calcium on the Nutrition Facts label.

However, some comments supported mandatory declaration for different reasons. Some comments focused on calcium's role in bone health, but most comments said that calcium is important for dialysis and renal patients.

(Response) While a mandatory calcium declaration may help patients who have chronic kidney disease, this was not a factor we considered in mandating the declaration of calcium. The Nutrition Facts label is not intended to focus on individuals with a specific acute or chronic disease (see part II.B.2). To evaluate the public health significance of essential vitamins and minerals, we considered several factors in determining the mandatory declaration of vitamins and minerals in the Nutrition Facts label. We considered the essential vitamins and minerals with the greatest public health significance to be those for which IOM based DRIs on chronic disease risk (*e.g.,* osteoporosis), a health-related condition (*e.g.,* high blood pressure), or a nutrient deficiency with clinical significance (*e.g.,* low iron storage leading to iron deficiency anemia) for which inadequate intake of these nutrients are likely to have important clinical consequences. We also considered whether the national survey data on nutrient intake and/or, when available, biomarkers of nutrient status, provide evidence of inadequate intake of the nutrient in the general healthy U.S. population, and whether a substantial prevalence of health consequences that was linked to the particular nutrient exists in the general healthy U.S. population (see 79 FR 11879 at 11890). In setting DRIs for calcium, the IOM reviewed various endpoints (*i.e.,* bone health, cancer, cardiovascular disease and diabetes), and bone health was the only endpoint with sufficient scientific evidence to set a DRI (Ref. 38). Therefore, given the benefits of adequate intake on bone health, reflected in the IOM's DRIs, relatively low intake of calcium (about 49 percent of individuals ages 4 years and older have usual calcium intake from conventional foods below the EAR and 37 percent have intakes from both conventional foods plus supplements below the EAR), and the high prevalence of osteoporosis and osteopenia among the U.S. population, we concluded that calcium is a nutrient of public health significance, and its declaration continues to be necessary to assist consumers in maintaining healthy dietary practices. Our preexisting regulation, at § 101.9(c)(8)(ii), continues to require the declaration of calcium content as a percent DV on the Nutrition Facts label, so the final rule does not affect the requirements for the declaration of calcium.

(Comment 354) One comment noted that adding calcium (plus vitamin D and potassium) to the Nutrition Facts label will be ''nice'' for those who understand these details, but, for most consumers (except perhaps those with Chronic Kidney Disease), information regarding calcium is just more information to sift through on an already-confusing food label.

(Response) We consider that a vitamin or mineral of public health significance should continue to be the key factor in deciding when to require mandatory declaration in labeling. Available quantitative evidence suggests that the declaration of nutrient of public health significance, including vitamins and minerals, can help consumers maintain healthy dietary practices (Refs. 187–188). Additionally, we intend to work with other Federal Agencies and organizations on communication and education for health professionals and consumers regarding the revised Nutrition Facts and Supplement Facts labels after we issue the final rule.

b. Iron. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of iron as a percent DV on the Nutrition Facts label. We require the declaration of iron because: (1) Iron was identified as a nutrient of public health significance in a 1990 IOM report and in other consensus reports; and (2) iron deficiency was a risk for certain segments of the U.S. population (*i.e.,* young children, adolescents and women of childbearing age and pregnant women, especially those with low incomes) (58 FR 2079 at 2106). In the preamble to the proposed rule (79 FR 11879 at 11919), we discussed our analysis of NHANES intake data showing that 3.5 percent of the population ages 4 years and older (excluding pregnant and lactating women) have inadequate iron intakes from conventional foods (*i.e.,* an intake below the EAR), and about 3.3 percent have inadequate iron intakes from conventional foods and dietary supplements. We also stated that about 11.2 and 10.4 percent of women of childbearing age (12 to 49 years old) continue to have iron intakes below the EAR, from conventional foods and conventional foods plus dietary supplements, respectively. We also considered data for several status biomarkers related to iron nutrition. Analyses of these data showed that about 14 percent of women of childbearing age (12 to 49 years) had serum ferritin concentration (the major iron storage compounds) less than 15 ng/mL, while 10 and 14.5 percent of women had inadequate stores of body iron based on the body iron model or ferritin model, respectively (see 79 FR 11879 at 11920). Additionally, about 3.76 million of these women of childbearing age are considered to have iron deficiency anemia, so that iron continues to be of public health significance among women of childbearing age and pregnant women, who account for 26 percent of the general U.S. population (id.).

We noted that iron continues to be identified as a nutrient of public health significance in consensus reports such as Healthy People 2020 and the 2010 DGA (see 79 FR 11879 at 11920). Thus, we did not propose any changes to the mandatory declaration of iron under § 101.9(c)(8)(ii).

(Comment 355) Most comments supported the mandatory declaration of iron on the Nutrition Facts label.

One comment suggested that, instead of declaring iron as ''iron,'' we should require the declaration of specific forms, such as ''reduced iron'' or ''ferrous sulfate,'' on the label. The comment said that some people have an allergic reaction to added iron, but do not react to natural iron.

(Response) We decline to revise the rule as suggested by the comment. Based on our regulations, only iron can be used on the food labels (§ 101.9(c)(8)(iv)), but the specific form that is added to the food, (*e.g.,* ferrous sulfate) must be listed in the ingredient list (§ 101.4). Individuals with allergic reactions to added iron in food are advised to check the ingredient list.

Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word ''as'' or ''from.'' When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, it will not be listed again in the ingredient statement.

Our preexisting regulation, at § 101.9(c)(8)(ii), continues to require the declaration of iron content as a percent DV on the Nutrition Facts label, so the final rule does not affect the requirements for the declaration of iron.

c. Vitamin A and Vitamin C. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of vitamins A and C as percent DVs on the Nutrition Facts label.

With respect to vitamin A, we require the declaration of vitamin A because: (1) It was found in a limited number of foods within the food supply; and (2) a 1990 IOM labeling report identified vitamin A as a nutrient of potential public health significance and stated that certain subpopulations (children under 5 years of age) were still at risk of deficiency for this vitamin (see 58 FR 2079 at 2106). In the preamble to the proposed rule (79 FR 11879 at 11920), we mentioned that, in response to the 2007 ANPRM, several comments recommended retaining the mandatory declaration of vitamin A, but we also said that, even though vitamin A intakes appear to be low, vitamin A deficiency based on an assessment of vitamin A status is rare in the U.S. population. Consequently, we tentatively concluded that vitamin A is no longer a nutrient of public health significance for the general U.S. population, and, consistent with the factors for declaration of these types of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to permit, but no longer require, the declaration of vitamin A on the Nutrition Facts label. However, vitamin A declaration would remain mandatory when vitamin A is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. The proposed rule also would not change the current provision for voluntary declaration of the percent of vitamin A that is present as β-carotene, as specified in § 101.9(c)(8)(vi). The preamble to the proposed rule (79 FR 11879 at 11920) did, however, invite comment on whether there is an appropriate alternative analysis to application of the factors regarding the mandatory declaration of vitamin A.

As for vitamin C, we require the declaration of vitamin C because: (1) A 1990 IOM labeling report identified vitamin C as a nutrient of potential public health significance and stated that certain subpopulations were considered at risk of deficiency (such as elderly individuals on inadequate diets and infants fed cow's milk exclusively); and (2) vitamin C was thought to play a role in promoting the intestinal absorption of non-heme iron, meaning that vitamin C in the same food as iron was considered to help prevent iron deficiency anemia, while excess vitamin C was considered to increase the risk of excessive iron absorption (55 FR 29487 at 29501). In the preamble to the proposed rule, we noted that, in response to the 2007 ANPRM, several comments recommended retaining the mandatory declaration of vitamin C, but we also noted that, while the prevalence of inadequate intake of vitamin C is high, prevalence of vitamin C deficiency is not apparent in the U.S. population as only about 6 percent of the general population had serum vitamin C concentrations below 11.4 micromoles (μmol)/L, a cutoff level that is used as an indicator of vitamin C deficiency (79 FR 11879 at 11921). We further noted that the effects of vitamin C on risk of chronic diseases, such as cardiovascular disease or cancer, are not conclusive, that, in a letter of enforcement discretion on qualified health claims for vitamin C supplement intake and reduced risk of cancers, we concluded that there was no credible evidence on the risk reduction from vitamin C for most cancers (squamous cell cancer of the esophagus, colorectal, laryngeal, lung, oral cavity, pancreatic, pharyngeal, renal cell, and salivary gland cancers), and very limited evidence for an association between vitamin C supplement intake and gastric cancer, and that the 2010 DGA does not include vitamin C among the list of nutrients of public health concern for the general U.S. population (id.). Consequently, we tentatively concluded that, while vitamin C intakes are low, vitamin C deficiency is uncommon, and vitamin C is no longer a nutrient of public health significance for the general U.S. population. Therefore, consistent with the factors we consider for declaration of these types of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to permit, but no longer require, the declaration of vitamin C on the Nutrition Facts label. However, vitamin C declaration would remain mandatory when vitamin C is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. The preamble to the proposed rule (79 FR 11879 at 11920) invited comment about whether there is an appropriate alternative analysis to the application of the factors regarding the mandatory declaration of vitamin C.

(Comment 356) Several comments agreed with our proposal to amend § 101.9(c)(8)(ii) to allow for the voluntary declaration of vitamins A and C. Although we invited comment on whether there is an appropriate alternative analysis to the application of factors regarding the mandatory declaration of vitamin A and vitamin C, we did not receive any comments on that topic other than general agreement with the factors we applied.

Most comments, however, disagreed with voluntary declaration. Many comments did not explain why they felt that mandatory declaration of vitamins A and C is necessary, but some comments provided a rationale. A few comments agreed that vitamins A and C deficiencies are not common in the general population, but said vitamins A and C are extremely important and that the public will benefit from seeing them on the label. The comments suggested that removing vitamins A or C from the label would prevent consumers from determining the amount of each vitamin in their diet. Other comments suggested keeping vitamins A and C on the label because we also proposed eliminating other portions of the Nutrition Facts label; thus, the comments said there should be adequate room for mandatory declaration of vitamins A and C.

(Response) We decline to amend the rule to require the disclosure of vitamins A and C. We base the mandatory listing of vitamins and minerals on public health significance relative to inadequate dietary intakes and biomarkers of nutrient status, as well as the possible association between the nutrients and the risk of chronic disease. Consistent with the factors set for the declaration of essential vitamins and minerals, we concluded that vitamins A and C are no longer considered nutrients of public health significance for mandatory declaration on the label, and the final rule removes vitamins A and C from the list of nutrients in § 101.9(c)(8)(ii) for which the quantitative amount by weight and percent of the RDI are required in nutrition labeling. However, manufacturers can declare these vitamins on the label voluntarily, and if vitamin A or vitamin C is added as a nutrient supplement or claims are made about the vitamin on the label or in labeling of foods, then they must be declared on the Nutrition Facts label.

As for the comment referring to other information that would be removed from the Nutrition Facts label, space constraints on the label were not the reason behind the removal of these vitamins from the Nutrition Facts label.

(Comment 357) One comment stated that vitamins A and C are markers for fruit and vegetable intake, and so declaring vitamins A and C on the label will promote increased intake of fruits and vegetables. Another comment noted that having vitamins A and C on the label will help consumers to figure out how much real fruits and vegetables are in a food product.

(Response) We consider whether a vitamin or mineral is of public health significance (rather than its possible role as a marker for certain food groups) to be a key factor in deciding whether to require mandatory declaration on the Nutrition Facts label. However, the four selected mandatory vitamins and minerals plus fiber represent various

food categories, such as fruits and vegetables. For example, potassium and fiber are found in fruits and vegetables and could be used as markers for fruits and vegetables, and non-heme iron sources come from plant foods, such as beans and lentils and some vegetables such as spinach. Paying particular attention to nutrients of public health significance on the Nutrition Facts label can help consumers in selecting a variety of foods in the diet and help the U.S. population make healthy dietary choices.

(Comment 358) One comment suggested that the reason why vitamin A and vitamin C deficiencies are rare is because they are on the Nutrition Facts label. The comment said that if we remove the vitamins from the label, there might be deficiencies in the future because manufacturers would not fortify the foods. Another comment stated that food fortification is a significant contributor to the intakes of both vitamins A and C and is instrumental for controlling vitamins A and C deficiency. The comment said we should consider the impact on the fortification and consumer access to vitamins A and C in foods if we do not require declaration of these vitamins. The comment said that presence of these vitamins on the Nutrition Facts label has encouraged fortification by the food industry and that a large percentage of vitamins A and C in the diet is supplied through food fortification. Thus, if declaration of vitamins A and C is not required, the comment said that the industry may reconsider fortifying foods with those vitamins. The comment stated that there are no data to indicate the impact that removing the requirement for vitamins A and C from the Nutrition Facts label will have on the practice of food fortification or on the adequacy of those vitamins in the U.S. population.

One comment stated that it is misleading and incorrect scientifically to consider any essential nutrient as being ''no longer of public health significance.'' Rather than removing two nutrients from the mandatory declaration list to make way for two new ones, the comment said it is important for consumers to know as much as possible about the micro-nutritional content of the foods they choose to purchase and consume. One comment asked whether one can really judge which vitamins and minerals are more important to people or whether vitamin D and potassium are more beneficial to people than vitamins A and C. The comment said that all vitamins and minerals play an important role in the healthy functioning of the human body. The comment suggested that, to determine which vitamins and minerals to list in the Nutrition Facts label, we should study which vitamins or minerals are more difficult for the body to synthesize or make on its own, and we should list those vitamins or minerals because consumers need to find other sources of those vitamins or minerals help their body function.

(Response) The preamble to the proposed rule invited comments, including the submission of data and information on whether the mandatory listing of vitamins and minerals impacts food fortification practices. We did not receive any comments providing data or information that inclusion of mandatory vitamins and minerals on the label will increase or decrease fortification practices. The comments also did not provide data to substantiate the claim that removing vitamins A and C from the label will change the industry fortification practices, although one comment suggested that such data does not exist. Consequently, we do not have evidence that would let us determine whether removing these nutrients from the Nutrition Facts label will affect fortification.

As for the claim that removing vitamins A and C from the Nutrition Facts label may cause deficiencies in the U.S. population, we have evaluated all essential vitamins and minerals intake (including vitamins A and C) in the U.S. population for purposes of determining the nutrients of public health significance, and we will continue monitoring vitamins A and C (among other nutrients) intake and the status (to determine both deficiency and excess) of the U.S. population after the final rule becomes effective. We also intend to monitor the marketplace to determine the impact of requiring the declaration of nutrients on the Nutrition Facts label or removing nutrients from the label on fortification practices.

As for the comment stating that it is misleading and incorrect scientifically to consider any essential nutrient as being ''no longer of public health significance,'' the fact that we do not require the declaration of a particular vitamin or mineral on the Nutrition Facts label should not be interpreted as saying that these vitamins and minerals are no longer essential nutrients or do not need to be consumed in adequate amounts each day. We base the mandatory listing of vitamins and minerals on several factors that link public health concerns relative to inadequate dietary intakes and status biomarker levels as well as the association between the nutrients and the risk of chronic disease and the prevalence of disease in the general U.S. population.

(Comment 359) One comment stated that, while frank vitamin C deficiency may not be common, almost 20 percent of individuals 6 years of age and older have serum vitamin C concentrations indicative of being at moderate risk for developing vitamin C deficiency and cited a published article as support (Ref. 189). The comment also said that individuals who smoke or who are in lower income categories may be more likely to be deficient in vitamin C (Ref. 189), which may put these vulnerable populations at higher risk for vitamin C deficiency and associated morbidity.

(Response) We disagree with the comment. Based on our data analysis (NHANES 2003–2006), we determined that about 6 percent of people ages 6 years and older (including smokers) have serum vitamin C concentrations below 11.4 µmol/L. This cutoff level is used as indictor of vitamin C deficiency (Refs. 190–191). The CDC analysis of NHANES 2003–2006 showed the same results as ours (Ref. 190).

As for the article cited by the comment, Schleicher et al., 2009 (Ref. 189), we note that the authors reported that 7.1 percent of the total population in NHANES 2003–2004 were deficient (using cutoff of less than 11.4 µmol/L). Additionally, in establishing the nutrients of public health significance, while nearly 35 percent of the general healthy U.S. population (4 years and older) have vitamin C intakes below the EAR from conventional foods, and nearly 28 percent of the general healthy U.S. population (4 years and older) have vitamin C intakes below the EAR from conventional foods plus dietary supplements, vitamin C deficiency is uncommon. Thus, it is no longer considered a nutrient of public health significance for the general U.S. population. Similar to our findings, vitamin C was not considered to be a nutrient of public health concern by the 2010 DGA and the 2015 DGAC, but these reports considered vitamin C to be a shortfall nutrient because intakes are below the recommended intake. (The 2015 DGAC states that ''shortfall nutrients'' are ''those that may be underconsumed either across the population or in specific groups relative to the IOM-based standards, such as the Estimated Average Requirement (EAR) or the Adequate Intake (AI)'' (Ref. 192).

We will continue monitoring all nutrient intake (including vitamins A and C) and the status of the U.S. population (to determine both deficiency and excess) after the final rule becomes effective.

(Comment 360) One comment said that segments of U.S. population have inadequate intakes of both vitamins A and C, so we should not remove vitamins A and C from the label. The comment said that provitamin A carotenoids provide approximately 26 and 34 percent of vitamin A consumed by men and women, respectively. Because recent data indicate a much lower conversion rate of carotenoids to vitamin A, the comment said that many reports of vitamin A intake have been over-estimated (Ref. 193). The comment also said that 45 percent of American males and females over the age of 2 years (excluding pregnant/lactating women) consume less than the EAR for vitamin A from food and that, even when dietary supplements were considered, 34 percent of Americans did not meet the EAR for vitamin A (Ref. 194). The comment also said that vitamin A intake from any source (naturally in foods, fortified in food and dietary supplement) were below the EAR in 25 percent of 9- to 13-year-old girls, and over 50 percent of 14 to 18 year olds failed to meet the EAR (Ref. 195). The comment added that 37 and 25 percent of Americans consume less than the EAR for vitamin C from food or from food plus dietary supplements, respectively (Ref. 194).

The comment said, similar to vitamin A, vitamin C intakes are poor in children (2 to 18 years old) (Ref. 195). Another comment stated that, given increased awareness and knowledge about the importance of nutrient interactions (*e.g.,* between calcium and magnesium, sodium, potassium, iron, copper, and vitamins D, K, and A), the best approach to providing informed choice to consumers is to require a declaration of all essential vitamins and minerals when present in a serving over a predetermined significant amount, for instance between 10 and 20 percent of the DV.

(Response) We considered whether a vitamin or mineral is of public health significance to be a key factor in deciding whether to require mandatory declaration of that vitamin or mineral on the Nutrition Facts label. We have done our own analyses of both intake and status (using biomarker data when available in NHANES with a valid cutoff) data from NHANES for those ages 4 years and older (excluding pregnant women) for all vitamins and minerals (including vitamins A and C). Based on the factors considered in establishing a nutrient of public health significance (see 79 FR 11879 at 11899 through 11891), we concluded that, while vitamins A and C intakes are low, their deficiency based on assessment of vitamin A or vitamin C status is not common in the general healthy U.S. population. Furthermore, the IOM did not set a quantitative intake recommendation for vitamins A or C based on a public health endpoint (see 79 FR 11879 at 11920 through 11921).

We also note that, similar to our findings, vitamins A and C were not considered to be nutrients of public health concern in the 2010 DGA (Ref. 30) and the 2015 DGAC (Ref. 19). However, both 2010 DGA and 2015 DGAC considered these vitamins to be shortfall nutrients because their intakes are below the recommended intake level.

As for the comment regarding declaration of all essential vitamins and minerals when present over a predetermined significant amount (10 to 20 percent of DV), we must be selective with regard to the information to be listed on the label. Therefore, we emphasize only the essential vitamins and minerals that meet our factors for determining nutrients with the greatest public health significance to be declared on the Nutrition Facts label in order to assist consumers in maintaining healthy dietary practices. We permit voluntary declaration of other vitamins and minerals on the Nutrition Facts label. However, the declaration of these vitamins and minerals will be mandatory when they are added as a nutrient supplement or claims are made about them on the label or in labeling of foods.

Thus, we decline to revise the rule as suggested by the comments.

(Comment 361) One comment said we were being inconsistent in our evaluation of non-statutory nutrients for mandatory declaration. The comment said that the intake data for vitamin A and calcium are very comparable, and so our proposal to include calcium on the label, while removing vitamin A, is inconsistent. The comment compared vitamin A to calcium consumption; it stated, for example, that 45 and 34 percent of Americans consume less than the EAR for vitamin A from food, or food plus dietary supplements, respectively, while 48.9 and 38 percent of Americans consume less than the EAR for calcium from food or food plus dietary supplements, respectively.

One comment said that removing vitamins A or C from the Nutrition Facts label will lead consumers to believe these vitamins are not nutrients of concern. The comment said the removal also may cause USDA nutrition programs, such as MyPlate, to reconsider their emphasis on vitamins A and C.

One comment said that consumers are still looking for vitamins A and C and, in fact, are trying to purchase more products containing these vitamins. The comment said that a study done by NPD reveals that 50 percent of shoppers are trying to get more vitamin C, and 40 percent are trying to get more vitamin A. Additionally, the 2013 HealthFocus Trend Report, A National Study of Public Attitudes and Actions, found that the importance of numerous label claims remains relatively steady with more than 40 percent of shoppers looking for ''good source claims.'' Specifically, the comment said, 40 percent are looking for food products that are a ''good source of antioxidants'' (*e.g.,* vitamin C).

(Response) Besides looking at only intake data, we also looked at biomarker data (when available) as well as the endpoints upon which the IOM based a DRI and the disease prevalence associated with that nutrient in order to determine public health significance of nutrients. For example, in view of the benefits of adequate calcium intake on bone health (established in the IOM's DRIs), low intakes of calcium, and the higher prevalence of osteoporosis and osteopenia among the U.S. population, we concluded that calcium is a nutrient of public health significance and its declaration continues to be necessary to assist consumers in maintain healthy dietary practices.

For vitamin A, although our analysis showed that vitamin A intakes appears to be low, vitamin A deficiency based on assessment of vitamin A status is rare in the U.S. population. The IOM did not set a quantitative intake recommendation for vitamin A based on a public health endpoint (Ref. 193). Thus, we concluded that vitamin A is no longer a nutrient of public health significance. We do not necessarily consider a high prevalence of nutrient intake inadequacy by itself as a sufficient justification of being a nutrient of public health significance and warranting mandatory declaration on the Nutrition Facts label (Ref. 196).

Vitamins A and C were not also considered to be nutrients of public health concern in the 2010 DGA (Ref. 30) and the 2015 DGAC (Ref. 19). However, both the 2010 DGA and the 2015 DGAC considered these vitamins to be shortfall nutrients because their intakes are below the recommended intake level.

As for the comment pertaining to MyPlate, MyPlate is based on the USDA food intake patterns, which provide a recommended daily selection of foods that is generally adequate in essential nutrients and moderate in food

components often consumed in excess. The USDA food intake patterns emphasize eating the recommended intake of all essential vitamins and minerals, regardless of whether those vitamins and minerals are on the Nutrition Facts label.

As for consumer interest or shopping patterns, we agree that many consumers may be interested about the levels of vitamins A and C, among other nutrients, on the label, but not all nutrient information can be mandated on the Nutrition Facts label. We consider mandatory declaration appropriate, for a nutrient that has a specific relationship to chronic disease risk or a health-related condition, when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI). We consider voluntary declaration to be appropriate when such a nutrient either has a quantitative intake recommendation, but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance. For vitamins A and C, the final rule provides for voluntary declarations, and, if the nutrient is added to a food or a claim is made on the label or in the labeling of food (*e.g.,* good source of vitamin C), the nutrient must be declared on the label.

(Comment 362) Some comments suggested that vitamin A can be toxic in high levels and can cause birth defects, so consumers need to know the amount of vitamin A on the label.

(Response) Consumption of vitamin A (as preformed vitamin A (retinol)) above the UL may pose risk of toxicity in the population. The IOM set a UL for preformed vitamin A based on teratogenicity in women of childbearing age or liver abnormalities in all other adults (Ref. 193). If a vitamin A is present at very high levels in a conventional food, it is most likely in the added form, therefore, it must be declared on the label, and the forms added must be listed in the ingredient list (§ 101.4). Consumers can check the ingredient list to learn about the forms of vitamin A added in the food. Furthermore, the amount of added vitamin A and its form must be reported either on the Supplements Facts label or the ingredient list of a dietary supplement (§ 101.36).

(Comment 363) One comment suggested that vitamin A is important in eye vision, immune function, and the prevention of other diseases, so we should continue to require the declaration of vitamin A on the Nutrition Facts label.

Another comment noted that scurvy is a big problem in the homeless population and in youth due to poor diet. The comment said it would be difficult for people to consume adequate amounts of vitamin C if we no longer required the declaration of vitamin C on the Nutrition Facts label.

(Response) We agree that adequate vitamin A intake is important for normal vision and immune function (Ref. 193). However, the IOM set the DRIs (EAR/RDA) based on the amount of dietary vitamin A required to maintain adequate liver stores in well-nourished subjects, rather than on normal vision or immune function (Ref. 193). Furthermore, there is no clear evidence that suggests a protective association between dietary vitamin A or β-carotene and reduction of risk for chronic disease, such as cardiovascular disease and cancer (Ref. 193). Instead, consistent with the factors we set forth regarding mandatory and voluntary declaration, we have determined that vitamin A is no longer a nutrient of public health significance and so the final rule does not require declaration of vitamin A on the Nutrition Facts label.

As for the comment regarding vitamin C and scurvy, the comment did not provide evidence to support the proposition that scurvy is high among homeless individuals and among youth. We do note that our regulations have required the declaration of vitamin C declaration on the Nutrition Facts label for over 20 years, so if we were to accept the comment's premise that scurvy is high among the homeless and youth, then it does not appear that declaring vitamin C on the Nutrition Facts label has affected the purchasing behavior of these subpopulations to buy products higher in vitamin C. Instead, based on the factors considered in determining mandatory declaration of essential vitamins and minerals, vitamin C was no longer considered as a nutrient of public health significance for the general U.S. population.

(Comment 364) One comment said that mandatory declaration of vitamins A and C is crucial for government food programs and that there might be an unintended consequence if we stopped requiring mandatory declaration of vitamin C. The comment said that the IOM recommended increasing vitamin C levels for women of reproductive age as a priority in the revision of food packages under the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), that vitamin C intake is important in reducing the risk of iron deficiency in women of child bearing age, and that the 2010 DGA emphasized vitamin C's importance in improving iron absorption. The comment also said that the WIC program has been successful in decreasing iron-deficiency anemia, and this may be, in part, because of nutrition education and the provision of easily identified vitamin C-rich foods, which aid in the absorption of iron. The comment said that WIC benefits for qualifying juices are issued monthly to 2.05 million pregnant and postpartum women who receive benefits for up to 144 fluid ounces of juice each month, and 4.58 million children ages 1 to 4 who receive benefits for 128 fluid ounces of juice each month. The comment said that, to be authorized for WIC purchase, juices must contain 30 mg of vitamin C per 100 mL of juice, which translates to 120 percent of vitamin C per eight ounce serving using the RDA for women. The comment said that consumers can identify WIC-authorized juices by reading the Nutrition Facts label to determine if the juice contributes 120 percent of vitamin C per serving. Thus, according to the comment, eliminating mandatory declaration of vitamin C on food labels removes the mechanism for WIC clients to readily identify WIC-approved juices while shopping. This may result in WIC clients forgoing this important benefit rather than risk potential product rejection and the associated embarrassment upon checkout.

The comment added that, if we no longer require declaration of vitamin C content in the Nutrition Facts label, State agencies will have to review all potential eligible juices from multiple manufacturers to meet regulation each time the food list is updated, and this process would create an unnecessary administrative burden for both the WIC State agencies and manufacturers.

(Response) We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration in labeling. As we explained in the preamble to the proposed rule (79 FR 11879 at 11921), while vitamin C intakes are low, vitamin C deficiency is uncommon, so we no longer find vitamin C to be a nutrient of public health significance for the general U.S. population. Juice manufacturers who would like their products to be authorized for WIC purchase can declare vitamin C voluntarily on their product labels.

All juices under the WIC authorization must meet the vitamin C minimum (at least 30 mg of vitamin C per 100 mL), either naturally or via fortification (Ref. 197). However, many eligible juices (*e.g.,* pineapple, apple, or grape juice) have to be fortified with

vitamin C to be authorized by WIC; so, because vitamin C is added to those juices, the declaration of vitamin C would be mandatory on the label.

As for the comment's statements regarding the rule's potential impact on WIC clients and the WIC program, such issues are outside the scope of this rulemaking.

(Comment 365) One comment supported voluntary declaration of vitamins A and C, but said that, because these two nutrients are linked to the minimum nutrient contribution requirements for the nutrient content claim ''healthy'' and for health claims, we should make any changes to the nutrient content and health claim regulations at the same time when we finalize the rule.

(Response) We decline to adopt the comment's suggestion. As we stated in the preamble to the proposed rule (79 FR 11879 at 11889), we plan to evaluate the final rule's impact on other FDA regulations and to address, as appropriate, the impact on other FDA regulations in future separate rulemakings. Issues related to nutrient content claims and health claims are outside the scope of this rulemaking (see part II.B.4).

3. Essential Vitamins and Minerals That Are Voluntary

a. Vitamin D. Our preexisting regulations, at § 101.9(c)(8)(ii), provide for the voluntary declaration of vitamin D content on the Nutrition Facts label, unless vitamin D is added as a nutrient supplement or claims are made about it. In 1993, we determined that vitamin D was not of particular public health significance in the United States because the human requirement for vitamin D could be met with sufficient exposure to sunlight and consumption of milk and other foods that were fortified with vitamin D; as a result, deficiencies in this vitamin were very rare (58 FR 2079 at 2107). In the preamble to the proposed rule (79 FR 11879 at 11921), however, we described how comments responding to the 2007 ANPRM recommended vitamin D for mandatory declaration citing vitamin D inadequacy; the relationship of vitamin D to chronic disease risk (*e.g.,* rheumatoid arthritis, multiple sclerosis, and cancers, such as prostate, breast, lung, colon, and colorectal cancers); and the 2005 DGA, which identified vitamin D as a nutrient of concern for certain subpopulations (*e.g.,* older adults, people with dark skin, and those exposed to insufficient ultraviolet band radiation). We also mentioned that the IOM set age and gender specific DRIs (EAR and RDA) for vitamin D at a level that would achieve and maintain serum 25-hydroxy vitamin D (25(OH)D) concentrations above a defined level (40 to 50 nanomoles per liter (nmol)/L) to maintain bone health and how, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease.

Additionally, the preamble to the proposed rule (79 FR 11879 at 11921) discussed how serum concentration of 25(OH)D is widely considered as a biomarker of total vitamin D nutritional status and is recommended to be used for assessing vitamin D total exposure from all sources, including conventional foods, dietary supplements, synthesis from sun, and conversion of vitamin D from adipose stores in the liver. We explained that our analysis of NHANES 2003–2006 data showed that about 18 percent of the U.S. population 4 years and older (excluding pregnant and lactating women) have serum 25(OH)D levels below the 40 nmol/L (a level set by IOM as equivalent to EAR), which indicates an increased risk of inadequate vitamin D exposure, but that this analysis might underestimate the prevalence of low serum vitamin D levels in the U.S. population (id.). Analysis of NHANES 2005–2008 dietary data showed that, about 94 percent of the U.S. population have usual vitamin D intakes below the EAR from conventional foods only and 62 percent have intakes below the EAR from conventional foods and supplements (table 1). The IOM set the DRIs (*e.g.,* EAR) assuming minimal sun exposure (Ref. 38).

We also noted that approximately 24 percent of the U.S. population ages 4 years and older have serum 25(OH)D concentrations between 30 and 50 nmol/L, levels that indicate risk for inadequacy according to the IOM and CDC (79 FR 11879 at 11921). Approximately 32 percent of the U.S. population has serum 25(OH)D levels below 50 nmol/L (a level set by IOM as equivalent to RDA and associated with optimal benefit for nearly all the population) (id.). We stated that about 8 percent have serum 25(OH)D levels below IOM's cutoff of 30 nmol/L and may be at increased risk of vitamin D deficiency. Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis. The 2010 DGA, too, highlighted vitamin D as a nutrient of concern for the U.S. population, in general, rather than for specific population groups alone.

Thus, given the benefits of adequate vitamin D intakes on bone health, data indicating inadequate intakes, poor vitamin D status, and high prevalence of osteoporosis and osteopenia among the general U.S. population, we tentatively concluded that vitamin D is a nutrient of ''public health significance,'' and so mandatory declaration of vitamin D is necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors we consider for mandatory declaration of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of vitamin D on the Nutrition Facts label, and we invited comment on whether there is an appropriate alternative analysis to the application of the factors regarding the mandatory declaration of vitamin D.

(Comment 366) Most comments supported the mandatory declaration of vitamin D on the Nutrition Facts label, but did not explain the reasons for their support.

One comment supported the mandatory declaration of vitamin D declaration on the label, but said that a food or beverage that is not a significant source of vitamin D should declare that fact as part of the ''Not a significant source of (listing the vitamins or minerals omitted)'' statement included at the bottom of the table of nutrient values.

(Response) We agree with the comment. Under our preexisting regulations at § 101.9(c)(8)(iii), if any mandatory essential vitamin or mineral is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of . . . . (Listing the amount of vitamins and minerals)'' is placed at the bottom of the table of nutrient values. No changes to the rule, however, are necessary as a result of this comment, and the final rule requires the mandatory declaration of vitamin D on the Nutrition Facts label.

(Comment 367) Some comments noted that vitamin D is used in fortification and that dietary supplements may be in various forms such as vitamin D_2 (ergocalciferol) or vitamin D_3 (cholecalciferol). The comments said that the form of vitamin D added to foods may be important to vegetarians because the vitamin D_3 commonly used in dietary supplements and in fortified foods is derived from lanolin from sheep's wool and is not considered to be vegan. Some comments said that foods and dietary supplements might list vitamin D without specifying the form. Thus, the comments said that requiring manufacturers to specify the

form of vitamin D would be helpful to vegans and to those who prefer to use a specific form of vitamin D.

Another comment asked whether we consider the main two forms of vitamin D (D_2 and D_3) to be bioequivalent. The comment said it would be helpful if we could either define them as bioequivalent or list a potency conversion factor if we consider one form to be more bioactive than the other.

(Response) We decline to revise the rule as suggested by the comments. We note that our GRAS affirmation regulation (§ 184.1950 (21 CFR 184.1950)) includes both D_2 and D_3 and their resins. The food additive regulations are specific to one form or another (and even more specific, to the crystalline forms or vitamin D_2 baker's yeast) because that is what the petitioner requested. With respect to the Nutrition Facts label, only vitamin D can be used on the food labels (see § 101.9(c)(8)(iv)), but the specific form that is added to a food (*e.g.,* ergocalciferol) must be listed in the ingredient list (§ 101.4). People who are interested in knowing the forms of vitamin D in the food should check the ingredient list.

As for dietary supplements, under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified within the nutrition label in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word ''as'' or ''from.'' When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, it will not be listed again in the ingredient statement.

(Comment 368) Some comments objected to the mandatory declaration of vitamin D on the label, although most comments did not explain why they opposed mandatory declaration.

Other comments objecting to the mandatory declaration of vitamin D said there are not very many food sources that contain vitamin D, and they would prefer retaining other vitamins on the Nutrition Facts label instead. The comments noted that most vitamin D is produced by the body with the aid of exposure to the sun.

Other comments suggested not permitting food companies to use statements such as ''fortified with Vitamin D'' or ''good source of Vitamin D'' because, the comments said, vitamin D is a hormone synthesized by the action of sunlight on skin, and so, for this reason alone, it does not belong on the food label.

One comment suggested vitamin D fortification should be viewed as hormone replacement therapy and that it raises questions about efficacy, dose, and side effects that should be asked about all such therapies. The comment said it would be misleading, and possibly harmful, to the public to add this hormone to food and to promote it as something that promotes better health.

(Response) We agree that vitamin D is synthesized by the body via sunlight exposure. However, the IOM set the DRIs for vitamin D based on minimal sun exposure because sun exposure is a risk factor for skin cancer (Ref. 38). Considering the factors for mandatory and voluntary declaration of vitamins and minerals, we determined that vitamin D is a nutrient of public health significance based on its contribution to bone health and because our analysis indicates that intake and status of vitamin D is inadequate in the U.S. population. Therefore, vitamin D met our factors for mandatory declaration, and its inclusion on the label will assist consumers in maintaining healthy dietary practices.

As for the comment regarding vitamin D fortification and hormone replacement therapy, vitamin D is a vitamin (Ref. 198), and its rational addition to foods is allowed under our current food additive (§ 172.380) and GRAS (§ 184.1950) regulations. The use of vitamin D as a food additive is not considered as hormone replacement therapy. Under our preexisting regulations, vitamin D can be added in specific amounts to selected foods such as breakfast cereals, grain products and pastas, fluid milks and milk products, and calcium-fortified juices.

(Comment 369) Some comments objected to the mandatory declaration of vitamin D on the Nutrition Facts label because, according to the comments, mandatory declaration of vitamin D will increase vitamin D fortification of foods because vitamin D is found in few foods and because consumers cannot expect to see a significant vitamin D contribution on the vast majority of food labels. The comments said that if we require the declaration of vitamin D on the Nutrition Facts label, more food manufacturers would make their food sound more nutritious by fortifying with vitamin D and promoting that on the label. Some comments said that a similar outcome occurred with vitamin C and calcium; other comments said that vitamin D can easily reach toxic levels in the diet and that most consumers do not realize this.

(Response) We disagree with the comments. To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, we affirmed vitamin D as GRAS with specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use of the ingredient, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950. A manufacturer would have to submit a petition to amend our regulations. Several food additive petitions for vitamin D have been submitted to FDA, resulting in food additive regulations. (see §§ 172.379, 172.380, and 172.381.)

Furthermore, while vitamin D can be produced in the body via sunlight, and there are a number of foods that can currently be fortified with vitamin D, total usual intakes for vitamin D from food and dietary supplements are below the EAR for the general U.S. population. The total usual intakes do not exceed the UL for any age group at the 90th percentile (Ref. 199). The percentage of the population that consumes vitamin D above the UL is very low (0.1 to 0.4 percent). In addition, the prevalence of high serum 25–OH–D concentration (greater than 125 nmol/L) for the U.S. population aged 1 year and older is 0.9 percent (NHANES 2003–2006) (Ref. 190). The IOM committee indicated that serum 25–OH–D concentration over 125 nmol/L may be reason for concern (Ref. 200). Thus, while some comments said that manufacturers would increase fortification of foods, we are not aware of evidence to support this statement. We do note that, in the preamble to the proposed rule (79 FR 11879 at 11923), we invited comment on whether the mandatory declaration of vitamins and minerals somehow impacts food fortification practices, and we did not receive any data to support an impact. We also do not have any data to determine whether there was an increase in vitamin C or calcium since the time they were first required to be listed on the label. However, we know that both vitamin C and calcium intake are not above the UL set by IOM (Ref. 199). We intend to continue monitoring the nutrients, including vitamin D, on the Nutrition Facts label, their intake, and status of the U.S. population (both deficiency and excess) through the national survey databases. We also intend to continue to monitor the

marketplace to determine if inappropriate fortification is occurring. If we find that there is an inappropriate fortification of foods with vitamin D or any other nutrients, we will take steps to help ensure that fortification does not result in the imbalance of essential nutrients in the diet of the U.S. population.

(Comment 370) One comment objected to mandatory declaration of vitamin D because, according to the comment, vitamin D does not occur naturally in most foods and because other FDA regulations would not allow manufacturers to make a significant impact on the dietary intake of vitamin D.

(Response) Considering the factors for mandatory and voluntary declaration of vitamins and minerals, we determined that vitamin D is a nutrient of public health significance based on its contribution to bone health and because our analysis indicates that intake and status of vitamin D is inadequate in the U.S. population. Therefore, we consider vitamin D to be a nutrient of public health significance and include vitamin D in the list of nutrients in § 101.9(c)(8)(ii) for which a quantitative amount by weight and percent of the RDI are required in nutrition labeling to assist the consumers in maintaining healthy dietary practices.

We note that, under our food additive and GRAS regulations (§ 172.380 and § 184.1950 respectively), vitamin D can be added in specific amounts to various foods such as breakfast cereals, grain products and pastas, fluid milks and milk products, and calcium-fortified juices. In addition vitamin D can be obtained through dietary sources, such as fish (*e.g.,* salmon, rockfish, and tuna) and shellfish, which are the primary natural food sources of vitamin D.

(Comment 371) One comment said the lack of compelling research has permitted vitamin D to become ''trendy,'' such that vitamin D is advertised on boxes of fortified cereals, has its own pro-supplement advocacy group, and generates millions of dollars in dietary supplement sales annually. The comment suggested that, in the absence of stronger evidence for benefit from fortification and some evidence from possible adverse consequences, we should not contribute to further commercialization of ''this misnamed hormone'' by declaring vitamin D on food labels.

(Response) The mandatory declaration of vitamin D on the Nutrition Facts label is not intended to promote or encourage excess fortification of foods with vitamin D. Given the benefits of adequate vitamin D intakes on bone health and calcium absorption, data indicating inadequate intakes, poor vitamin D status, and the high prevalence of osteoporosis and osteopenia (Ref. 201–202) among the general U.S. population, we concluded that this nutrient is a nutrient of public health significance and met the factors for mandatory declaration on the Nutrition Facts label. Furthermore, the 2010 DGA recommends increasing the amount and variety of seafood in place of some meat and poultry (Ref. 30). Fish/seafood is the primary source of naturally occurring vitamin D (Ref. 30). Data show that fish/seafood only provides 9 percent of the total vitamin D intake in the United States. Therefore, we conclude that mandatory declaration of vitamin D on the label would allow consumers to understand the relative significance of the contribution of vitamin D from natural food sources, in addition to fortified foods, in the context of the total daily diet and also is necessary to assist consumers in maintaining healthy dietary practices.

Also, as we stated in our response to comment 368, vitamin D is a vitamin and its rational addition to foods is allowed under our current food additive (§ 172.380) and GRAS (§ 184.1950) regulations.

(Comment 372) One comment stated that, beyond prevention of rickets, the importance of vitamin D and the optimum serum levels or dietary intake for chronic disease risk are hotly debated subjects, and it is premature to focus on this nutrient as being of particular concern. The comment said the U.S. Preventive Services Task Force concluded that the evidence is insufficient to determine how vitamin D supplementation (and, therefore, fortification) affects fracture incidence. The comment also noted that data from the Women's Health Initiative are consistent with largely inconclusive findings about hormone vitamin D supplements and bone health. The comment said that the IOM does not consider deficiency of vitamin D to be a serious problem in the United States, except among certain population groups. Instead, according to the comment, because of widespread fortification and supplementation, the IOM is concerned about the possibility of adverse consequences from over-consumption through supplementation or fortification.

(Response) We disagree with the comment that the association of vitamin D to bone health is inconclusive. The consensus report by IOM set the dietary reference intake for vitamin D based on its role in bone health and calcium absorption and uptake by bones (Ref. 38). The IOM set age and gender specific DRIs (EAR and RDA) for vitamin D to maintain bone health (Ref. 38). Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis (Ref. 203). In addition, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease. In view of the benefits of adequate vitamin D intakes on bone health, data indicating inadequate intakes, poor vitamin D status, and high prevalence of osteoporosis and osteopenia among the general U.S. population, we conclude that this nutrient is a nutrient of public health significance and meets our factors for mandatory declaration on the Nutrition Facts label.

As for the comment's claims that fortification will result in adverse consequences, while vitamin D can be produced in the body via sunlight and there are a number of foods that can currently be fortified with vitamin D, current total usual intakes for vitamin D from food and dietary supplements do not exceed the UL for any age group at the 90th percentile (Ref. 199). The percentage of the population that consumes total vitamin D (food and supplement) above the UL is low (0.1 to 0.4 percent). As for fortification, we reiterate that our food additive and GRAS regulations create a regulatory structure that does not allow for unilateral fortification of food; the addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950. The manufacturer has to formally petition FDA to amend the regulation.

(Comment 373) One comment said that there is inconsistency in vitamin D assays, and individuals may be told that they are deficient when they are not.

(Response) We recognize that there may be inconsistencies in serum vitamin D assays from various laboratories and that this inconsistency may cause variations in an individual's serum vitamin D analysis. However, for purposes of determining the nutrients of public health significance, our data indicating poor vitamin D status (through serum vitamin D analysis) were based on NHANES data. The serum data were analyzed by the same valid vitamin D method for the survey period (Ref. 190).

(Comment 374) One comment opposed the mandatory declaration of vitamin D because, according to the

comment, testing for vitamin D is very challenging and expensive. Other comments supported mandatory declaration of vitamin D, but said that limited data is available on the vitamin D content in many foods and ingredients, so manufacturers will need time and resources to obtain data for purposes of revising their Nutrition Facts labels. Some comments said that an analysis of the 7,189 foods in the USDA National Nutrient Database reveals that approximately one-third of those foods are missing values for vitamin D and that this does not take into account the thousands of other ingredients that are also missing vitamin D values.

(Response) We acknowledge that performing an accurate vitamin D analysis requires some expertise, but there are commercial laboratories with expertise in the analysis. Having quality control food matrix material certified for vitamin D is important, and the National Institute of Standards and Technology (NIST) has worked and continues to work to come up with better standard reference material for quality control of vitamin D analysis. Under our preexisting regulations, declaration of vitamin D was mandatory when vitamin D was added as a nutrient supplement or claims are made about it on the label or labeling. Therefore, manufacturers who have added vitamin D to their products have already been using methods for testing and determining vitamin D content of foods, so, with respect to those manufacturers, additional time and resources to conduct analyses for vitamin D may not be necessary.

As for other products whose manufacturers have not added vitamin D to the food, there is adequate methodology for determining vitamin D in the foods. However, an analysis may not be needed for vitamin D where reliable databases or scientific knowledge establish that a nutrient is not present in the food. For example, there might not be a need to analyze for vitamin D in foods that are not natural sources of vitamin D, and to which our regulations, at § 172.380 and § 184.1950, do not allow vitamin D to be added. Therefore, regarding the analytical burden, if a manufacturer has adequate and reliable reasons to believe that vitamin D is not present, there is no need to analyze for it: It can be declared as zero or the manufacturer can state at the bottom of the nutrition label ''not a significance source of vitamin D.'' Costs associated with nutrition labeling will be contained by not analyzing for a nutrient where there is no reasonable expectation that the nutrient occurs in the food.

We also agree that USDA nutrient databases may be missing vitamin D values for nearly one-third of the products in those databases. Vitamin D occurs naturally in a limited number of foods, such as mushrooms exposed to UV light, egg yolks (often the feed is supplemented with D_3 or 25(OH)D_3), and meats or other animal products. There is usually a minimal amount of vitamin D in milk and cheese unless the food is fortified. Many foods that would be reporting vitamin D on labels greater than zero are fortified (with the exception of foods listed previously or foods that contain them) and already would have declarations. The USDA national nutrient database (standard reference (SR)) provides a complete set of all nutrients (including vitamin D) to use with NHANES database (Ref. 4). However, vitamin D may not be always required to be filled in the SR. USDA is working with various industries to determine the vitamin D values on meats and eggs, and it plans to have these data available in future SR releases. We intend to work with USDA to determine ways to have more values for vitamin D on the SR databases.

b. Potassium. Under our preexisting regulations, at § 101.9(c)(5), the declaration of potassium content is voluntary, except when a claim is made about it. In the preamble to the proposed rule (79 FR 11879 at 11922), we discussed how the scientific evidence regarding potassium had changed, such that we recognized potassium's importance in the risk reduction of certain chronic diseases. We also noted that the 2010 DGA concluded that potassium is a nutrient of concern for the general U.S. population. Given the benefits of adequate potassium intake in lowering blood pressure, reflected in IOM's DRIs, and data indicating low likelihood of potassium adequacy and high prevalence of hypertension among the general population, we tentatively concluded that potassium is a nutrient of public health significance for the general U.S. population and proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of potassium.

(Comment 375) Almost all comments supported the mandatory declaration of potassium on the Nutrition Facts label.

Some comments, however, supported mandatory declaration of potassium for different reasons. Many comments would require mandatory declaration of potassium because potassium is important for dialysis and renal patients.

(Response) While mandatory labeling of potassium may help patients with chronic kidney disease, this was not a factor we considered when we proposed the mandatory declaration of potassium on the Nutrition Facts label. As we stated in the preamble to the proposed rule (79 FR 11879 at 11890) and maintain in this final rule, we consider mandatory declaration appropriate for these types of nutrients when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI), although we also have considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient in a specific relationship to chronic disease risk. For potassium, we concluded that potassium is a nutrient of public health significance for the general U.S. population and its declaration is necessary to assist consumers in maintaining healthy dietary practices. Therefore, the final rule, at § 101.9(c)(8)(ii), requires the mandatory declaration of potassium.

(Comment 376) One comment stated that food manufacturers may start to fortify their foods with potassium in an attempt to offset the sodium content of a food product. The comment said we should monitor how food manufacturers respond to this new requirement. The comment also said that, as part of an overall consumer education campaign, we should encourage consumers to obtain potassium through a diet high in fruits and vegetables and recommend amounts of low-fat/fat-free dairy products rather than obtain potassium from dietary supplements or potassium fortified foods.

(Response) The comment did not provide any evidence to suggest that mandatory declaration of potassium on the Nutrition Facts label will increase fortification of foods; consequently, we are unable to determine whether such fortification is likely or the extent to which it might occur. The final rule requires mandatory labeling of potassium and other essential vitamins and minerals on the Nutrition Facts label to assist consumers in maintaining health dietary practices.

With respect to fortification, we note that we published a policy statement on the rational addition of nutrients to foods (§ 104.20). We urge manufacturers, if they elect to add nutrients to a food, to follow the guidelines stated in the fortification policy for rational addition of nutrient to foods to preserve a balance of nutrients in the diet of the U.S. population. We intend to continue assessing the nutritional status

(inadequacy and excess) of potassium consumption, among other nutrients, in the general healthy U.S. population after the final rule's compliance dates. We also intend to monitor the market to assess fortification practices in response to the revised Nutrition Facts label. With respect to educational activities, we intend to work with other Federal Agencies and organizations to emphasize the changes to the Nutrition Facts label (see part II.B.1). However, consistent with our mission, our educational activities will focus on the Nutrition Facts label rather than fresh produce (*i.e.,* fresh fruits and vegetables). The reason for the mandatory declaration of potassium and other essential vitamins and minerals on the Nutrition Facts label is to assist consumers in maintaining health dietary practices rather than to recommend consumption of specific foods or products.

(Comment 377) Several comments suggested that potassium should appear on the Nutrition Facts label after sodium. The comments said that there is an association between potassium intake and reduced blood pressure in certain individuals, so potassium should appear below sodium. The comments said this placement will help consumers understand that these two nutrients and their respective amounts in a food are related.

(Response) We decline to revise the rule as suggested by the comment. We stated in the preamble to the 1993 final rule (58 FR 2079 at 2106) that, for essential vitamins and minerals, the decisions about mandatory or voluntary declarations were based on public health concerns relative to inadequate dietary intakes as well as the possible association between several of these nutrients and the risk of chronic disease. The main difference between the DRV and RDI nutrients was/is that DRV nutrients are: (1) Nutrients to limit (*e.g.,* sat fat, cholesterol, and *trans* fat); or (2) based on a specific caloric intake (*e.g.,* fat, carbohydrate, protein, and dietary fiber). However, RDIs have been and are being proposed based on age specific RDAs (and now AIs). In 1993, there were not age specific RDAs for potassium. Currently, there are age specific AIs for potassium that are based on chronic disease risk. Thus, because potassium is now being assigned an RDI, rather than a DRV, we are moving it down in the label with the other essential vitamins and minerals that have RDIs. Furthermore, the comment did not provide any evidence to support the claim that having sodium and potassium near each other on the label would help consumers understand that these two nutrients and their respective amounts in a food are related. Consequently, we cannot evaluate the comment's claim regarding placement and consumer understanding.

(Comment 378) One comment said the mandatory declaration of potassium on the Nutrition Facts label will pose challenges for very small packages (because another line in the label would be needed). Additionally, some comments noted that beverages, such as plain unsweetened coffee and tea, are exempt from nutrition labeling (under § 101.9(j)(4)) because they contain insignificant amounts of all nutrients required to be declared on the Nutrition Facts label. According to the comments, plain coffee and tea may have low, but declarable, levels of potassium, so the mandatory declaration of potassium would cause plain coffee and tea to lose their current exemption from nutrition labeling. The comments said we should examine § 101.9(j)(4) and make any necessary adjustments. The comment suggested that, when levels of potassium are less than 5 percent of the DV and on small packs with limited space, declaration of potassium would be voluntary.

(Response) We recognize the discrepancy between the exemption under § 101.9(j)(4) and the labeling that would be required for products that have significant levels of nutrients. In the proposed rule, we did not ask for comments specifically about the continued applicability of this exemption from nutrition labeling provisions in light of what would be a changing level of nutrients that will be considered ''insignificant'' as a result of this rule and the final rule entitled ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (Serving Size final rule) published elsewhere in this issue of the **Federal Register**. Therefore, we intend to consider the future applicability of the exemption with respect to mandatory nutrition labeling on products that would have been exempt under § 101.9(j)(4) prior to the effective date of this rule and the Serving Size final rule. After the effective date of this final rule, we intend to consider the exercise of enforcement discretion with respect to the use of mandatory nutrition labeling on such products that would have been exempt under § 101.9(j)(4).

We understand that providing Nutrition Facts labels on packages with limited space may be challenging for manufacturers; thus, our preexisting regulation, at § 101.9(j)(13), provides for special labeling provisions for packages with limited space.

(Comment 379) Several comments said that manufacturers would need more than 2 years to gather nutrition data for potassium and to comply with the mandatory declaration of potassium on the Nutrition Facts label. Some comments said that the data are often lacking in many company and public databases, so time will be needed to collect the data.

(Response) We disagree, in part, with the comments. There are public databases, such as USDA Nutrient Data Database, that can provide information regarding the potassium content of foods. For example, in the USDA Nutrient Data Database for current Standard Reference (SR 27), nearly 8,200 of the approximately 8,600 foods in the database, or approximately 95 percent of the foods, have potassium values.

Additionally, the operations involved and equipment required for the methods for potassium determination are standard in analytical laboratories. Nevertheless, we have revised the compliance dates for the final rule (see part III).

(Comment 380) One comment asked us to clarify the use of potassium in dietary supplement products. The comment said that many dietary supplement companies have been limiting potassium in their formulas to 99 mg per serving and that 99 mg of potassium is not an appreciable fraction of the current (3,500 mg) or proposed (4,700 mg) reference daily intake for potassium. The comment said that this limitation is based on a position we took in 1975 that any capsule or coated tablet of a potassium salt intended for oral ingestion (without prior dilution with an adequate volume of liquid to preclude gastrointestinal injury) should carry a warning statement regarding small-bowel lesions related to the use of oral drug products containing 100 mg or more potassium. The comment said we have not established an upper limit for potassium in dietary supplement formulations, so the comment asked us to clarify how potassium might be used in solid oral dietary supplements.

(Response) We have not established any limits on potency or recommended uses for dietary supplements that contain potassium salts. Under the FD&C Act, a manufacturer or distributor is responsible for ensuring that the dietary supplements are safe and meet other applicable requirements of the FD&C Act and its implementing

regulations. The safety of or need for a warning statement on dietary supplements with certain potencies of potassium are outside the scope of this rulemaking.

(Comment 381) Several comments did not support mandatory declaration of potassium on the Nutrition Facts label. Some comments said that consumers do not know what potassium is, so the declaration of potassium on the label would not be helpful. The comments said it would be better to omit potassium from the label so that the Nutrition Facts label is less cluttered, can be better organized, and be less likely to overwhelm the consumer with information.

(Response) We decline to revise the rule as suggested by the comments. We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration on the Nutrition Facts label. Available quantitative evidence suggests that the declaration of nutrients of public health significance including vitamins and minerals can help consumers maintain healthy dietary practices. We consider potassium to be a nutrient of public health significance, and the final rule includes potassium in the list of nutrients in § 101.9(c)(8)(ii) for which a quantitative amount by weight and percent of the RDI are required in nutrition labeling to assist the consumers in maintaining healthy dietary practices.

As for the comment's mention of clutter, we consider clutter as a matter of graphic design, but possible clutter is not our basis for omitting or removing a nutrient of public health significance from the Nutrition Facts label.

(Comment 382) One comment suggested that potassium should be a qualifying nutrient for ''Healthy'' claim criteria.

(Response) Issues regarding labeling outside the Nutrition Facts and Supplement Facts labels, such as nutrient content claims, are outside the scope of this rulemaking (see part II.B.4).

4. Other Essential Vitamins and Minerals

Under our preexisting regulations, at § 101.9, several other essential vitamins and minerals, in addition to vitamin D and potassium, may be declared voluntarily on the Nutrition Facts label, *i.e.,* vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride. In the preamble to the proposed rule (79 FR 11879 at 11922 through 11923), we explained how we had considered comments to the 2007 ANPRM recommending mandatory declaration of vitamin E, folate, vitamin B_{12}, magnesium, and phosphorus and how, based on our analysis of available data and using the factors we consider for mandatory and voluntary declaration of non-statutory nutrients, we did not propose any changes to the provisions for voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride.

Several comments addressed the voluntary declaration of specific vitamins or nutrients, and we discuss those comments in this section.

a. Phosphorus.

(Comment 383) Most comments asked that we amend our regulations so that declaration of phosphorus is mandatory rather than voluntary.

Most comments said that many people have kidney problems, and patients under dialysis have to watch their intake of phosphorous in addition to potassium and calcium. The comments said that it can be very difficult for individuals who are on a low potassium and phosphorous diet to calculate their daily intake. The comments said that dialysis patients are educated about foods high in phosphorus, but it is difficult to manage one's phosphorus intake when phosphorus is ''in almost everything.'' The comments said that many dialysis patients have neither the motivation nor the resources to be diligent about monitoring phosphorus in their diet. One comment stated that phosphorus can occur naturally in various forms of food, or as a component in commonly used food additives, and that the processing of meat and fish products increases the phosphorus content above the naturally occurring levels in the protein itself. The comment said that the addition of phosphorous to the Nutrition Facts label will help kidney patients to be aware of the high amount of phosphorus in foods. The comment noted that, in determining mandatory or voluntary labeling, FDA considers whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint and whether there is evidence of a problem related to health in the general U.S population. Thus, the comment said, using these considerations, we should revise the rule to require the mandatory declaration of phosphorus on the Nutrition Facts label.

(Response) While a mandatory phosphorous declaration may aid patients with chronic kidney disease and dialysis patients, the Nutrition Facts label is not targeted to individuals with a particular acute or chronic disease (see part II.B.2). The information on the label is meant for the general healthy U.S. population. For determining the nutrients of public health significance, we considered the factors that were discussed in the proposed rule and determined that phosphorous intakes are generally adequate and not of public health significance in the general, healthy U.S. population (Ref. 204). Furthermore, total intakes (food and supplement) among the general U.S. population were not found to be above the UL (Ref. 199). Based on these factors, we determined that phosphorous is considered a voluntary nutrient for the general healthy U.S. population, and are not making changes to the voluntary declaration of phosphorus in response to this comment. Therefore, manufacturers can declare phosphorus on the Nutrition Facts label voluntarily. However, if phosphorous is added as a nutrient supplement or claims are made about it on the label or in labeling of foods, then it must be declared on the label. All ingredients, including phosphate compounds, must be declared in the ingredient list on the label.

b. Magnesium.

(Comment 384) Several comments would revise the rule so that declaration of magnesium on the Nutrition Facts label would be mandatory instead of voluntary. Several comments stated that magnesium is needed for dialysis patients. One comment said that, instead of paying too much emphasis on calcium for adults, we should pay more attention to magnesium because, according to the comment, nearly 90 percent of dialysis patients are deficient in magnesium.

(Response) We decline to revise the rule as suggested by the comments. As we stated in part II.B.2, the Nutrition Facts label is not targeted to individuals who have a specific acute or chronic disease.

(Comment 385) Some comments said that magnesium is an essential mineral and necessary for maintaining more than 300 essential metabolic reactions in the human body. One comment said that magnesium interacts with calcium and potassium and foods and that dietary supplements are frequently enriched with calcium. The comment

said that magnesium deficiency in the face of a normal calcium intake can lead to soft tissue calcification in animals (Refs. 205–206). The comment said that the most prominent feature of magnesium deficiency is the calcification predominantly of arteries (Refs. 207–209) and that magnesium inhibits the release of calcium ion from the sarcoplasmic reticulum, blocks the influx of calcium ion into the cell by inactivating the calcium channels in the cell membrane, and competes with calcium ions at binding sites on troponin C and myosin, thereby inhibiting the ability of calcium ions to stimulate myocardial tension (Refs. 210–212). The comment noted that magnesium, a calcium antagonist, substitutes itself for the calcium ions on hydroxyapatite, producing more soluble phosphate salts and thus inhibiting bone formation and perhaps aortic valve stenosis (Ref. 213).

One comment stated that the absorption of calcium and magnesium may be altered depending upon the levels and ratio between them. The comment said that emerging evidence indicates that it may be better to optimize one's intake of calcium and magnesium rather than supplementing with either mineral alone. The comment said that the mandatory declaration of magnesium on the Nutrition Facts label will help consumers avoid an imbalance of calcium and magnesium by highlighting to the consumer how inadequate his or her magnesium intake is in relation to the calcium content of packaged foods (which the comment said are frequently supplemented with calcium). The comment also stated that the IOM has said that ''magnesium is necessary for sodium, potassium-ATPase activity, which is responsible for active transport of potassium'' (Ref. 214) and that magnesium regulates the outward movement of potassium in myocardial cells (Ref. 215). The comment further stated that magnesium inadequacy has a variety of other adverse health effects and that dietary magnesium intake was found to be inversely associated with mortality risk in individuals at high risk of cardiovascular disease (Ref. 216). In addition, the comment said, a higher dietary magnesium intake is associated with lower fasting glucose and insulin (Ref. 217), and dietary magnesium intake is inversely associated with plasma concentrations of the inflammation indicator C-reactive protein (CRP).

One comment stated that national survey data indicate that dietary magnesium intake is inadequate in the general U.S. population, particularly among adolescent girls, adult women, and the elderly. One comment stated that the impact of adding another item to the label is minimal compared to overall costs. The comment said that, given that the costs are inevitable, it is better to add all mandatory declarations to the label at one time. In other words, if a manufacturer is already changing the label for potassium for example, there is a minimal incremental cost to add magnesium at the same time.

One comment noted that, from a food processing perspective, given the label desirability of increasing potassium and reducing sodium levels, manufacturers might replace a portion of currently used sodium salts, such as sodium citrate and sodium phosphate, with the potassium salts with equivalent functional characteristics. Thus, the comment said, labeling of magnesium content becomes more important to avoid creating an imbalance of potassium and magnesium.

(Response) We agree that magnesium is an essential nutrient and that it is important in many different pathways and functions of the body (Ref. 218). However, consistent with our consideration of the factors for mandatory and voluntary declaration of vitamins and minerals (see part II.D), while magnesium dietary intake is currently low, the IOM recommended intake is not set based on a public health endpoint (*e.g.,* a chronic disease), and the overt symptoms of magnesium deficiency are rarely seen among general healthy U.S population. Consequently, we do not consider magnesium to be a nutrient of public health significance for the general U.S. population (Ref. 204). We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration on the Nutrition Facts label, cost consideration was not a factor in determining nutrients of public health significant.

In the case of magnesium, similar to our recommendation, the 2010 DGA and 2015 DGAC did not include magnesium as a nutrient of public health concern for the general U.S. population. (The 2015–2020 DGA also does not include magnesium as a nutrient of public health concern.) Magnesium was considered as a shortfall nutrient. Although some comments cited published articles, most articles cited by the comments are either animal studies, not using valid surrogate endpoints (such as C-reactive protein), or are based on single studies and emerging evidence and the conclusions are not based on the totality of scientific data.

(Comment 386) One comment noted that some manufacturers already include magnesium content on the Nutrition Facts label for their products. The comment said that, for example, Kelloggs includes magnesium content on Raisin Bran cereal (but not on its Corn Flakes), Nestle includes magnesium content on its Instant Breakfast products, and General Mills includes magnesium content on Cheerios cereal. The comment suggested that these steps are to be encouraged and broadened.

(Response) We are not making changes to the voluntary declaration of magnesium in the final rule, and therefore, manufacturers may declare magnesium voluntarily on the Nutrition Facts label. However, if magnesium is added as a nutrient supplement or claims are made about it on the label or in labeling of foods, then it must be declared on the label.

c. Vitamin K.

(Comment 387) Several comments stated that declaration of vitamin K on the Nutrition Facts label is necessary for individuals who are on blood thinners.

(Response) We decline to revise the rule as suggested by the comment, and vitamin K remains a voluntarily declared nutrient in the final rule. While information regarding vitamin K may help patients on blood thinners, as we stated in part II.B.2, the Nutrition Facts label is for the general, healthy U.S. population rather than for individuals with acute or chronic disease.

d. Choline.

(Comment 388) In general, comments regarding the declaration of choline on the Nutrition Facts label supported voluntary declaration.

(Response) Because declaration of choline on the Nutrition Facts label is already voluntary, no changes to the rule are necessary.

e. Vitamin B_{12}.

(Comment 389) One comment stated that fortified foods and dietary supplements are the only reliable way for individuals who avoid all animal products to obtain vitamin B_{12}. The comment said that including the amount of vitamin B_{12} added to fortified foods and dietary supplements would enable these individuals to monitor their intake of this essential vitamin. The comment said that labeling also would help individuals aged 50 years and older who are advised to meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing dietary supplements.

(Response) Declaration of vitamin B_{12} on the Nutrition Facts or Supplement Facts label is mandatory when vitamin B_{12} is added as a nutrient supplement or

when claims are made about it on the label or in labeling of foods. Thus, because the information is already available to consumers under the circumstances described in the comment, no changes to the rule are necessary.

M. Reference Daily Intakes for Vitamins and Minerals

1. Need To Update RDIs

Our preexisting regulations, at § 101.9(c)(8)(iv), set forth RDIs used to calculate the percent DVs for vitamins and minerals that are required or permitted to be declared on the Nutrition Facts label. RDIs are intended as general food labeling reference values and are not intended to represent dietary allowances for individuals. They function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods.

The preamble to the proposed rule discussed how new information caused us to reconsider the RDIs and our approach to setting RDIs (79 FR 11879 at 11925 through 11928). In brief, the proposed rule would revise the existing RDIs for vitamins and minerals based on the DRIs set by the IOM (1997 to 2010) and would consider the RDAs, when available, as the basis for establishing RDIs, instead of the EAR. Using corresponding RDAs, proposed § 101.9(c)(8)(iv) would update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E and zinc (see 79 FR 11879 at 11926 through 11927).

2. Approach To Setting RDIs: EAR Versus RDA

In the preamble to the proposed rule (79 FR 11879 at 11926 through 11927), we explained our approach to setting RDIs. In brief, the percent DV advises the consumer how much of the recommended intake of a particular nutrient is provided by the food. The DV for a nutrient is not to be interpreted as a precise recommended intake level for an individual; instead, it is a general guide or a reference value that the consumer can use to help judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (id. at 11926). Two types of reference values, the Reference Daily Intakes (RDIs) for vitamins and minerals and Daily Reference Values (DRVs) for certain nutrients, are used to declare nutrient contents as percent DVs (id. at 11883, 11926), and the RDIs for vitamins and minerals have been based primarily on RDAs (or on other available quantitative intake recommendations if an RDA has not been established for a particular vitamin or mineral).

The preamble to the proposed rule also stated that the RDA was developed as a target intake level for individuals and is designed to meet the nutrient needs of practically all (97 to 98 percent) individuals within a life stage and gender group (id. at 11926). RDAs are available for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E, and zinc (id.).

In contrast, the EAR is the median requirement that is most likely to be close to an individual's actual needs within a particular life stage and gender group (id.). The EAR is a quantitative intake recommendation that is used to derive target nutrient intake goals for the planning of diets for groups (such as planning diets in an assisted living facility for senior citizens or planning menus for a school nutrition program), but is not used as a target intake goal for individuals. The EAR is not intended to be a target intake level for individuals because an individual does not know how his or her needs relate to the EAR. Therefore, if the RDI were to be based on the EAR, the RDI would not meet the daily nutrient requirements for some consumers and would understate target intake levels. In contrast, an RDI that is based on a RDA would meet the daily nutrient requirements for most individuals 4 years of age and older. An RDI based on the RDA would mean that a product with 100 percent of the DV would have a higher probability of meeting an individual's nutrient needs than if the RDI was based on the EAR. As a result, in the preamble to the proposed rule (id. at 11927), we stated that RDAs, when available, provide the most appropriate basis for establishing RDIs and, using corresponding RDAs, we proposed, at § 101.9(c)(8)(iv), to update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E, and zinc.

(Comment 390) Several comments supported using the RDA, rather than the EAR, as the basis for establishing RDIs.

In contrast, one comment opposed using the RDA and supported using the EAR. The comment asserted that we should not dismiss the recommendations of the IOM Labeling report (Ref. 219) to use the EAR as the basis for setting DVs, in favor of the 2003 IOM Planning report (Ref. 220) recommendation to use RDAs to plan diets of individuals. The comment stated that there is no better reference value against which to appraise the nutritional contribution of a product than a DV based on a population weighted EAR and that any other basis for the DV will either understate or overstate the nutritional contribution of a food product when considered in comparison to the population weighted EAR. The comment said that we misinterpreted the purpose of the 2003 IOM Planning report recommendation to use the RDA to plan diets and that there is no reason to assume that the very specific notion of dietary planning for individuals (as described in the 2003 IOM Planning report) is what consumers mean when they say they use the label for planning purposes. The comment further stated that the DVs are not appropriate to use for planning an individual's entire diet because they do not represent the individual's age and sex, and that this nutrition information is only provided on packaged foods (not fresh fruits and vegetables, meat, poultry, fish). The comment also said that this information is only available for nutrients that are mandatory on the Nutrition Facts label.

(Response) We continue to believe that the RDA is the most appropriate reference value to use to establish RDIs, considering the purpose of the DV. As we noted in the preamble to the proposed rule (79 FR 11879 at 11926), the percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food. While the DV for a nutrient is not to be interpreted as a precise recommended intake level for an individual, it is a general guide or a reference value that the consumer can use to help judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (*id.*). The EAR is not intended to be a target intake level for individuals because an individual does not know how his or her needs relate to the EAR. While the RDA may not be the best estimate of any given individual's nutrient requirements, which are usually unknown, the RDA was developed as a target intake level for individuals. The RDA is designed to meet the needs of practically all (97 to 98 percent) individuals within a life stage and gender group. If the RDI was

based on the EAR, the RDI would not meet the daily nutrient requirements for some consumers and would understate target intake levels.

We also disagree with the comment's characterization of the 2003 IOM Planning report recommendations. The 2003 IOM Planning report noted that intake goals (*i.e.,* RDAs) should be translated into dietary plans to help individuals choose foods that will make up a healthy diet. The 2003 IOM Planning report gave several examples of dietary plans such as the Nutrition Facts label, the U.S. Food Guide Pyramid, and the Dietary Guidelines for Americans that are intended to help consumers choose foods that are part of a healthful diet (Ref. 220). The 2003 IOM Planning report noted that, when food guides are used, reference standards for nutrients such as the RDAs are implicitly used in planning individual diets (see 79 FR 11879 at 11926). Therefore, we disagree with the comment's suggestion that the 2003 IOM Planning report is somehow at odds with the use of the RDA as a reference value for establishing RDIs. Furthermore, we disagree with the comments' assertion that the DVs are not appropriate to use for planning an individual's entire diet because nutrition information is only provided on packaged foods (and not on fresh fruits and vegetables, meat, poultry, or fish). Retail stores that sell raw fruits, vegetables, and fish participate in the voluntary point-of-purchase nutrition information program (§§ 101.42 through 101.45). Additionally, we have developed posters that provide nutrition information for the 20 most commonly consumed fruits, vegetables and seafood that are available to consumers and industry (Ref. 221). Similarly, USDA requires that retail stores that sell meat and poultry to label products with nutrition information or to post point-of-purchase nutrition information. USDA also has developed posters for nutrition information for meat and poultry that are available for use by consumers and industry (75 FR 82148) (Ref. 222). For these reasons, we are making no changes to the rule based on the comment.

We address comments on specific vitamins and minerals at parts II.M.6 and II.M.7.

3. Approach To Setting RDIs: Adequate Intake

In the preamble to the proposed rule (79 FR 11879 at 11927), we explained that, in the absence of RDAs, AIs represent the best estimate of an adequate daily nutrient intake level based on available science and, as such, they provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs. Consequently, we proposed to use the AI to set RDIs for biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K.

(Comment 391) Several comments supported using the AI as the basis for establishing RDIs for those vitamins and minerals where data were insufficient to determine a RDA. However, other comments opposed using the AI for potassium to establish an RDI of 4,700 mg and recommended that we retain the current DRV of 3,500 mg. The comments stated that the AI is established at a level assumed to ensure nutritional adequacy in all members of a healthy population when there is insufficient scientific evidence to develop an RDA. The comments said that using a reference value based on inadequate quantity or quality science would be providing inconclusive information to consumers. A few comments noted that there is now additional evidence (Refs. 223–224) that is more reflective of the current state of the science and recognizes the sodium to potassium ratio. Some comments also suggested that the IOM should re-assess the DRI for potassium in light of the new data to determine if the current AI is truly reflective of the actual requirements. One comment suggested that increasing the RDI could result in increased reliance on fortification or use of dietary supplements.

(Response) We agree with the comments that support the use of the AI to set the RDIs for nutrients that do not have a RDA. We disagree that we should not use the AI to set an RDI for potassium and that the existing DV of 3,500 mg should be retained. The existing DV for potassium was set in 1993 based on the 1989 Diet and Health report and no longer represents the most current recommendations for potassium intake. As discussed in the preamble to the proposed rule (79 FR 11879 at 11927), while there is more uncertainty with an AI than an EAR or RDA, in the case of nutrients without established RDAs, the AI reflects the most current scientific recommendations for intake (*id.*). When establishing RDIs, we consider the quantitative intake recommendations from U.S. consensus reports (*e.g.,* the IOM DRI reports) (see 79 FR 11879 at 11890).

We disagree that the sodium and potassium ratio should be used to set a DV for potassium. First, sodium is not presented on the label as a ratio of sodium and potassium. As discussed in part II.L.3.b, the final rule requires the declaration of potassium on the label. Thus, if consumers are interested in the sodium and potassium ratio, they will have both the absolute amounts as well as the percent DV for both nutrients. In addition, the Aburto et al., 2013 systematic review and meta-analysis cited by the comment concluded that daily potassium intakes in the range of 90 to 120 mmol (3,519 mg to 4,700 mg) were associated with lower risk of stroke (Ref. 223). This range is consistent with the AI of 120 mmol (4,700 mg/day) that was based on potassium's ability to blunt the effects of sodium intake on blood pressure and to reduce the risk of kidney stones. Furthermore, Aburto et al. 2013 noted their analysis of randomized trials that examined how sodium intakes influence potassium's effect on blood pressure shows there was no statistically different effect among subgroups based on sodium intake. A majority of the individual studies cited in the Aburto et al., 2013 meta-analysis were reviewed in the 2005 Electrolytes report which concluded that data on the sodium and potassium ratio was insufficient to be used to set requirements (Ref. 223). The other article cited in the comment (Ref. 224) is a review article that does not include the totality of the scientific evidence and does not provide sufficient information for FDA to review. While we recognize that the intakes of sodium and potassium are interrelated, we do not consider the evidence to be sufficient to set an RDI based on the sodium and potassium ratio, and we continue to consider that the AI set by the IOM is appropriate to use for setting the RDI. Additionally, given the extensive reviews already conducted by the IOM, we do not agree that it is necessary to ask the IOM to reevaluate the existing evidence for potassium.

As for the comment regarding fortification, the comment did not provide any evidence, and we are not aware of any evidence, that suggests using the AI would lead to excessive fortification and increased use of dietary supplements. Currently, the adequacy of intakes for potassium is very low (see 79 FR 11879 at 11922). Only 1.9 percent of the general population has usual potassium intake above the AI from conventional foods only, and 2.4 percent have intakes above the AI from conventional foods plus dietary supplements. RDIs which are expressed on the label as a percent DV, give a consumer a general idea how much of a nutrient they should consume. While RDIs may influence the vitamin or

mineral content of foods, FDA's principles of rational fortification are expressed in our fortification policy (§ 104.20). The addition of nutrients to foods is also governed by the requirements established in food standards of identity (21 CFR parts 130 to 169), nutrition quality guidelines (21 CFR part 104), substitute food regulations (§ 101.3(e)), and relevant specifications in food additive and food substance regulations (*e.g.,* folic acid (§ 172.345) and vitamin D (§§ 184.1950 and 172.380)). Consistent with our previous position (58 FR 2206 at 2210), we acknowledge that some manufacturers may fortify products to a specific percentage of the DV (*e.g.,* 25 percent) and, to the extent this practice continues, nutrient levels in these foods would be affected by updated RDI values. Manufacturers must comply with relevant regulations, and we urge them to follow the principles stated in our fortification policy. We conclude that the AIs set by the IOM provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs and will not be making a change as a result of this comment.

4. Approach To Setting RDIs: Tolerable Upper Intake Level

The preamble to the proposed rule (79 FR 11879 at 11928) explained that the UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. As intake increases above the UL, potential risk of adverse effects may increase. The UL can be used to estimate the percentage of the population at potential risk of adverse effects from excess nutrient intake, but it is not intended to be a recommended level of intake for vitamins and minerals where excess intake is not a concern, as there is generally no established benefit for consuming amounts of nutrients above the RDA or AI. Thus, we do not consider the UL to be an appropriate basis for setting RDIs for vitamins and minerals.

We did not receive comments on this topic.

5. Approach To Setting RDIs: Population-Weighted Versus Population-Coverage

In the preamble to the proposed rule (*id.*), we discussed how we considered recommendations of current consensus reports, scientific review articles, and comments to the 2007 ANPRM. We tentatively concluded that RDIs for vitamins and minerals should continue to be based on a population-coverage approach (rather than a population-weighted approach), using the highest RDA and, where an RDA has not been established, the highest AI (79 FR 11879 at 11928). We explained that using a population-coverage approach would avoid a higher risk of nutrient inadequacy among certain segments of the population because the RDA/AI value is not derived from averaging the requirements for populations with lower needs (children and elderly) and those with greater needs (adolescents or adults). We acknowledged that, for some nutrients, the population-coverage RDA approach would result in RDIs that are higher than the nutrient requirements for some consumers, but said that the RDA, by definition, is the target intake goal for nutrient intakes for individuals (*id.*).

We proposed to amend § 101.9(c)(8)(iv) to update RDIs and to present the updated RDIs in a table.

(Comment 392) Several comments supported the use of the population-coverage approach, using the highest RDA or AI to set the RDIs. Other comments, however, said we should use the population-weighted approach. Comments supporting the use of a population-weighted approach asserted that a DV derived from the population-coverage RDA will result in setting target intakes for nutrients above the needs for the majority of the population, that the use of a population-weighted RDA would still result in an increase in the RDIs for calcium, vitamin D, and potassium, and that the RDI for iron would decrease from 18 mg to 11 mg, but that this level would still exceed or meet the RDA for 80 percent of the population.

One comment supporting use of a population-weighted EAR disagreed with our rationale that using a population-coverage approach ensures that vulnerable groups are covered; the comment stated that, with the exception of iron, the highest RDAs are those for young men who are not vulnerable to nutrient inadequacies.

A few comments suggested that using a population-coverage approach would set nutrient targets unnecessarily too high and would make it harder for consumers to meet their nutrient requirements while staying within energy needs. Another comment suggested that using a population-coverage approach might lead to consumer confusion and frustration.

(Response) As we discussed in the preamble to the proposed rule (79 FR 11879 at 11928), using the highest age and gender group RDA/AI value (*i.e.,* a population-coverage approach) would avoid a higher risk of nutrient inadequacy among certain segments of the population because such a value is not derived from averaging the requirements for populations with lower needs (children and elderly) and those with greater needs (adolescents or adults). While incidences of deficiency diseases, such as pellagra, are now rare, intakes and status biomarkers of certain nutrients continue to be inadequate and of public health significance. Furthermore, in addition to iron, the proposed RDIs for calcium and vitamin D were based on vulnerable groups. The RDI for calcium was based on the highest RDA of 1,300 mg/day for 9 to 18 year olds, and the proposed RDI of 20 mcg for vitamin D was based on the RDA for adults 70 years and older. All three nutrients have been identified as nutrients of public health concern (see 79 FR 11879 at 11918 through 11922). We continue to use the population-coverage approach to set RDIs and decline to make a change based on this comment.

As for the comment suggesting that using a population-coverage approach would set nutrient targets unnecessarily too high and would make it harder for consumers to meet their nutrient requirements while staying within energy needs, we acknowledge that, for some nutrients, the population-coverage RDA approach will result in RDIs that are higher than the nutrient requirements for some consumers. However, the RDA, by definition, is the target intake goal for nutrient intakes for individuals. In addition, unlike the population-weighted approach, the population-coverage approach would not be susceptible to changes in age demographics of the population. Therefore, any future revisions to RDIs would be based primarily on new scientific data related to nutrition or new dietary recommendations, and we would not need to revise RDIs solely based on the availability of new census data (see 79 FR 11879 at 11928). Furthermore, because many of the new RDAs and AIs established by the IOM are now lower than the older RDAs or ESADDIs that were used in the past to develop RDIs, the new RDIs established in the final rule based on a population-coverage RDA for many nutrients will be lower. We are not aware of, nor did the comment provide, any evidence to suggest that retaining the population-coverage approach would make it harder for consumers to meet their nutrient requirements while staying within energy needs.

As for the assertion that consumers confusion may result, the comments did not provide any data or information that such difficulties or consumer confusion exists or the extent to which such

difficulties or confusion exists, so we are unable to determine the nature or severity, if any, of such consumer difficulties or confusion. We do note that the current DVs on the label are based on a population-coverage approach, and we are not aware of any data and information that the population-coverage approach, which we have used for decades, has caused consumer confusion.

We conclude that setting RDIs based on a population-coverage approach is more appropriate than a population-weighted approach, and we are not making changes to the rule based on these comments. Thus, the final rule, at § 101.9(c)(8)(iv), updates the RDIs for various nutrients and presents them in table form, although we have, on our own initiative, elected to use non-italicized numbers for RDI values that were italicized in the proposed rule and deleted the footnote regarding the declaration of a percent daily value for ''bolded'' (italicized) nutrients.

(Comment 393) Some comments agreed that using the population-coverage RDA does not lead to excessive intakes of nutrients due to over fortification of foods. The comments noted several recent analyses that support our analysis and conclusions that a population coverage RDA would not lead to excessive intakes of nutrients from fortified foods (Refs. 194–195, 225). One comment pointed out that RDIs would likely reset levels of vitamins and minerals in discretionary enriched/fortified foods as manufacturers adjust absolute levels to maintain current label claims. The comment said that, based on diet modeling done by Murphy et al. that assumes that discretionary enrichment/fortification levels reset, a population-coverage RDA would be likely to result in a greater percentage of Americas meeting their nutrient requirements compared to a population-weighted EAR (Ref. 225). Furthermore, the comment said, the results of diet modeling conducted by Murphy that assumed that discretionary enrichment/fortification levels would reset indicated that using a population-coverage approach would result in less than 1 percent of the total populations 4 years of age and older having intakes above the ULs (Ref. 225).

Some comments suggested that the use of a population-coverage RDA could result in over-fortification of products. One comment noted that intakes of zinc exceed the UL for young children. The comment stated that we should not dismiss this finding by challenging the basis for the UL, because doing so fails to recognize the extent to which many American children's intakes currently exceed the UL. The comment stated that the proposed RDI (11 mg) is more than two times the RDA for children 4 to 8 years (5 mg/day) and almost four times the RDA for children 1 through 3 years (3 mg/day). The comment said that a product with 20 percent of the DV for zinc (*e.g.* 11 mg × 0.20 = 2.2 mg) declared on the label would provide almost 100 percent of the zinc RDA for a young child (3 mg/day).

(Response) We disagree with the comment that stated that the use of a population-coverage RDA would lead to excessive fortification and intakes of nutrients. Instead, we agree with the comments that stated that a population-coverage RDA would not lead to excessive intakes of nutrients from fortified foods. As noted in the preamble to the proposed rule (79 FR 11879 at 11928) and the accompanying memorandum to the file (Ref. 199), intakes of vitamins and minerals generally do not exceed the ULs under current RDIs that are based on a population-coverage RDA approach, except for zinc, vitamin A (preformed), iodine, and folic acid among children 4 to 8 years. In these few instances where total usual intakes of vitamins and minerals by children 4 to 8 years exceed corresponding ULs, we have determined that such intakes are not of public health significance, and for some nutrients, are not as a result of fortification (Ref. 199). Analyses done by other groups also have determined that fortified foods contribute to the nutrient intakes and adequacy of many nutrients without leading to excessive intakes for most vitamins and minerals (Refs. 194–195, 225). Furthermore, because many of the new RDAs and AIs established by the IOM are now lower than the older RDAs or ESADDIs that were used in the past to develop RDIs, the final rule's RDIs, based on population-coverage RDAs for many nutrients, will be lower. We consider that, from a public health perspective, it is more important for the DV of vitamins and minerals to cover the intake needs of most consumers than it is for certain age and gender groups to be covered by the DV based on their proportion of the overall population. As discussed in the 2014 memo to the file, we acknowledge that total usual zinc intakes from conventional foods and dietary supplements exceed the UL for approximately 33 percent of children 4 to 8 years of age. The UL for zinc of 12 mg/day was extrapolated upward from the UL set for infants based on decreased copper absorption (Ref. 226). In addition to intake data, we considered whether there is public health significance to exceeding the UL. As noted in the 2014 memo to the file, no reports on adverse effects of zinc on copper absorption have been reported in children and adolescents (Ref. 199). A dose response intervention study published in 2013 found that supplementation with 5 to 15 mg/day of zinc for 4 months did not alter copper status in healthy Canadian boys aged 6 to 8 years (Ref. 227). Furthermore, the proposed RDI for zinc of 11 mg, which is based on the highest new RDA, decreases by 27 percent from the current RDI of 15 mg. In addition, the proposed RDI for zinc of 11 mg does not exceed the UL for children 4 to 8 years of age. The RDIs are currently intended for adults and children 4 or more years of age and not younger children because children over the age of 4 years consume the same foods that the rest of the population consumes. However, as discussed in part II.O.6.k, we also are establishing a RDI of 3 mg for zinc for younger children 1 through 3 years of age.

(Comment 394) Several comments opposed any revision to the RDIs that would lower the RDIs. The comments stated that Americans need more vitamins and minerals because toxin intake is increasing and nutrient intake is decreasing. The comments suggested that our goal was to harmonize our food laws to Codex standards and guidelines and stated that this has been specifically prohibited by Congress. The comments requested that we obey the law and withdraw the proposal rule for revision and bring it in line with modern science which, according to the comments, shows that we need higher daily intake of vitamin B and other vitamins as well as more minerals such as magnesium and selenium.

(Response) We disagree that the RDIs should not be revised. As we discussed in the preamble to the proposed rule, we are revising the RDIs based on our consideration of the RDA or AI set in the most recent IOM DRI reports that are U.S. consensus reports (see 79 FR 11879 at 11926). The comments did not provide any data, information, or explanation to support the various assertions made, including that Americans need more vitamins and minerals due to increased toxins, that the IOM DRI reports are incorrect, that our proposed actions are not consistent with the law and the proposed rule should be withdrawn, or that our goal is to harmonize food labeling with Codex standards and guidelines. We are unaware of new consensus research that would lead us to change our proposed approach to revise the RDIs. Therefore,

we are not making changes or taking any action in response to these comments.

(Comment 395) Several comments objected to lowering the RDIs for specific nutrients such as biotin, niacin, pantothenic acid, riboflavin, thiamin, vitamin B_6, chromium, copper, molybdenum, selenium, and zinc. One comment suggested that we did not outline our specific reasoning for lowering the RDIs for these particular nutrients. Another comment stated that we should reevaluate more recent science that evaluates the effects of high doses of nutrients from foods and supplements and look at clear differences between synthetic and naturally occurring vitamins. Another comment stated that the proposed changes will lead to consumer confusion and a drop in intake as consumers will now perceive foods and supplements to contain a much larger percentage of these nutrients when, in reality, the nutrient level is the same.

(Response) We disagree that RDIs for biotin, niacin, pantothenic acid, riboflavin, thiamin, vitamin B_6, chromium, copper, molybdenum, selenium, and zinc should not be revised. As discussed in the preamble to the proposed rule (see 79 FR 11879 at 11890), we are revising the RDIs based on our consideration of the RDA or AIs set in the IOM DRI reports that are U.S. consensus reports. We consider the quantitative intake recommendations from these reports when establishing RDIs.

As for the comment suggesting that we consider new more recent science, the comment did not identify any new references for us to consider, and we are unaware of any new consensus from a body of research that would lead us to change the rule. However, with respect to synthetic and naturally occurring nutrients, in establishing RDAs or AIs, the IOM does consider the various sources of nutrients (synthetic and naturally occurring) when establishing the nutrient requirements.

As for possible consumer confusion or lower intakes by consumers, we are not aware of any data or information about that outcome, nor did the comment provide any to support its assertions. Although the final rule lowers many RDIs, using the population-coverage RDA to set the RDIs would cover the needs of most individuals in the population. For these reasons, we are making no further changes to the rule based on these comments.

(Comment 396) One comment stated that the current RDIs which are largely based on preventing deficiency diseases are out of date and do not consider nutrient intakes over the lifespan and do not provide consumers with information on optimal amounts of nutrients for good health. The comment cited a review by McCann and Ames that suggest modest deficiency of selenium my increase the risk of age-associated diseases (Ref. 228).

(Response) We agree that the current RDIs are out of date and should be revised. The RDAs set by the IOM which are the basis for the new RDIs, did consider intakes over the lifespan and to the extent possible based on available data consider the relationship between optimal health and intakes of nutrients. The article cited by the comment was a review article and does not include the totality of the scientific evidence for FDA to review. The RDIs are based on our consideration of the RDA or AIs set in the IOM DRI reports that are U.S. consensus reports and we are not aware of any new consensus from a body of research that would lead us to change our proposed approach to revise the RDI for selenium. Therefore, we are not making changes or taking any action in response to this comment.

(Comment 397) Some comments questioned why we are increasing the DV for vitamin C from 60 mg to 90 mg when we determined that the declaration of vitamin C on the Nutrition Facts or Supplement Facts label should no longer be mandatory. A few comments suggested that increasing the DV for vitamin C may negatively impact the consumer perception of this vitamin and result in consumer confusion. The comments suggested the percent DV declaration will be lower because the DV is higher for vitamin C, and so consumers may perceive that the product has changed when it has not. A few comments also suggested that, if the higher DV for vitamin C is adopted, we should engage in consumer education.

(Response) The preexisting RDI of 60 mg was based on the 1968 RDA which is outdated and does not reflect current recommendations for intake of vitamin C. We disagree that the RDI for vitamin C should not be increased because we are no longer requiring mandatory declaration. As we stated in the preamble to the proposed rule (79 FR 11879 at 11928), we are basing the RDIs for vitamins and minerals, including vitamin C, on the highest RDA set by the IOM. Thus, for vitamin C, we set the RDI at 90 mg. The RDIs, which are expressed on the label through the percent DV, give a consumer a general idea how much of a nutrient they should consume.

We recognize that consumer education on the various changes to the label will be important (see part II.B.1). Furthermore, we are not aware of, nor did the comment provide, any data or information that increasing the RDI for vitamin C will lead to consumer confusion.

6. Declaration of Absolute Amounts of Vitamins and Minerals

Our preexisting regulations, at § 101.9(d)(7)(i), require the declaration of mandatory nutrients and, when declared, voluntary nutrients by their absolute amounts in weight on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium). Thus, except when the linear label format is used (§ 101.9(j)(13)(ii)(A)(*2*)), listings for sodium and potassium (when declared) appear above the third bar and include both weight amounts and percent DVs, while vitamins A and C, calcium, and iron appear below the third bar and include percent DVs only. In the case of dietary supplements, both the quantitative amount by weight and percent DV (if available) are required to be declared on the Supplement Facts label (§ 101.36(b)(2)(ii) and (iii)). The proposed rule would require that, similar to the requirement for dietary supplements (§ 101.36(b)(2)(i)(A)), all vitamins and minerals declared on the Nutrition Facts label include their quantitative amounts (in addition to the requirement for corresponding percent DV declaration) (proposed § 101.9(c)(8)). We address the comments to this proposed requirement in part II.Q.9.

The proposed rule also would remove the specific requirements for the declaration of potassium in § 101.9(c)(5) and provide, instead, for the declaration of fluoride. The proposed rule also would require that, when a product contains less than 2 percent of the RDI for a vitamin or mineral, the manufacturer must declare the quantitative amount of the vitamin or mineral and the percent DV in the same manner. For example, if a serving of the product contains less than 2 percent of the RDI for calcium, both the quantitative amount and the percent DV for calcium may be listed as zero or an asterisk (or symbol) directing the consumer to a statement at the bottom of the label may be used in place of both the quantitative amount and the percent DV declaration for calcium. We stated that we saw no reason to provide different declaration increments for the Nutrition Facts label than those that have already been established for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label in § 101.36(b)(2)(ii).

We also invited comment on whether quantitative amounts for nutrients with

RDI values that contain three or four digits should be rounded, what the rounding increments should be, and data to support rounding increments (79 FR 11879 at 11930, 11961).

(Comment 398) For conventional foods, we specify in § 101.9(c)(8)(iii) that the percent DV declaration for vitamins and minerals present at less than 2 percent of the RDI is not required for nutrition labeling, but may be declared as zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, the statement ''Not a significant source of (listing the vitamins or minerals omitted)'' may be placed at the bottom of the table of nutrient values.

One comment said that quantitative amounts less than 2 percent of the DV should be exempt from declaration as such amounts are nutritionally insignificant. Other comments suggested that we should not allow for the amount of a nutrient to be declared as zero. These comments suggested that, if there is even the smallest amount of the nutrient in a serving of the product, the amount should be declared.

(Response) We decline to revise the rule to require the declaration of small, quantitative amounts of vitamins and minerals on the Nutrition Facts label. While it may be desirable to have a precise nutrient value on the label, such precision is impractical. There is variability inherent in the food supply. Nutrients found in foods can vary slightly due to many factors such as the season of the year, soil type, variety (cultivar), and weather conditions. The processing that a food undergoes also can alter its nutrient content. The rounding rules were established to avoid the impression of unwarranted accuracy as well as to make a label easier for the consumer to review and understand.

Furthermore, very small quantities of nutrients in a food product do not contribute significantly to nutrient requirements for the total daily diet. A consumer would most likely exceed their calorie needs trying to obtain the recommended amount of a certain nutrient if their diet is made up of only foods that contribute less than 2 percent of the DV for that nutrient. To obtain the recommend amount of that nutrient for the day, the consumer would need to consume other foods containing larger quantities (at least more than 2 percent of the DV for that nutrient) of the nutrient.

(Comment 399) We proposed to use the same declaration increments for the Nutrition Facts label as those that have already been established for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label in § 101.36(b)(2)(ii). The proposed rule, at § 101.9(c)(8)(iii), would require that the quantitative amounts of vitamins and minerals on the Nutrition Facts label, excluding sodium, be the amount of the vitamin or mineral included in one serving of the product, using the units of measure and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

Several comments would change the rule's declaration increments. Two comments asked us to ensure that there is consistency between the rounded absolute amount and the declared percent DV. One comment stated that any declaration of quantitative amounts of vitamins and minerals should provide for declaration of a quantitative amount that corresponds to the nearest whole number of the percent DV beginning with 2 percent. Another comment said that most consumers will not do the math to convert the absolute amount of the percent DV, but providing both absolute amount and percentages could result in different values for similar products in the marketplace.

(Response) We agree that the rounded absolute amount and the declared percent DV may be slightly inconsistent. For example, if the quantitative amount of the vitamin or mineral is rounded after the rounding rules for the percent DV declaration are applied, it could result in a rounded value that is significantly different than the actual amount of the nutrient in a serving of a food. For example, if a product is determined by analytical methods to have 1,550 mg of potassium per serving, the percent DV declaration would be determined by dividing 1,550 mg by the RDI of 4,700 mg for a value of 33 percent. After application of the rounding requirements for the percent DV declaration, the declared percent DV value would be rounded to 35 percent. If the declared quantitative amount of potassium in a serving of the product is then multiplied by 35 percent by the RDI of 4,700, the declared quantitative amount of would be 1,645 mg of potassium. This is a difference of 95 mg between the value obtained before and after applying the rounding rules for the percent DV declaration.

In addition, requiring a declaration of the amount of the nutrient that corresponds to the nearest whole number of the percent DV calculated before rounding could result in declared quantitative amounts that are different than what has been determined by analytical methods, but still not correspond with the rounded percent DV declaration. For example, if testing is done to determine that a product contains 300 mg of potassium per serving, the calculated percentage of the RDI for potassium of 4,700 is 6.4 percent. If that percentage is then rounded to the nearest whole number of 6 percent and then multiplied by the RDI for potassium, it would result in a declared value of 282 mg, which is different than the value which is determined by analytical methods.

The approaches suggested by comments to make the quantitative amount of a vitamin or mineral declared on the label as close as possible to the quantitative amount calculated from the percent DV declaration would either result in a declared value that is either less accurate or no better that the proposed approach. Therefore, we decline to make changes to our label declaration increments.

(Comment 400) One comment said that nutrients with ''equivalents,'' such as Vitamin A, folate, and niacin, make it impossible to simply convert a numerical value to a percentage and could create consumer confusion.

(Response) We disagree with the comment. For those nutrients with ''equivalents,'' the equivalent amount should already be determined for the purposes of the amount declared on the label. For calculation of the percent DV, the declared amount should be divided by the RDI for that nutrient and multiplied by 100. The equivalent amount should already be determined for the label declaration and would not prevent a manufacturer from determining the percent DV declaration for vitamin A, niacin, folate, or folic acid.

(Comment 401) Some comments suggested that less precision is needed for declaration of quantitative amounts of nutrients declared on the label. One comment suggested that the declared amounts should be rounded to whole numbers because they are easier for consumers to understand.

Another comment suggested that any nutrient in an amount greater than 10 units (*e.g.,* 10 mg or 10 mcg) should be rounded to the nearest 1 (unless a larger increment is specified in the proposed

rule, such as ''Calories from saturated fat '' for which 5 calorie increments are specified for amounts up to and including 50 calories), those in an amount greater than 100 units should be rounded to the nearest 10 units (unless a larger increment is specified in the rule), and those in amounts greater than 1,000 units should be rounded to the nearest 100 (unless a larger increment is specified in the rule). The comment suggested that rounding should be based on the declared quantity of a nutrient rather than on the RDI or DRV for the nutrient.

One comment recommended that numbers ending in ''5'' should be rounded up. The comment suggested that we could consider alternatively allowing for numbers ending in 5 to be rounded to the nearest even number, but said this could be confusing and counterintuitive for most members of industry.

Other comments suggested that more precision is needed for declaration of quantitative amounts of nutrients declared on the label. One comment recommended that quantitative amounts be rounded to the nearest tenth instead of to the nearest integer. The comment indicated that rounding errors can occur when quantitative amounts are rounded to the nearest integer.

Another comment also recommended that nutrients be rounded to the nearest tenth of a gram for quantities under 10 grams per serving.

(Response) We disagree that the same rounding increments should be used for quantitative amounts of all vitamins and minerals. Some nutrients, such as potassium, have a relatively large RDI value (4,700 mg) while others, such as thiamin, have a relatively small RDI value (1.2 mg). The declaration of those nutrients with relatively smaller RDI values requires greater specificity than those with relatively larger RDI values. Furthermore, for some nutrients with relatively larger RDI values, it may not be possible, given current analytical methods, to determine the amount of the nutrient with precision when very small quantities are present (*e.g.,* at a level of less than 1 mg).

The comments recommending specific rounding increments of all nutrients based on the number of units in the RDI or DRV value did not explain why those increments are appropriate so that we might determine if the approaches suggested are merited. By using the levels of significance provided in the RDI table in § 101.9(c)(8)(iv), allowing for zeros following decimal points to be dropped, and allowing for additional levels of significance to be used when the number of decimal places indicated is not sufficient to express lower amounts for those nutrients with small RDI values, we are giving manufacturers some flexibility to determine if the value should be rounded to the nearest whole number or to a fraction of a whole number based on the nutrient and the quantity present in a serving of the food.

We recognize that determining the appropriate value to declare for quantitative amounts of vitamins and minerals could be confusing to manufacturers when the rule provides some flexibility based on the RDI and the quantity of the nutrient present in a serving of food, especially for nutrients with relatively small RDIs. For example, the rounding requirements allow a manufacturer to declare an amount of zinc as 2 mg or 2.4 mg per serving. Additionally, consumers use the information found on the label in different ways. Some may use it to get enough of certain nutrients whereas others may be more concerned with not exceeding a certain calorie level. There has always been built in variability in the label declarations due to variation in the food supply and variance in the analytical methods used to determine the amount of nutrients in a serving of a food. The amount of vitamins and minerals declared on a label is not always the exact amount of the nutrient in a serving of the food. Therefore, we decline to revise the increments used for declaration of quantitative amounts of vitamins and minerals as suggested by the comments.

(Comment 402) One comment said that, if the final rule requires the declaration of quantitative amounts of vitamins and minerals, we should provide sufficient guidance regarding rounding rules and how to quantify amounts of naturally occurring substances that inherently are subject to variability (*e.g.,* vitamins and minerals from plants that are subject to variable growing conditions that affect nutrient content).

(Response) There may be different ways in which manufacturers may want to consider the variability in the foods they produce. Manufacturers should know how much variability to expect in the foods they produce based on adequate sampling. Manufacturers should consider the range of nutrients which may be in a finished food product and determine the label value which they think will best meet the requirements for class II nutrients in § 101.9(g).

(Comment 403) One comment suggested we should test any rounding rules which are adopted to ensure that consumers are not confused.

(Response) We established the rounding rules to provide an accurate representation of the amount of a nutrient in the product so that consumers can determine how the nutrients in a serving of a food contribute to their total daily diet. The rounding rules also allow for natural variability in the nutrient content of foods, analytical variability in test methods, and statistical probability, and we have set practical limits of variation in nutrient levels since 1973 (see 38 FR 2125 at 2128 (January 19, 1973) (final rule titled ''Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act Nutrition Labeling'')). We appreciate the need for consumers to be able to understand the information on a product label, yet the comment did not provide information to show how our rounding rules have confused consumers nor did it suggest how such tests would be done. We do not consider the changes we are making to the rounding rules to require consumer testing.

(Comment 404) Our preexisting regulations, at § 101.9(c), provide for the rounding of quantitative amounts of calories and macronutrients declared on the Nutrition Facts label. The requirements vary based on the nutrient. For example, our regulations state that quantitative amounts in milligrams may be listed on the Nutrition Facts label for only two minerals: Sodium (§ 101.9(c)(4)) and potassium (§ 101.9(c)(5)). Our regulations state that, when a serving contains less than 5 mg of sodium or potassium, the value must be declared as zero; when a serving contains 5 to 140 mg of sodium or potassium, the declared value must be rounded to the nearest 5 milligram increment; and when a serving contains greater than 140 mg of sodium or potassium, the declared value must be rounded to the nearest 10 mg increment.

We did not propose any changes to these requirements.

One comment suggested that the amount of calories in a serving of a product should not be rounded because people who are counting calories need to know exactly how many calories are in the product.

(Response) We disagree with the comment. As with quantitative amounts of nutrients, determining the exact amount of calories in a serving of a specific package of food is not possible or practical. The determination of calories is a somewhat imprecise measure. The exact amount of calories per serving in a given food may vary from package to package. Therefore, providing an exact amount of calories

on a food label would give the consumer the incorrect impression that the declared amount is a precise value. Furthermore, providing an exact amount of calories rather than a rounded value is unlikely to provide consumers who count their calories for weight management purposes more helpful information because consumption of an extra 5 or 10 calories in a given food is unlikely to have a significant impact on body weight when most adults need to consume well over 1,000 calories per day, even when trying to lose weight.

(Comment 405) Our preexisting regulations, at § 101.9(g)(5), state, in part, that a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The regulation goes on to say ''Provided, That no regulatory action will be based'' on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

The proposed rule would amend § 101.9(g)(5) to insert ''added sugars'' after the word ''sugars'' and delete the words ''Provided, That.''

One comment would revise § 101.9(g)(5) to stipulate that products labeled in accordance with the rounding or increment requirements are not misbranded if the use of such rounding or increments causes the content of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium to be understated by more than 20 percent. The comment explained that § 101.9(g)(5) leaves companies vulnerable to lawsuits under state consumer protection laws because a company could be sued for selling a ''misbranded'' product labeled as containing 5 calories per serving when the actual caloric content is just over 6 calories per serving, despite the fact that the product's labeling meets our requirement to express the number of calories to the nearest 5 calories.

(Response) We decline to revise the rule as suggested by the comment. Section 101.9(g)(6) states that reasonable deficiencies of calories under labeled amounts are acceptable within current good manufacturing practice. We continue to consider the variability generally recognized for the analytical method used and reasonable deficiencies of declared amounts acceptable within current good manufacturing practice when evaluating label compliance and making determinations regarding misbranding charges. We also recognize that § 101.9(c)(1) provides several methods for determining calories, which also allows manufacturers flexibility in determining the declared calorie value. Thus, the regulations provide for variability that is acceptable under our regulations.

(Comment 406) One comment recommended that fractions of quantities should be shown per serving for nutrients such as *trans* fat because some people consume multiple servings of a product at the same time and may not realize that they add up to greater than 1 gram per serving.

(Response) We decline to revise the rule as suggested by the comment. We note that the requirements of § 101.9(c) do require the declaration of total fat, saturated fat, *trans* fat, and monounsaturated fat be expressed using fractions, which are the nearest 0.5 gram increment below 5 grams. For many macronutrients, it is not possible for manufacturers to declare fractions of a gram or mg amount on the label due to the level of variability inherent in the analytical methods used to determine the amount of the nutrient.

Similar comments recommended that we require manufacturers to declare amounts of *trans* fat when present at less than 0.5 grams per serving of a food. We address those comments in part II.F.3.d.

(Comment 407) One comment suggested that we allow for grams of dietary fiber to be rounded to the nearest 0.5 grams. The comment noted that the proposed DV for children 1 through 3 years of age is 14 grams. Therefore, the comment said, 10 percent of the DV for that age group would be equivalent to 1.5 grams of dietary fiber, and 20 percent of the DV for that age group would be 2.5 grams. The comment also noted that 10 percent of the current DV for the general population of 25 g would be 2.5 grams. The comment suggested that allowing for fiber to be declared in 0.5 gram increments up to 5 grams could help facilitate consumer communication and help reduce any confusion with respect to claims.

(Response) We decline to revise the rule as suggested by the comment. The declaration of dietary fiber is expressed in increments of 1 gram due to the level of precision of analytical methods for dietary fiber. The level of precision of the methods for determining dietary fiber do not allow for the accurate determination of the amount of dietary fiber in increments of less than 1 gram per serving.

7. Issues Concerning Specific Vitamins and Minerals

The preamble to the proposed rule discussed issues related to RDIs for vitamin K, chloride, potassium, choline, and vitamin B_{12} (79 FR 11879 at 11930).

a. Vitamin K. The preamble to the proposed rule noted that there are three general forms of vitamin K: Phylloquinone (vitamin K_1), menaquinone (vitamin K_2), and menadione (vitamin K_3) (id.). For labeling purposes, there is no specific definition for vitamin K and the AI for vitamin K is based on the intake of phylloquinone, the major form of vitamin K in the diet. The proposed rule, at § 101.9(c)(8)(iv), would establish 120 mcg as the RDI for vitamin K.

(Comment 408) One comment supported using the AI for vitamin K which pertains only to phylloquinone.

Other comments objected to limiting the RDI for vitamin K to phylloquinone (Vitamin K_1). The comments stated that menaquinone contributes to the nutritional requirements for vitamin K and should be included in the definition. One comment stated that inclusion of menaquinone would be in line with other regulatory bodies such as EFSA and Health Canada. One comment also noted that dairy and meat products are important sources of menaquinone and contribute to the daily intake of vitamin K. The comment stated that the bioavailability of menaquinone has been demonstrated using both in vitro and in vivo studies. The comment also stated that menaquinone is rapidly absorbed intact from the gastrointestinal tract (Ref. 229) and is more bioavailable than phylloquinone, which is strongly bound to vegetable fiber (Refs. 229–230). The comment also noted that it has been well-established that dietary intake of phylloquinone meets the nutritional requirements necessary for coagulation through the activation of biochemical pathways in the liver. The comment also noted that menaquinone has similar activity as phylloquinone in the blood coagulation system (Ref. 229), and data also suggest an important role for menaquinone in extra-hepatic processes. The comment stated that menaquinone intake has been shown to have a protective effect against CHD (Ref. 231), helps regulate bone metabolism, and plays a role in reducing the risk of osteoporotic fractures (Refs. 229, 232). The comment pointed out that the USDA database (2014) now includes vitamin K_2. The comment also requested that we include phytonadione, which is an additional

name for vitamin K_1, in the definition of vitamin K.

(Response) We agree that the AI should be used as the basis for the RDI for vitamin K. However, we disagree that the definition of vitamin K should include menaquinones. While the comment referred to actions by Health Canada, we note that Health Canada also is proposing using the AI for the RDI for vitamin K (Ref. 233). Furthermore, the EFSA review cited by the comment was a safety assessment for vitamin K_2 as a source of vitamin K added to foods and was not an assessment of the possible nutritional benefits of vitamin K_2 (Ref. 229). One study (Ref. 232) submitted by a comment was a review article on menaquinone-4 and osteoporosis and did not provide data for us to evaluate. It does not represent the totality of the scientific evidence on menaquinones and does not provide sufficient information for FDA to review. The other two studies, Gast et al., 2009 and Geleijnse et al., 2004, were prospective cohort studies that showed an association of menaquinone intake and reduced risk of CHD. Intakes for menaquinone in these two studies were estimated from food frequency questionnaires and, because food composition data for menaquinones is limited, the results of these studies should be interpreted with caution (Refs. 230–231). As we stated in the preamble to the proposed rule (79 FR 11879 at 11930), the AI for vitamin K does not account for the intake of menaquinone or menadione because: (1) The NHANES data that was used as the basis for the AI only included the phylloquinone content of foods; (2) the contribution of menaquinones, which can be produced by bacteria in the gut, to the maintenance of vitamin K status has not been established; and (3) menadione is a synthetic form of vitamin K that can be converted to a form of menaquinone in animal tissues. In addition, menaquinones are poorly understood in terms of vitamin K absorption and utilization (Refs. 234–236). Unlike phylloquinone, there have been no stable isotope studies conducted with menaquinones that are needed to improve the understanding of menaquinone bioavailability and metabolism (Ref. 235). While the USDA National Nutrient Database for Standard Reference Release 27 includes data on one form of menaquinones (menaquinone-4), there are limited food composition data available (490 foods out of 8,618 or <6 percent in USDA NND SR27) (Ref. 4), and estimates of intakes of menaquinones are very limited. Furthermore, we generally consider U.S. dietary recommendations, consensus reports, and U.S. national survey data to develop our regulations.

While we decline to include menaquinone in a definition of vitamin K, we note that information about menaquinones that might be added to a food may be listed in the ingredient list to alert consumers that other forms of vitamin K are present in the product. We also discuss the labeling of menaquinone as a dietary ingredient in part II.P (Dietary Supplements).

We also disagree that the term phytonadione should be included in the definition for vitamin K. ''Phytonadione'' is U.S. Pharmacopeia Convention's (USP) nomenclature for ''phylloquinone,'' and both have the same structure (Ref. 237). In the Nutrition Facts label, phylloquinone is declared as vitamin K (§ 101.9(c)(8)). Furthermore, for dietary supplements, labeling representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or the ingredient list (*e.g.,* calcium (as calcium carbonate USP) (§ 101.36(d)(3)).

Thus, the final rule establishes, in § 101.9(c)(8)(iv), an RDI for vitamin K of 120 mcg based on the AI that pertains only to phylloquinone. We are making no changes to the rule based on these comments.

b. Chloride. The preamble to the proposed rule (79 FR 11879 at 11930) stated that, under our preexisting regulations, the RDI for chloride is 3,400 mg (§ 101.9(c)(8)(iv)) and is based on the midpoint of the range (1,700 to 5,100 mg/day) of the ESADDI. The proposed rule would have chloride remain a RDI, but based on a population-coverage AI of 2,300 mg/day.

We did not receive comments on the RDI for chloride and have finalized it without change.

c. Potassium. The preamble to the proposed rule (id.) explained that the DRV of 3,500 mg for potassium was established based on its beneficial health effects (*e.g.,* reduction in blood pressure) and that we established a DRV rather than an RDI because an RDA for specific age and gender groups was not established in 1990 (when we issued various regulations related to nutrition information on food labels). However, because potassium is an essential mineral and because age- and gender-specific AIs became available in 2005, we proposed to establish an RDI for potassium, instead of the DRV, and thus revise § 101.9(c)(8)(iv) to set the RDI for potassium at 4,700 mg.

We did not receive comments directly on the RDI for potassium, although some comments opposed using the AI for potassium to establish an RDI of 4,700 mg. We address those comments in part II.M.3 (see comment 391). The final rule, at § 101.9(c)(8)(iv), establishes an RDI of 4,700 mg for potassium.

d. Choline. Our existing regulations do not establish a reference value for choline. The preamble to the proposed rule noted that the IOM established age- and gender-specific AIs for choline based on intakes necessary to maintain liver function and that, in 2001, we received a FDAMA notification under section 403(r)(2)(G) of the FD&C Act for the use of certain nutrient content claims for choline (79 FR 11879 at 11930). The FDAMA notification identified the DV for choline as 550 mg, which was based on the population-coverage AI for choline. Thus, the proposed rule, at § 101.9(c)(8)(iv), would set an RDI of 550 mg for choline based on the population-coverage AI.

(Comment 409) Several comments agreed with the proposed RDI for choline.

(Response) The final rule, at § 101.9(c)(8)(iv), establishes an RDI of 550 mg for choline.

e. Vitamin B_{12}. The proposed rule would lower the RDI for Vitamin B_{12} from 6 mcg/day to 2.4 mcg/day to reflect the population-coverage RDA for Vitamin B_{12} established by the IOM in 2000 (Ref. 238). We acknowledged that lowering the RDI from 6 to 2.4 mcg could result in a reduction of the fortification level in foods, such as ready-to-eat breakfast cereals, thereby decreasing the overall amount of crystalline vitamin B_{12} in the food supply (see 79 FR 11879 at 11930). (The preamble to the proposed rule (id.) also noted that individuals older than 50 years of age meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing supplements.)

(Comment 410) Some comments supported our use of the RDA set by the IOM to revise the RDI for vitamin B_{12}. One comment noted that, if the proposed RDI was adopted, manufacturers of fortified ready-to-eat cereals and other products may adjust fortification levels of vitamin B_{12} to maintain their current DV claim levels, thereby reducing the amount of crystalline vitamin B_{12} in the food supply. However, the comment stated that, based on an analysis by Murphy et al., this change would not lead to a significant increase in the proportion of the population with inadequate dietary intakes of vitamin B_{12}. The comment said that the Murphy study indicated that the difference in the proportion of the total population with usual intakes

of vitamin B_{12} less than the EAR would be about 3 percent regardless of whether the revised RDI was based on a population-weighted EAR or a population-coverage RDA, and this would be within 2 percentage points of the percentage calculated by using the current DV. The comment noted that the results for older adults and teenage girls were a little higher, but similar regardless of the approach. The comment recommended that we continue to promote vitamin B_{12} intake in at-risk subpopulation groups and to continue monitoring population intake.

Other comments opposed lowering the RDI for vitamin B_{12} and said we should retain the RDI of 6 mcg for vitamin B_{12}. The comments expressed concern that a substantial decrease in the RDI would result in lower amounts of crystalline vitamin B_{12} in food and dietary supplements. The comments stated that this decrease would make it more difficult for those at-risk for deficiency, including older adults, vegetarians, and vegans, to achieve adequacy for this nutrient. The comments noted that the IOM and DGA recommended these at-risk groups should consume the crystalline forms.

(Response) The final rule adopts an RDI for vitamin B_{12} of 2.4 mcg based on the RDA. The RDA was established by the IOM in 2000 for all adults and can be met by consuming natural and crystalline forms. While the IOM noted that it is advisable that individuals older than 50 years of age meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing supplements, less than 1 percent of men and 6.4 to 7.5 percent of women older than 50 years of age consume below the EAR for vitamin B_{12}, while only 3 to 5 percent of men and women in this age group have serum vitamin B_{12} levels that are considered to be inadequate (2003–2006 NHANES) (see 79 FR 11879 at 11930). Based on the data provided by the comment in support of lowering the RDI, it is unlikely that lowering the RDI will result in a significant increase in the proportion of the population with inadequate dietary intakes of vitamin B_{12}. If we became aware that foods are formulated as a result of this final rule, leading to lower amounts of crystalline B_{12} are in the food supply, we would consider the need for consumer education, particularly for at-risk individuals who may need to increase intake of certain foods to meet nutrient needs.

N. Units of Measure, Analytical Methods, and Terms for Vitamins and Minerals

The preamble to the proposed rule (79 FR 11879 at 11931) discussed how the IOM set DRIs using new units of measure for vitamin A, vitamin E, and folate and provided recommendations on the use of International Units (IUs) and the expression of weight amounts for sodium, potassium, copper, and chloride. The new units of measure for vitamin A, vitamin E, and folate affect how total amount of each nutrient is measured.

1. General Comments

(Comment 411) While we did not request comment on using teaspoons or tablespoons as units of measure, several comments supported using teaspoons (tsp) and tablespoons (tbsp) in addition to or instead of grams (g) for nutrients. The comments said that consumers use these common household measures in recipes and can visualize them.

In contrast, other comments recommended using only metric units, such as grams, only because they are more precise and used by other countries.

(Response) We address this issue in part II.B.3.

2. Sodium, Potassium, Copper, and Chloride

Our preexisting regulations at § 101.9(c)(9) and (c)(8)(iv) express the units of measurement for sodium, potassium, copper, and chloride in milligrams. Although the preamble to the proposed rule (79 FR 11879 at 11931) discussed IOM recommendations to use grams rather than milligrams (mg) and how comments to the 2007 ANPRM supported retaining mg instead of using grams, we declined to propose any changes to the units of measure for these nutrients.

(Comment 412) Several comments supported retaining the declaration of ''mg'' for sodium and potassium. Other comments recommended the use of ''mg'' for calcium and phosphorus, but did not explain their reasoning.

(Response) For reasons stated in the preamble to the proposed rule (79 FR 11879 at 11931), we agree with retaining ''mg'' for the units of measure for sodium, potassium, copper, and chloride, so the units of measure in § 101.9(c)(8)(iv) and (c)(9) remain unchanged.

As for calcium and phosphorus, we did not propose changing the units of measure, and so the final rule continues to use ''mg'' as the unit of measure for calcium and phosphorus.

3. Folate and Folic Acid

a. Units of measure. Our preexisting regulations, at § 101.9(c)(8)(iv), have the RDI for ''folate'' in micrograms. In the preamble to the proposed rule (79 FR 11879 at 11931 through 11932), we explained how, in 1998, the IOM set the RDA for folate expressed as microgram (mcg) Dietary Folate Equivalents (DFE) and how the IOM Labeling Committee recommended that the use of similar units of measure in nutrition labeling. The preamble to the proposed rule explained how the IOM developed the new term, DFE, to account for the greater bioavailability of synthetic folic acid that is added to fortified foods or dietary supplements than folate that occurs naturally in foods (food folate) and that mcg DFE is equivalent to mcg food folate + (1.7 × mcg synthetic folic acid) (id. at 11932). The proposed rule would amend § 101.9(c)(8)(iv) to use mcg DFE to declare the amount of total folate (food folate and synthetic folic acid) on the Nutrition Facts label. The proposed rule would make a similar change, at § 101.36(b)(2)(ii)(B), with respect to the declaration of folic acid on the Supplement Facts label.

The preamble to the proposed rule (79 FR 11879 at 11932) also stated that we are aware that education efforts should be provided to help consumers understand the new ''equivalent'' units of measurement for folic acid. We said that one option to help ensure consumer understanding would be to allow the declaration of the mcg amount of folic acid in parentheses in addition to declaring the amount of folate in mcg DFE and percent DV based on mcg DFE.

(Comment 413) Although one comment supported using DFEs as the unit of measure, many comments said we should retain the preexisting DV of 400 mcg folate or folic acid and not adopt DFEs as the unit of measure.

Several comments stated that using mcg DFE as the unit of measure will confuse the public, limit the ability to monitor folate/folic acid intake and safety, and could negatively impact birth outcomes. The comments said that entities such as the IOM, the Centers for Disease Control and Prevention, the U.S. Public Health Service (USPHS), and the March of Dimes have educated the public on the importance of women of child-bearing age consuming at least 400 mcg of synthetic folic acid daily to help prevent neural tube defects. The comments said that changing the unit of measure may promote suboptimal intake of the nutrient, especially if women do not understand the difference in the bioavailability of

naturally occurring folate versus synthetic folic acid.

Other comments stated that an educational campaign would be necessary, especially for obstetricians and women of child-bearing age, to teach them how to achieve adequate dietary folate levels if we were to use mcg DFE as the unit of measure. The comments said we should continue to declare the amount of folic acid in micrograms along with the percent of DV (based on the PHS recommendation) in both the Nutrition and Supplement Facts.

(Response) As we stated in the preamble to proposed rule (79 FR 11879 at 11932), the IOM developed the DFEs to reflect the most current recommendation for folate/folic acid for the general healthy U.S. population. The DFE accounts for the differences in bioavailability between food folate (natural folate) and folic acid which is more bioavailable (about 1.7 times more bioavailable). Use of mcg DFE on the label is important to make sure that the consumer is aware of the total amount of folate in a serving of food. For example, assume that the level of total folate in a packaged cereal is approximately 200 mcg folate per serving. If all of the folate in the cereal is added folic acid, then the amount of folate would be 340 mcg DFE (200 mcg $\times$ 1.7) because folic acid is more bioavailable than folate. This value is higher than the RDA set by IOM for children 4 to 8 years of age (200 mcg DFE). Thus, if we retained mcg as the only unit of measure for folate, we would not differentiate between folic acid and food folate in food, and we would underestimate the contribution of fortified foods to the folate requirement; consequently, consumers may think they need more folate/folic acid than they receive from a food that contains both folate and folic acid.

As for the comment suggesting that we allow the use of both mcg and mcg DFE as units of measure, we agree that declaring the amount of folic acid in mcg will provide information that women of childbearing age need in order to understand the unique contribution of synthetic folic acid from a food, given the differences in bioavailability compared to folate and nutrition recommendations for risk reduction of neural tube defects (Ref. 238).

With respect to dietary supplement labeling, if a dietary supplement has added synthetic folate or a claim is made about folate, the manufacturer must include the declaration of folate as a quantitative amount by weight of folate (mcg DFE folate), and the percent DV based on mcg DFE folate in the Supplement Facts label. If a dietary supplement has added folic acid (alone or in combination with natural or synthetic folate), or a claim is made about folic acid, the nutrient declaration must include folate as a quantitative amount by weight of folate (mcg DFE folate), and the percent DV based on mcg DFE folate, in addition to the quantitative amount by weight of folic acid (mcg folic acid) in parentheses. If a dietary supplement has naturally occurring folate (with no folic acid added) and a claim is not made about folate, the manufacturer may voluntarily declare folate as a quantitative amount by weight in mcg DFE and percent DV based on mcg DFE folate.

With respect to conventional food labeling, if a conventional food has naturally occurring folate (with no folic acid added) and there is no claim made about folate, the manufacturer can voluntarily declare folate in the Nutrition Facts label. If the manufacturer voluntarily declares folate, the manufacturer may declare folate followed by the percent DV based on mcg DFE folate, or alternatively, can declare the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate. If a claim is made about folate, the manufacturer must declare folate either by declaring folate as the percent DV folate based on mcg DFE folate, or as the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate. If folic acid is added to the conventional food, the manufacturer must declare folate either by declaring folate as the percent DV folate based on mcg DFE, or as the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate, in addition to the quantitative amount of folic acid in mcg in parentheses. This will provide the needed information about the amount of folic acid in a conventional food or dietary supplement for women who are capable of becoming pregnant. Declaring folate, either as a quantitative amount in mcg DFE followed by the percent DV or only as a percent DV based on mcg DFE, and, mcg folic acid, in circumstances when folic acid is added or claims are made about folic acid, the declaration of folate/folic acid should provide adequate and correct information for the general U.S. population, including the women of childbearing age.

As for the comments regarding the need for an educational campaign, we agree that it is important for changes to the labeling to be accompanied by education efforts to help consumers understand the new labels (see part II.B.1). We intend to coordinate education and outreach efforts with Federal Agencies and other organizations with an interest in nutrition and health to emphasize, among other things, the newly adopted units of measure for folate in mcg DFE, percent DV based on mcg DFE, and mcg of folic acid for the first time on the Nutrition Facts and Supplement Facts labels.

(Comment 414) Several comments were concerned about the removal of mcg folic acid from the food label. Some comments stated that, by only reporting mcg DFE folate on the label, it would no longer be possible to measure the percentage of a subpopulation that consumes in excess of the UL for folic acid. The comments said that intake data is obtained through the NHANES, which uses food labels to collect information on the type and amount of micronutrients (including folic acid) contained in food products.

Other comments stated that limiting the units of measure to mcg DFE would make it difficult for consumers to make an informed decision regarding their actual folic acid intake. The comments said that this is a particular concern for older adults who are at greater risk for developing macrocytic anemia due to a deficiency of vitamin B_{12} and that this condition could be masked by excessive intake of folic acid from fortified foods and/or supplements. Other comments stated that the introduction of mcg DFE as the unit of measure for folic acid may prompt some manufacturers (who currently provide 100 percent of the DV for folic acid) to reduce the amount of folic acid in their products. For example, the manufacturer of a dietary supplement that currently contains 100 percent of DV for folic acid (400 mcg folic acid) may reduce the amount to 235 mcg folic acid or 400 mcg DFE to retain 100 percent DV.

(Response) As stated in our response to comment 413, we are not limiting the units of measure for folic acid to mcg DFE folate on the Nutrition Facts label. If folic acid is added or claims are made about folic acid, the Nutrition Facts label must include the declaration of folic acid as a quantitative amount by weight in mcg folic acid.

With respect to measuring the percentage of a subpopulation that consumes in excess of the UL for folic acid, we note that the rule was not intended nor designed to facilitate such research. The Nutrition Facts label provides information to assist consumers in maintaining healthy dietary practices. By having only mcg DFE or mcg of folic acid on the label,

it would not be possible to determine the percentage of a subpopulation that exceeds the UL for folic acid. To determine the percentage of a subpopulation with folic acid intake in excess of the UL, one would have to perform an analysis using the consumption data from NHANES and the UL set by IOM for various age and gender groups.

As for the comment's statements regarding NHANES, What We Eat in America (WWEIA)/NHANES does not use only food labels to collect information on the type and amount of micronutrients contained in food products. The preexisting Nutrition Facts label declares folate in mcg which represents both natural folate and synthetic folic acid, without taking into account differences in bioavailability factors. The WWEIA/NHANES currently reports the amount of folate consumed as mcg DFE, as well as folic acid (mcg), food folate (mcg), and total folate (mcg). Thus, the Nutrition Facts label is not the sole source of information for folate and folic acid for this database.

As for older adults and the risk of developing macrocytic anemia due to a deficiency of vitamin B_{12}, we disagree that using mcg DFE on the label will put older adults at greater risk. The current Nutrition Facts label does not differentiate between synthetic folic acid and naturally occurring folate in the food label. The folate RDA for individuals 19 years of age and older is 400 mcg DFE, and not 400 mcg folic acid. The DFE accounts for the differences in bioavailability between food folate (natural folate) and folic acid (which is approximately 1.7 times more bioavailable than food folate). Therefore, by declaring folate as mcg DFE and percent DV based on mcg DFE folate, as applicable, on the Nutrition Facts label, the total folate will be reported and will provide the majority of the general, healthy U.S. population (including older individuals) a more accurate amount of their intake. Furthermore, by requiring the mandatory declaration of the amount of folic acid as mcg folic acid in parentheses, when folic acid is added or a claim is made about it, women of childbearing age will have the information they need to understand the unique contribution of synthetic folic acid from a food to adhere to nutrition recommendations to reduce the risk of neural tube defects. In addition, other consumers, such as older adults, can determine how much folic acid is in a serving of food.

With respect to reformulation, the comment did not provide any evidence to suggest that reformulation would occur, and so we have no basis to determine the extent to which reformulation might occur or whether reformulation would present any potential issues with respect to consumption of folate. We note, however, that if manufacturers decrease the amount of folic acid from 400 mcg folic acid to 400 mcg DFE to retain the 100 percent DV, the needs of the majority of the U.S. population will be met. For the majority of U.S. population, the RDA and its unit of measure is mcg DFE folate and not mcg of folic acid. Therefore, reporting total folate as mcg DFE folate and percent DV based on mcg DFE is more accurate.

(Comment 415) Several comments stated that, for a dietary supplement that is ingested on an empty stomach, 1 mcg DFE is equivalent to 0.5 mg folic acid and is therefore subject to the conversion factor of 2.0 not 1.7. The comment said we should clarify this in the final rule if we adopt DFEs as the unit of measure.

(Response) We are not limiting the units of measure to DFEs in the final rule. The IOM defined DFE as follows: 1 mcg DFE = 1 mcg food folate; 1 mcg DFE = 0.6 mcg folic acid from fortified foods or dietary supplements consumed with foods; 1 mcg DFE = 0.5 mcg folic acid from dietary supplements taken on an empty stomach. We do not know how many people take a supplement containing folic acid on an empty stomach or with a meal. To ensure consistency in the labeling of conventional foods fortified with folic acid, dietary supplements containing folic acid, and dietary supplements containing folic acid that may also contribute calories and other nutrients, we conclude that using the conversion factor of 0.6 mcg (multiply by 1.7) for folic acid is appropriate. The final rule requires dietary supplements to include the declaration of the quantitative amount of folic acid, when added or when a claim is made about folic acid, in addition to folate in mcg DFE and percent DV based on mcg DFE. The final rule also states that 1 mcg DFE is equal to 1 mcg naturally occurring folate and equal to 0.6 mcg folic acid.

(Comment 416) Some comments said that mcg DFE fails to take into consideration the higher bioavailability of synthetic folates compared with naturally occurring dietary folate and should not be used on labels. The comments said that added L–5-methyltetrahydrofolate (also known as L–5–MTHF or L–MTHF) would be assigned the same bioavailability as naturally occurring folate and would underestimate the true bioavailability of the folate in the food. The comments noted that both the calcium and glucosamine salts of L–5–MTHF have bioavailabilities similar to folic acid. The comments said we should support a conversion factor equivalent to that for folic acid (× 1.7) for the labeling of these synthetic folates in dietary supplements and conventional foods.

(Response) The use of synthetic folates (*i.e.,* calcium and glucosamine salts of L–MTHF) in dietary supplements, and the appropriate conversion factor for these substances, warrants further review. We are not aware of the use of any synthetic folates, including calcium and glucosamine salts of L–5–MTHF, in conventional food. We note that folic acid is regulated as a food additive under § 172.345; the additive is identified as (N-[4-[[(2-amino-1,4-dihydro-4-oxo-6-pteridinyl) methyl]amino]benzoyl]-L-glutamic acid; CAS Reg. 59–30–3) for use as a nutrient in foods and may be added to conventional foods subject to a standard of identity when the standard provides for the addition of folic acid; to breakfast cereal and corn grits at specified levels; and to infant formula according to applicable regulations (§ 172.345). Conditions of use of folic acid in medical foods, foods for special dietary use, and for meal-replacement products also are included in § 172.345. Additional uses of folic acid as described in § 172.345 would require submission of a food additive petition asking us to amend the regulations to allow for the additional use. Information on submitting a food additive petition is described in § 171.1. Manufacturers of food products that contain other forms of folic acid or synthetic folate, such as calcium and/or glucosamine salts of L–5–MTHF should consult the Office of Food Additive Safety to determine the appropriate regulatory pathway for the lawful use of their products.

Although we asked for comment in the 2007 ANPRM about whether the current DV units for folate (mcg folate) should be consistent with the IOM DRI reports for folate (mcg DFE) (72 FR 62149 at 62170), we did not ask about the use of synthetic folate, such as calcium and/or glucosamine salts of L–5–MTHF in food, including dietary supplements, or invite comment about the conversion factor for synthetic folate compared to that for folic acid. Therefore, we intend to consider the comparability of synthetic folates in dietary supplements and the need for a conversion factor for each in a separate rulemaking. Until such rulemaking is completed, we do not intend to object to a manufacturer using its own established conversation factors, provided that the declaration is truthful and not misleading. We would not

expect a conversion factor to exceed 1.7 (comparable to folic acid) when reporting mcg DFE on the Supplement Facts label. Any declaration of mcg DFE for a dietary supplement that represents in whole or in part the amount of synthetic folate present, for which a conversion factor was applied, must be truthful and not misleading under section 403(a) and 201(n) of the FD&C Act. We will be able to determine the conversion factor used through information obtained from records required by this final rule for natural folate, folic acid, and synthetic folate present in the product and the declared mcg DFE on the label.

(Comment 417) The preamble to the proposed rule also stated that we are aware that education efforts should be provided to help consumers understand the new ''equivalent'' units of measure for folic acid (79 FR 11879 at 11932). We also said that one option to help ensure consumer understanding would be to allow the declaration of the amount of folic acid in parentheses in addition to declaring the amount in mcg DFE, and we invited comment on this option (id.).

Several comments stated that, if DFEs are to be included on food labels, the mcg of folic acid must be included in parentheses. The comments said that the IOM recommended that women who may become pregnant consume 400 mcg of folic acid in addition to the RDA. The comments also said that using mcg DFE alone as the unit of measure will make it difficult for women to discern how much of their daily intake is from folic acid and which foods would be best choices for ensuring a daily intake of 400 mcg folic acid a day. The comments added that this approach could put women at higher risk for having a neural tube defect affecting a pregnancy. Some comments also noted that there may also be conventional foods containing only added folic acid, such as meal replacement foods based on protein concentrates that do not contain significant levels of naturally occurring folate.

(Response) We agree that including the mcg folic acid when added to a food or when a claim is made about folic acid is necessary to help women of childbearing age determine the amount of folic acid in each food. Thus, we have revised § 101.9(c)(8)(iv) and (c)(8)(vii) to require the declaration of folic acid in mcg under such circumstances.

(Comment 418) Some comments stated that we should retain the current DV of 400 mcg as folate or folic acid without adopting a DFE approach, along with the percent DV (based on the PHS recommendation) in both the Nutrition and Supplement Facts labels. One comment suggested that an educational campaign would be necessary, especially for obstetricians and women of child-bearing age, to teach them how to achieve adequate dietary folate levels if we adopt the mcg DFE unit of measure.

(Response) We agree that consumer education regarding the new unit of measure will be helpful (see part II.B.1 for a discussion of educational activities). We disagree that we should retain the DV and the percent DV based on the amount of mcg of folic acid. The DV and the percent DV should be based on mcg DFE, which reflects the most current recommendation for folate/folic acid for the general U.S. population and takes into account the differences in bioavailability between food folate and folic acid which is more bioavailable.

b. Analytical methods. The preamble to the proposed rule (79 FR 11879 at 11932) noted that available analytical methods cannot distinguish between naturally occurring folate in conventional food and folic acid that is added to conventional food products. To calculate DFEs, the preamble to the proposed rule (id.) explained that it is necessary to know both the amount of folate and folic acid in the food product, and so proposed § 101.9(g)(10) would require manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food, when a mixture of both naturally occurring folate and added folic acid are present in the food.

(Comment 419) We did not receive any comments with respect to scientifically valid methods for determining folate and folic acid separately. However, one comment objected to the proposed recordkeeping requirement.

(Response) We decline to revise the rule to remove the recordkeeping requirement. In the absence of an analytical method that distinguishes between folate and folic acid, records are necessary to demonstrate compliance with the label declaration and include written records of the amount of folic acid added to the food (conventional food or dietary supplement), the amount of synthetic folate, if added to the dietary supplement, and naturally occurring folate in the finished product. Without such records, we would be unable to determine or verify the amounts and also would not be able to determine whether the mcg DFE value listed on the label is correct.

(Comment 420) Proposed § 101.9(g)(10)(vii) would require manufacturers to make and keep written records of the amount of folic acid added to the food and folate in the finished food when a mixture of folate and folic acid is present in that food. One comment would revise § 101.9(g)(10)(vii) to state that, when folic acid and/or purified folate salts (*e.g.,* L-methylfolate) is added to a food, manufacturers must make and keep written records of the amount of folic acid, and/or purified folate salt, added to the food, as well as the amount of naturally occurring folate if present. The comment noted that these records will be necessary any time folic acid or folate salt is added to food to justify the calculation of the declared mcg DFE, even if no naturally occurring folate is present.

(Response) We agree that when folic acid is added to a conventional food or dietary supplement and synthetic folate (*e.g.,* L–5–MTHF) is added to a dietary supplement, manufacturers must keep written records of the amount of synthetic folate added to a dietary supplement and the amount of folic acid added to the conventional food or dietary supplement as well as the amount of naturally occurring folate in the finished conventional food or dietary supplement. We have revised § 101.9(g)(10)(vii) accordingly.

c. Terms to declare folate. Our preexisting regulations identify ''folic acid'' and ''folacin'' as synonyms of folate and allow these terms to be added in parentheses after folate or listed without parentheses in lieu of ''folate'' on the Nutrition Facts label (§ 101.9(c)(8)(v)) or on the Supplement Facts label (§ 101.36(b)(2)(B)(2)).

Consistent with the proposed amendments related to the units of measure for folate that take into account the differences between folate and folic acid, the proposed rule would: (1) Eliminate the synonym ''folacin'' specified in §§ 101.9(c)(8)(v) and 101.36(b)(2)(i)(B)(2); (2) require, in proposed § 101.9(c)(8)(vii), that the term ''folate'' be used in the labeling of conventional foods that contain either folate only or a mixture of folate and folic acid; and (3) require that the term ''folic acid'' be used in the labeling of dietary supplements only. Thus, under the proposed rule, conventional foods would not be permitted to use the term ''folic acid.''

(Comment 421) One comment supported eliminating the term ''folacin'' from the Nutrition Facts and Supplement Facts labels. However, other comments asked that we continue to allow the use of the term ''folate'' on Supplement Facts labels. Several comments stated that the use of the term folate on dietary supplement labels

refers to dietary folates which are members of the folate group that can be found in food, including folinic acid (5-fomryltetrahyrofolate). For some dietary supplements, calcium L-methylfolate (L–5 MTHF), and various other tetrahydrofolates, as synthetic folate, may be added. In comparison, the comments said that folic acid is synthetically produced and refers to only one member of the folate group (pteroylmonoglutamic acid). The comments said it would be scientifically and chemically incorrect and misleading to consumers to refer to the reduced folate forms in dietary supplements as folic acid, given that folic acid represents only the monoglutamic form.

Other comments noted there are a large number of dietary supplements that are ''whole food'' supplements containing naturally occurring folate rather than added folic acid (*e.g.,* multivitamin capsules manufactured using powdered cultured yeast).

(Response) We agree that there are dietary supplements that may contain natural folate from food or synthetic folate (*e.g.,* L–5–MTHF). If synthetic folate is added to a dietary supplement, folate must be declared as mcg DFE folate and percent DV based on DFE. This will result in consistency in the nutrient terms used and units of measure for the declaration of folate on both conventional foods and dietary supplements, which will avoid confusion among consumers. We are not aware of a manufacturer choosing to voluntary declare naturally occurring folate in a dietary supplement ingredient, but if not added for the purpose of supplementation, the manufacturer is not required to declare the quantitative amount or the percent DV for naturally occurring folate. If a manufacturer chooses to voluntary declare naturally occurring folate, the manufacturer must declare both the quantitative amount in mcg DFE and the percent DV. In addition, if folic acid is added to the dietary supplement that has naturally occurring folate present, the quantitative amount of folate, the quantitative amount of folic acid, and the % DV must be declared. The terminology for the units of measure in the Supplement Facts label will be consistent with the terminology in the Nutrition Facts label. Therefore, the final rule removes ''folacin'' from the list of synonyms that may be used for folate in the Nutrition Facts label in § 101.9(c)(8)(v) and the Supplement Facts label in § 101.36(b)(2)(i)(B)(*2*)). In addition, the final rule removes the term ''folic acid'' from the list of synonyms that may be added in parentheses immediately following ''folate'' on the Nutrition Facts label in § 101.9(c)(8)(v) or in place of the term ''folate'' on the Supplement Facts label in § 101.36(b)(2)(i)(B)(*2*) because we are now requiring that both the terms ''folate'' and ''folic acid'' be included, when declared, on both the Nutrition and Supplement Facts label.

(Comment 422) Several comments suggested that not allowing the use of the term ''folate'' on Supplement Facts labels and not considering L–5 MTHF calcium (Metafolin) to be equivalent to folic acid would have devastating, negative effects on industry. The comments said that eliminating the term ''folate'' would prevent dietary supplement manufacturers from being able to use L-methylfolate in their products. Other comments said we should clarify how L–5 MTHF should be labeled.

(Response) The final rule requires the use of the term ''folate'' on Supplement Facts labels and achieves consistency between the Supplement Facts and Nutrition Facts labels.

We also intend to consider the comparability of synthetic folates (*e.g.,* L–5–MTHF calcium (metafolin)) in dietary supplements and the need for a conversion factor for each in a separate rulemaking. In the interim, manufacturers of synthetic folates, such as calcium and/or glucosamine salts of L–5- MTHF may use their established conversation factors (not to exceed 1.7 (comparable to folic acid)) when reporting mcg DFE, and we can determine what conversion factor is being used through information obtained from records required by this final rule for natural folate, folic acid, and synthetic folate present in the product and the declared folate mcg DFE on the label.

(Comment 423) Some comments stated that limiting the use of the term ''folate'' to conventional food only would effectively make drug companies the only source for people who have a genetic polymorphism in the MTHFR gene. Some comments stated that it is important and essential that the labeling of dietary supplements explicitly state the form or forms of folate they contain because many people are not able to convert folic acid to folate. The comments added that, although there is no agreement regarding the number of people whose bodies have difficulty converting folic acid to folate, there is agreement that it is a serious concern for many individuals. The comments said there is much knowledge available regarding defects in two deoxyribonucleic acid (DNA) sequences responsible for producing enzymes needed for the final stage of conversion of folic acid into the active form needed by the human body and that these defects relate to an enzyme called MTHFR and are very common, although the defects vary enormously between ethnic groups and regions. The comments said that the defects can be found in as many as 44 percent of North American Caucasians and over 50 percent of Italians and are more common among those predisposed to diseases such as cancer, heart disease, and autism. The comments said that these estimates do not account for mutations in other genes involved in folate metabolism, such as DHFR, where data have only been emerging recently. For individuals who have mutations impacting MTHFR or other genes relating to folate metabolism, the comments said there is a distinct possibility of building up too much un-metabolized folic acid thereby potentially increasing the risk of cancer, heart disease or stroke. Consequently, a substantial segment of the population needs to consume folate rather than folic acid and would not be able to process dietary supplements containing folic acid.

Several comments stated that requiring dietary supplement labels to use the term ''folic acid,'' when the product only contains folates found in food, would mislabel the product.

(Response) When folic acid is added to conventional food, the final rule requires the declaration of mcg folic acid in addition to the declaration of folate as a percent DV based on mcg DFE or as a quantitative amount by weight in mcg DFE and the percent DV based on mcg DFE. When folic acid is added to dietary supplements, the final rule requires the the quantitative amount by weight for folate (mcg DFE folate) and the percent DV based on mcg DFE for folate, in addition to the mcg folic acid in parentheses. This should address the comments' concerns.

(Comment 424) One comment would revise the rule to state that the term ''folic acid'' should be used in the labeling of dietary supplements, but that the term ''folate'' should be used if the dietary supplement contains folates in food as opposed to folic acid. The comment said that conventional foods would not be permitted to use the term ''folic acid'' unless they are fortified with folic acid. The comment said this result would be consistent with our intent to distinguish between items containing folate and those that primarily contain synthetic folic acid.

Another comment would revise footnote 3 in proposed § 101.9(c)(8)(iv). The proposed footnote would state that

folic acid ''must be used for purpose of declaration in the labeling of dietary supplements'' and ''must also be declared in mcg DFE.'' The comment would revise the footnote to say that folic acid ''must be used for foods that contain this nutrient solely in the form of added folic acid. Foods which supply both folate and folic acid must list the predominant form. Folate and folic acid must both be declared in mcg DFE. Additional information regarding the types(s) or sources(s) of the nutrients (*e.g.,* folate, folic acid, or L5–MTHF) and or/relative amounts where more than one form is present, may be included in parentheses.'' The comment also would revise § 101.9(c)(8)(vii) to require ''folate'' ''for products containing only or predominantly folate'' and ''folic acid'' for ''products containing only or predominantly folic acid.'' (The proposed rule would require, when the amount of folate is declared in the labeling of a conventional food, the use of the name ''folate'' for products containing either folate alone or a mixture of folate and folic acid and the use of the term ''folic acid'' when the nutrient is declared in the labeling of a dietary supplement.) The comment also would revise the rule to say that additional information regarding the types(s) or sources(s) of the nutrients (*e.g.,* folate, folic acid, or L-methylfolate) and or/relative amounts where more than one form is present, may be included in parentheses.

(Response) The final rule requires the use of the term ''folate'' on Supplement Facts labels when folic acid or synthetic folate is added and must be declared and when naturally occurring folate is present and may be declared. The final rule also requires the use of the term ''folic acid'' in mcg folic acid when folic acid is present. This achieves consistency in terminology between the Supplement Facts and Nutrition Facts labels. If folic acid is declared, manufacturers of dietary supplements must also declare the quantitative amount of folate. The mcg DFE reflects the higher bioavailability of folic acid and certain synthetic folate (*e.g.,* L–5–MTHF) than that of food folate and is the basis of DV.

Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the word ''as'' or ''from.'' When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, we do not require it to be listed again in the ingredient statement. With respect to conventional food, the only form that currently can be added to conventional food is folic acid under § 172.345 and not any other forms. If folic acid is added to a conventional food, folic acid must be listed in the ingredient list (§ 101.4(a)).

(Comment 425) Some comments stated that not allowing the term ''folate'' on dietary supplement labels violates the First Amendment. The comments said we cannot require that labeling to refer to folate as folic acid because, according to the comments, such labeling would then be false.

(Response) The final rule requires the use of the terms ''folate'' and ''folic acid,'' when declared, on Supplement Facts labels and achieves consistency between the terms used and units of measure in the Supplement Facts and Nutrition Facts labels. Therefore, the comments' First Amendment concerns are no longer applicable.

(Comment 426) One comment said that there is sufficient theoretical and circumstantial evidence that could compel the informed consumer to seek dietary supplements containing methyl folate rather than folic acid. Other comments suggested putting the term ''folate'' on conventional foods and dietary supplement labels, and using ''folic acid'' on dietary supplement labels with the source in parentheses (*e.g.,* Folic acid as calcium l-5 methyltetrahyrofolate).

(Response) Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the word ''as'' or ''from'' (*e.g.,* ''folate (as L–5–MTHF-calcium)).'' When a source ingredient is not identified within the Nutrition Facts label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the Nutrition Facts label, it will not be listed again in the ingredient statement. For conventional food, under § 172.345, the only form that currently can be added to conventional food is folic acid and not any other forms. If folic acid is added to a conventional food, folic acid must be listed in the ingredient list (§ 101.4(a)).

(Comment 427) One comment stated that it is reasonable not to permit the term folate to be used alone on dietary supplement labels because it is not sufficiently specific. The comment added that if DFE is used for foods, it should be used for dietary supplements as well, but that correct calculation is uncertain. The comment suggested using the term FAE (folic acid equivalent) instead of DFE because FAE is based on a well-defined compound, unlike folate naturally present in unspecified food. Furthermore, the comment said, when the folic acid dose is sufficiently small, the biological availability is much better defined than folate from unspecified food. The calculation of FAE would include contribution from all folates, which would include folic acid and L–5–MTHF salts. The comment also stated that, as understanding of folate naturally occurring in food improved, the calculation of its contribution to FAE can be improved.

(Response) We address the requirements for labeling folate in our response to comment 413.

We disagree that the term FAE should be used on the label instead of DFE. Based on the IOM report (IOM 1998), the correct terminology that is accepted by the scientific community is mcg DFE and not FAE. We will, however, monitor the science in this area and, if there are any major changes based on the future consensus report, we will consider whether further changes are needed.

(Comment 428) One comment stated that, while there is consensus that pure folic acid is more bioavailable than naturally occurring folate in food, there is currently no scientific consensus as to the magnitude of this effect. The comment said that one recent review states that the bioavailability of food folate is commonly estimated at 50 percent of folic acid bioavailability, but said this should be considered a rough estimate because the data on the bioavailability of food folate vary between 30 and 98 percent. The comment noted that, even if a dietary supplement's direction for use specifies taking the products with food or alone, many consumers may not comply. The comment also stated that the more precise estimates (*i.e.,* based on consumption of the nutrient in fortified food or a supplement taken with food vs. supplement taken alone) are not justified by the available data. The comment said that our proposed definition, based on IOM recommendations dating to 1998, no longer represents current knowledge and developments in the formulation of foods and supplements accurately. The comment would revise the definition to assign a value to naturally occurring folate at 50 percent of the value of folic acid (as well as at 50 percent of the value of L–MTHF salts on the equimolar basis to folic acid.

The comment also would revise footnote 4 in § 101.9(c)(8)(iv). As

proposed, the footnote would explain that DFE stands for ''Dietary folate equivalents'' and that 1 DFE equals 1 microgram food folate and equals 0.6 micrograms folic acid from fortified food or as a supplement consumed with food equals 0.5 micrograms of a supplement. The comment would revise the footnote to capitalize the first letters in ''folate equivalents'' and to state that ''1 DFE = 1 mcg naturally occurring folate = 0.5 mcg folic acid (anhydrous basis)* = 0.56 mcg of L-methylfolate calcium salt (anhydrous basis, molecular weight of 497.5))* = 0.93 mcg L-methylfolate glucosamine salt (anhydrous basis, molecular weight of 817.8))*. With respect to the asterisks, the comment said that, because these numbers will often be calculated rather than determined through testing, it is important to specify how water present in the ingredient is to be accounted for in the calculation.

(Response) We disagree that we should assign the value of naturally occurring folate at 50 percent of the value of folic acid (folic acid multiply by 2 instead of 1.7). We agree that the bioavailability of food folate at 50 percent of the bioavailability of folic acid is considered a rough estimate, as data on the bioavailability of food folate may vary between 30 percent and 98 percent. While we recognize that the IOM recommendation dates to 1998, it remains the best scientific consensus report that is available now. We will monitor the science in this area and, if there are any changes based on the future consensus report, we will consider whether to make modifications.

In regard to taking into account the weights of the salts in the formula weights of the available 5–MTHF derivatives, label values and requirements are presented on labels on a weight basis (*e.g.,* mg of calcium, rather than molar equivalents of calcium). Manufacturers are responsible for calculating amounts of the salt forms that, when added, will provide accurate amounts of folate for the label declaration. This is routinely done with other compounds such as minerals (*e.g.,* for calcium, the label states the amount of calcium, not the amount of calcium carbonate that is added).

As for the footnote pertaining to DFE in § 101.9(c)(8)(iv), we have revised it to read as follows: ''DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally occurring folate = 0.6 mcg folic acid.''

4. Vitamins A, D, and E

Our preexisting regulations, at §§ 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B), require the use of International Units (IUs) for the labeling of vitamins A, D, and E on the Nutrition and Supplements Facts labels. The preamble to the proposed rule (79 FR 11879 at 11932) described how changes in our understanding of vitamin activity, along with the IOM Labeling Committee's recommendation to change the units of measure for these nutrients to be consistent with the units in the new DRI reports, led us to propose amending § 101.9(c)(8)(iv) to replace IUs for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E.

a. General comments.

(Comment 429) Several comments supported changing the units of measure for vitamin A, vitamin D, and vitamin E. One comment supported using mg because, the comment asserted, that is how most registered dietitians give recommendations. Another comment cited a study that reported that physicians typically prescribe vitamin and mineral intakes in mg (Ref. 239). Other comments asked us to retain IUs rather than change to mcg RAE, mcg vitamin D, and mg vitamin E. The comments said that consumers are familiar with IUs and would be confused by use of new units for these nutrients. Other comments seeking to retain IUs as the unit of measure for vitamin D noted that IUs are used on dietary supplements and by clinicians. Another comment requested that the unit of measure for vitamin D be consistent for foods and supplements. One comment supporting the continued use of IUs as a unit of measure noted that the IOM uses IUs for vitamin D.

Other comments recommended that we develop an educational campaign to help consumers understand that changes in the units of measure. Some comments suggested that we make a gradual transition to the new units of measure, including a period during which the labels could use IUs in addition to the new units of measure to help consumer understanding.

(Response) We acknowledge that consumers may need some time to adjust to the new units and consider educational activities important to assist consumers to understand the changes made. However, unlike for vitamins A and E, we have further considered the use of IUs for vitamin D and have determined there are good reasons, specific to vitamin D, to permit the voluntary labeling in IUs for vitamin D in addition to requiring the new mcg units. First, although the IOM Labeling Report (Ref. 25) recommended the use of mcg as the unit of measure for vitamin D, some other IOM materials such as the IOM report on calcium and vitamin D (Ref. 200) present both IUs and mcg as the unit of measure. Thus, we agree, in part, with the comment noting that the IOM uses IUs as the unit of measure. Second, we found that the majority of the U.S. population has usual intakes of vitamin D below the EAR from conventional foods alone, and even when combined with dietary supplements (79 FR 11879 at 11922). Moreover, certain segments of the U.S. population are at risk for inadequacy and may be at increased risk of deficiency. Inadequate intakes of vitamin D are associated with osteoporosis and osteopenia (id.). Third, there are not a wide variety of food sources of vitamin D (79 FR 11879 at 11921), and many individuals rely on vitamin D supplements labeled in IUs to achieve an optimal intake, often on the advice and prescription of a clinician. For these reasons, we have determined it is appropriate to permit the voluntary labeling of vitamin D in IUs, in parentheses, alongside the mandatory declaration in mcg units. In this way, the manufacturer can determine whether to include IUs on the label for its products, based on the use of the product and consumers who may be relying on the advice of a clinician who recommends or prescribes vitamin D in IUs alone, or combined with, mcg units. The reasons we provide for the need for voluntary labeling of IUs for vitamin D are not present with respect to vitamin A or E as the IOM is consistent in presenting units of measure for these nutrients and we have determined them not to be nutrients of public health significance. Therefore, we are replacing IUs with mcg which will be consistent with the IOM Labeling Committee's recommendation that the units of measure be consistent with the DRIs. We agree that the unit of measure for vitamin D should be consistent for foods and supplements. We note that the Supplement Facts label reflects the unit of measure for vitamin D required by §§ 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B) thus will reflect mcg as the unit of measure for both conventional foods and dietary supplements.

Furthermore, we provide for voluntary labeling of vitamin D in IUs on both conventional food and dietary supplements. Because we have determined that vitamin D is a nutrient of public health significance, we consider that voluntary labeling in IUs for vitamin D will assist consumers in maintaining healthy dietary practices. The voluntary listing of the amount of vitamin D in IUs should be listed in

parentheses next to the mcg amount for vitamin D.

As for a transition period to the new units of measure, we note that the final rule has a compliance date of July 26, 2018, although the compliance date for manufacturers with less than $10 million in annual food sales is July 26, 2019. This should give manufacturers and consumers some time to convert to the new units of measure and also give us some time to educate consumers about the change.

(Comment 430) Some comments urged that we use the symbol 'µg' instead of 'mcg'.

(Response) We decline to amend the rule as suggested by the comment. While the abbreviation ''µg'' may also be used for micrograms, the use of ''mcg' instead of ''µg'' may prevent consumers from misinterpreting the prefix µ as m (milli).

b. Specific comments on the units of measure for individual vitamins. Several comments focused on the units of measure for individual vitamins.

(Comment 431) We proposed to change the units of measure for vitamin A in § 101.9(c)(8)(iv) by replacing ''IU'' with ''mcg,'' representing mcg Retinol Activity Equivalents (RAE). The preamble to the proposed rule explained that the IU for vitamin A does not reflect the carotene:retinol equivalency ratio, that the vitamin A activity of provitamin A carotenoids (such as β-carotene) is less than pre-formed vitamin A (retinol), and that RAEs consider 6 mcg of dietary β-carotene to be equivalent to 1 mcg of purified β-carotene in supplements (79 FR 11879 at 11932). We proposed a similar change dietary supplements in proposed § 101.36(b)(2)(i)(B)(3).

Several comments agreed with the change to mcg RAE. However, other comments opposed changing IUs to mcg RAE; the comments said that the change fails to distinguish between synthetic β-carotene and naturally derived β-carotene in foods and supplements and results in less vitamin A declared on supplements.

One comment noted that we provided only RAE conversions for retinol, beta-carotene, alpha-carotene and beta-cryptoxanthin and said it would be incorrect to apply the same conversion factor to naturally occurring, as compared to synthetically derived, β-carotene.

(Response) We agree there is a difference in biological activity between synthetic and naturally derived β-carotene. Information presented in Table 2 of the proposed rule (79 FR 11879 at 11931) inadvertently omitted a conversion for RAE from β-carotene from supplements. The table in § 101.9(c)(8)(iv) of the final rule includes the conversions for mcg RAE to mcg supplemental β-carotene:

1 retinol activity equivalent (mcg RAE) = 1 mcg retinol
2 mcg supplemental β-carotene
12 mcg of dietary β-carotene
24 mcg of other dietary provitamin A carotenoids (α-carotene or β-cryptoxanthin)

(Comment 432) The proposed rule, at § 101.9(c)(8)(iv), would change the units of measure for vitamin E by replacing ''IU'' with ''mg,'' representing mg α-tocopherol. The preamble to the proposed rule (79 FR 11879 at 11932) explained that the new measure of vitamin E activity would account for the difference in activity between naturally occurring and synthetic vitamin E.

Several comments supported the definition of vitamin E as mg α-tocopherol. However, other comments disagreed with mg α-tocopherol and recommended that we include other forms, in addition to α-tocopherol, in the definition of vitamin E. The comments said that other forms of vitamin E have biological activity and that some forms are linked to cancer, stroke, and neurodegeneration. One comment cited several studies to support the assertion that other forms of vitamin E have bioactivities that are important to disease prevention and/or therapy (Refs. 240–245). One comment disagreed with the use of mg α-tocopherol for vitamin E and suggested we include different forms of vitamin E and relative amounts so that the vitamin E declaration is not misleading.

(Response) We decline to include other forms in the definition of vitamin E. As we noted in the preamble to the proposed rule (79 FR 11879 at 11926), RDIs for vitamins and minerals are based on the DRIs set by the IOM that reflect the most current science regarding nutrient requirements. The RDA for vitamin E was established for mg of α-tocopherol because α-tocopherol is the only form of vitamin E that is maintained in blood and has biological activity (79 FR 11879 at 11933). We acknowledge the studies submitted to support the assertion that other forms of vitamin E, such as gamma-tocopherol, have biological activity that may be pertinent to disease prevention and/or therapy. However, these individual studies measured outcomes other than induced human vitamin E deficiency assessed by the correlation between red blood cell lysis and plasma α-tocopherol on which the RDA was based (Ref. 246). Jiang *et al.* 2003 studied gamma tocopherol and its metabolite on markers of inflammation in rats (Ref. 241). Mahabir *et al.* 2008 studied the associations between 4 tocopherols (α-, β-, c-, and d-tocopherol) in human diets and lung cancer risk (Ref. 243). The review article by Wolf discussed the biochemical mechanism by which α-tocopherol influences gamma-tocopherol (Ref. 245). Christen et al. 1997 studied the effects of gamma-tocopherol on lipid peroxidation in vitro (Ref. 240). Jiang et al. 2008 studied the effect of different forms of vitamin E and their metabolites on enzyme reactions involved in the inflammation pathway (cyclooxygenase-catalyzed reactions) in vitro (Ref. 242). The review article by Sen *et al.* 2007 discussed tocotrienols and their biological functions. While these animal studies and review articles may suggest biological activity of other forms of vitamin E, outcomes in humans are lacking, thus a totality of evidence for a role of other forms of vitamin E in human health is lacking (Ref. 246). We consider the totality of evidence, such as what is presented in consensus reports like those issued by the IOM, rather than individual studies, to establish the RDIs. Therefore, based on the information provided in the comment, we do not have a basis to include other forms of vitamin E in our definition.

We note, however, that other forms of vitamin E can be listed in the ingredient statement for foods.

(Comment 433) The proposed rule, at § 101.9(g)(10), would require manufacturers to verify the declared amount of both *all rac*-α-tocopherol acetate and RRR-α-tocopherol in the finished food product. The preamble to the proposed rule (79 FR 11879 at 11933) explained that the RDA for vitamin E is 15 mg/day of α-tocopherol and that α-tocopherol is the only form of vitamin E that is maintained in blood and has biological activity. The preamble to the proposed rule also explained that there are eight stereoisomers of α-tocopherol (RRR, RSR, RRS, RSS, SRR, SSR, SRS, SSS) and that only RRR α-tocopherol occurs naturally in foods. Commercially available vitamin E that is used to fortify foods and used in dietary supplements contains esters of either the natural RRR- or, more commonly, mixtures of the 8 stereoisomers (*e.g., all rac*-α-tocopherol acetate). Four stereoisomers (SRR, SSR, SRS, and SSS) are not maintained in human plasma or tissues, so we proposed to limit the new RDA for vitamin E to the four 2R stereoisomeric forms (RRR, RSR, RRS and RSS) of α-tocopherol. We stated that these four forms of α-tocopherol are found in nonfortified and fortified

conventional foods and dietary supplements and that the *all rac*-α-tocopherol acetate in fortified foods or dietary supplements has one-half the activity of RRR-α-tocopherol naturally found in foods or the 2R stereoisomeric forms of α-tocopherol (id.). However, because AOAC methods cannot individually measure the naturally occurring and synthetic forms of vitamin E, it is necessary to know the amount of both RRR-α-tocopherol and *all rac*-α-tocopherol in a food product to calculate vitamin E activity for declaration as mg α-tocopherol.

One comment suggested that it is more practical for manufacturers of vitamin E esters to ascertain the RRR, RSR, RRS and RSS content in their ingredients and to disclose this information to finished food manufacturers for use in calculating the declared amount of vitamin E, instead of requiring finished food manufacturer to test the finished product to verify the amounts of various forms of vitamin E, especially since valid methods for many food matrices may not be available. The comment was concerned that, even if they can be identified, analytical methods may not be valid for a wide variety of food matrices and may be prohibitively expensive.

Another comment asked that we affirmatively state that, if appropriate new methods become available to distinguish natural and synthetic vitamin E, manufacturers must declare the amount of vitamin E by appropriate and reliable analytical testing.

Another comment disagreed with narrowing the definition of vitamin E to four stereoisomers and said it is burdensome to confirm which stereoisomer is present in synthetic vitamin E additives compared to simply confirming that the additive is, indeed, vitamin E.

(Response) We decline to revise the rule as suggested by the comments.

However, on our own initiative, we are correcting an inadvertent error that we made in the proposed rule. The proposed rule used the term ''*all rac*-α-tocopherol acetate'' when referring to the synthetic form of vitamin E in fortified foods or dietary supplements because esters of synthetic vitamin E are commonly used in fortified foods and dietary supplements. However, the correct term for synthetic vitamin E is *all rac*-α-tocopherol, just as the term for naturally occurring vitamin is *RRR*-α-tocopherol. Esters of synthetic vitamin E are not limited only to ''*all rac*-α-tocopherol acetate'' and also include ''*all rac*-α-tocopheryl succinate.'' We note that the term '*all rac*-α-tocopherol' is the correct term to refer to the synthetic form of vitamin E.

With respect to analytical testing, we decline to speculate on the methods that manufacturers may deem practical to verify the declared amount of both RRR-α-tocopherol and *all rac*-α-tocopherol in finished food products. We acknowledge that it is a new requirement to verify the amount of both RRR-α-tocopherol in the finished food and *all rac*-α-tocopherol added to the food in finished food products when a mixture of both are present in a food. However, without AOAC methods to individually measure these two forms of vitamin E and the inability to determine the amount of RRR-α-tocopherol in a food by subtracting the amount of *all rac*-α-tocopherol from the total amount declared, we need to rely on recordkeeping to verify the amount of vitamin E in a product.

As for the comment's statement that analytical methods may be prohibitively expensive, the practicality or feasibility of using new analytical methods can depend on a variety of factors. For example, a method that uses equipment or technology that is readily available may be less costly compared to a method that uses proprietary equipment or technology. The number of facilities that can use a new analytical method may influence cost. For example, if a large number of facilities are able to use a new analytical method, then testing costs between facilities may become competitive; in contrast, if there are few facilities that can use the analytical method, then testing costs may be less sensitive to competition. Consequently, because we do not know what new analytical methods may exist in the future or the market for those new methods, we cannot say whether those methods will be prohibitively expensive.

We also decline to revise the rule to affirmatively state that manufacturers declare the amounts of vitamin E by appropriate and reliable analytical testing, if appropriate new methods become available. The comment did not explain how manufacturers would be able to determine whether a new method was ''appropriate'' or ''available'' or how differences in opinion as to whether a particular method is ''appropriate'' or ''available'' might be resolved. Current AOAC methods cannot individually measure naturally occurring vitamin E (RRR-α-tocopherol) and synthetic vitamin E (*all rac*-α-tocopherol and its esters) in food products. Nevertheless, we will continue to monitor developments regarding methods to distinguish natural and synthetic vitamin E.

As for the comment objecting to narrowing the definition of vitamin E to four stereoisomers because it is burdensome to confirm which stereoisomer is present in synthetic vitamin E additives, we point out that providing information that a vitamin E additive is only present in a product (rather than confirming the stereoisomers present in the synthetic vitamin E additive) would provide an inaccurate estimation of the vitamin E activity in the body. We reiterate that the RDI for vitamin E is based on the RDA for vitamin E which is limited to the four 2R stereoisomeric forms (RRR, RSR, RRS, and RSS) of α-tocopherol (79 FR 11879 at 11926). Because synthetic vitamin E, also referred to as *all rac*-α-tocopherol, contains both 2R- and 2S-stereoisomers of α-tocopherol and has one-half the activity of the RRR-α-tocopherol naturally found in foods or the other 2R stereoisomers of α-tocopherol, it is necessary to determine the stereoisomers present in a food to determine vitamin E activity.

(Comment 434) One comment noted that the proposed rule did not mention other esters of both natural (d-α-tocopheryl acetate) and synthetic forms of vitamin E (α-tocopheryl succinate) and said we should revise the rule to include these forms.

(Response) We agree that the ester forms of natural and synthetic vitamin E are considered as α-tocopherol forms of vitamin E. The RDA for α-tocopherol is limited to RRR-α-tocopherol (historically and incorrectly labeled d-α-tocopherol) the only form of α-tocopherol that occurs naturally in foods, and the other 2R-stereoisomeric forms of α-tocopherol (RSR-, RRS-, and RSS-α-tocopherol) that are synthesized chemically and found in fortified foods and supplements. Vitamin E compounds include RRR-α-tocopherol (also referred to as d-α-tocopherol or natural) and its esters (*i.e.* RRR-α -tocopheryl acetate, RRR-α -tocopheryl succinate) and *all rac*-α-tocopherol (also referred to as dl-α-tocopherol) and its esters (*i.e., all rac*-α-tocopheryl acetate, *all rac*-α-tocopheryol succinate) (Ref. 247). We note that all of these vitamin E compounds may be present in fortified foods and multivitamins. We have revised the rule to include the ester forms of natural and synthetic vitamin E.

(Comment 435) Another comment requested we provide a conversion in the final rule stating 1 mg α-tocopherol (label claim) = 1 mg RRR-α-tocopherol; 1 mg α-tocopherol (label claim) = 2 mg *all rac*-α-tocopherol.

(Response) We agree with the comment. The final rule provides this

conversion as a footnote in the table in § 101.9(c)(8)(iv): 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*- α-tocopherol.

(Comment 436) Some comments objected to changing the units of measure for vitamin E. Several comments stated that there are no AOAC international official methods to distinguish between different forms of vitamin E in foods and supplements. One comment objected the change to mg α-tocopherol and said there is a lack of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol acetate and RRR-α-tocopherol.

Another comment said that it is not possible to measure total vitamin E by subtracting *all rac*-α-tocopherol acetate from total vitamin E to determine RRR-α-tocopherol.

(Response) We agree that current AOAC methods cannot individually measure naturally occurring vitamin E (RRR-α-tocopherol) and *all rac*-α-tocopherol in foods. We also agree that it is not possible to measure total vitamin E by subtracting *all rac*-α-tocopherol from total vitamin E to determine RRR-α-tocopherol. For this reason, the final rule, at § 101.9(g)(10)(vi), requires manufacturers to make and keep written records of the amount of *all rac*- α-tocopherol added to the food and RRR-α-tocopherol in the finished food.

We disagree with the comment objecting to changing the unit of measure to mg α-tocopherol because there is a lack of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol and RRR-α-tocopherol. We consider the DRIs that reflect the most current science regarding nutrient requirements as the basis for establishing RDIs and, therefore, the declaration of vitamin E as mg α-tocopherol. The choice of unit of measure for vitamin E is not based on the availability of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol and RRR-α-tocopherol.

5. Niacin

(Comment 437) Our preexisting regulations, at § 101.9(c)(8)(iv), state that the RDI for niacin is 20 mg. The proposed rule would amend § 101.9(c)(8)(iv), in relevant part, by changing the unit of measure from ''mg'' to ''milligrams NE'' where ''NE'' would stand for ''niacin equivalents,'' and a footnote to proposed § 101.9(c)(8)(iv) would explain that 1 milligram NE is equal to 1 milligram niacin or also equal to 60 milligrams of tryptophan. The preamble to the proposed rule discussed updating the RDIs for various nutrients (including niacin) and compared the current RDI of 20 mg against the proposed RDI of 16 mg NE (79 FR 11879 at 11927, 11931).

Several comments supported changing ''mg'' niacin to mg niacin equivalents (NE). The comments said the change would be consistent with the IOM's use of RDAs as the basis for establishing reference values for purposes of food labeling. Another comment referred to the footnote in proposed § 101.9(c)(8)(iv) and noted that ''milligrams NE'' is different from the existing regulation's use of ''milligrams.'' The comment said that it assumed that compliance would be determined by testing the product using AOAC methods for both niacin and tryptophan and that this, if correct, would increase the burden on manufacturers because it will necessitate additional testing.

In contrast, other comments would have us continue to use milligrams as the unit of measure for niacin.

(Response) The RDA for niacin is expressed as niacin equivalents (NE) because the body's niacin requirement is met not only by preformed niacin (nicotinamide, nicotinic acid, and its derivatives) in the diet, but also from conversion from dietary protein containing tryptophan (Ref. 248).

We agree with the comment that compliance with a voluntary declaration of niacin would be determined by analysis, using AOAC methods, for both niacin and tryptophan, or by reference to existing databases for both nutrients. Niacin equivalents would be calculated using the following conversion: NE (niacin equivalents): 1 mg NE = 1 mg preformed niacin = 60 milligrams of tryptophan. While the unit of measurement for the RDI for niacin is listed as mg NE in § 101.9(c)(8)(iv), only the amount ''mg'' will continue to be declared on nutrition and supplement facts labeling.

(Comment 438) One comment asked how compliance will be determined and asked us to clarify whether a declaration of niacin content will be required for products that contain no actual niacin. The comment would revise the rule to include a provision specifying that products containing more than 19 mg of tryptophan (corresponding to 0.32 mg of niacin or 2 percent of the RDI) must declare niacin even if there is no actual niacin present or else the manufacturers of such products might not notice the revised requirements for niacin declaration. Another comment noted that, for many protein-containing products for which there is presently no information on tryptophan required, manufacturers would be required to determine niacin and tryptophan content, either through analytic testing or existing databases.

(Response) The declaration of niacin is voluntary unless it is added as a nutrient supplement to the food or if the label makes a nutrition claim about it. Compliance may be determined by measuring niacin and tryptophan separately. The unit of measure (mg NE) includes both preformed niacin (from nicotinic acid and nicotinamide in the diet or niacin) and niacin resulting from the conversion of tryptophan (Ref. 249), and AOAC methods exist for both niacin and tryptophan. Thus, a declaration of niacin content requires products to include contributions from preformed niacin as well as tryptophan, including those that may not contain preformed niacin.

As for the comment's statement that manufacturers may not notice the revised requirements for niacin declaration, we decline to revise the rule as suggested by the comment. We note that § 101.3(e)(4)(ii) (regarding identity labeling of food in packaged form) states, in relevant part, that a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv) per reference amount customarily consumed. We recognize that manufacturers may be unaware of the requirement for niacin declaration in mg and plan to engage in education and outreach explaining the revised changes to units of measurement for vitamins and minerals.

As for the comment that manufacturers would be required to determine niacin and tryptophan content, either through analytic testing or existing databases, we note we have not stated how a company should determine the nutrient content of their product for labeling purposes (Ref. 122). Regardless of its source, a company is responsible for the accuracy and the compliance of the information presented on the label. Use of a database that we have accepted may give manufacturers some assurance in that we have stated that we will work with industry to resolve any compliance problems that might arise for food labeled on the basis of a database that we have accepted. A manual entitled ''FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases'' is available online.

(Comment 439) One comment pointed out that the use of mg NE may not accurately reflect niacin contribution in

foods because the conversion of tryptophan to niacin is highly variable among individuals and because the body uses tryptophan primarily for its role in protein synthesis instead of niacin production. The comment said that using mg NE as the unit of measure could represent an over-estimate of niacin intake in the diet. Another comment was concerned there could be an extra step in food labeling and another potential source of error.

(Response) We disagree that using mg NE may lead to overestimates of niacin intake from foods. We acknowledge that the conversion of tryptophan to niacin may vary among individuals and that tryptophan has a role in protein synthesis. The conversion factor of 1 mg NE = 60 mg tryptophan is the mean of a wide range of individual values from human studies that measured the conversion of tryptophan to urinary niacin metabolites (Ref. 248).

We acknowledge the concern that using mg NE involves an added step of measuring tryptophan, but note that tryptophan is converted to niacin by the body and using mg NE provides a more accurate estimation of available niacin in the body compared to mg of niacin.

(Comment 440) The proposed rule, at § 101.9(c)(8)(iv), would include a footnote stating that ''NE'' means niacin equivalents and that ''1 milligram niacin = 60 milligrams of tryptophan.'' One comment suggested that, for additional clarity and consistency, we should revise footnote 2 to say ''NE = Niacin equivalents, 1 NE = 1 milligram niacin = 60 milligrams of tryptophan.''

(Response) We agree with the comment and have revised the footnote for NE as follows: NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.''

O. Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

In the preamble to the proposed rule (79 FR 11879 at 11933), we explained that our general labeling requirements for foods in § 101.9(c) apply to foods for infants, young children, and pregnant and lactating women, with certain exceptions. For example, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years of age are not permitted to include declarations of percent DV for the following nutrients: Total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate and dietary fiber (§ 101.9(j)(5)(ii)(A)). As another example, foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat and cholesterol on the Nutrition Facts label (§ 101.9(j)(5)(i)).

The preamble to the proposed rule (79 FR 11879 at 11933) also mentioned that our regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant and lactating women, but there are requirements for a DRV for protein for children 4 or more years of age and RDIs for protein for each of the following subpopulations: (1) Children less than 4 years of age; (2) infants; (3) pregnant women; and (4) lactating women (§ 101.9(c)(7)(iii)).

1. Age Range for Infants and Young Children

Our preexisting regulations, at § 101.9(j)(5), use the age ranges ''less than 2 years of age'' and ''less than 4 years of age'' to establish labeling requirements for foods represented or purported to be specifically for infants and young children. The preamble to the proposed rule (79 FR 11879 at 11933 through 11934) stated that comments to our 2007 ANPRM recommended changing the age categories to infants 7 to 12 months and young children 1 through 3 years (13 through 48 months), consistent with the age ranges used in the IOM's age-specific DRI recommendations. In the preamble to the proposed rule (79 FR 11879 at 11933 through 11934), we discussed why we considered it appropriate to adopt the same age categories as those used in the IOM DRIs for infants and children. In brief, we said:

- Our proposed DVs are based on these age-specific DRIs;
- Infants are transitioning to eating solid foods by 7 through 12 months, and there are a number of foods in the marketplace identified for this age group;
- With respect to children 1 through 3 years of age, using the DRI age range would result in infants no longer being the lower end of the age range in the category of infants and children less than 2 years and less than 4 years of age as specified in § 101.9(j)(5);
- Assigning DVs for children 1 through 3 years of age would ensure consistency with the 1 through 3 year toddler age category established for RACCs specified in § 101.12(a)(2); and
- Because the growth velocity in height is most similar for children 1 through 3 years of age, we consider it appropriate to revise the age range to include children of these ages into a single category for food labeling purposes.

Therefore, we proposed to revise the exceptions for requirements for nutrition labeling provided in § 101.9(j)(5)(i) and the exception to the requirement for the format used for nutrient information on food labeling in § 101.9(d)(1) for foods represented or purported to be specifically for infants and children less than 4 years of age. Specifically, we proposed to replace the current category of infants and children less than 4 years with infants 7 through 12 months and children 1 through 3 years of age.

(Comment 441) Several comments supported providing nutrition information for children less than 4 years because, according to the comments, these subgroups have different nutritional needs. Another comment recommended mandatory nutrition labeling for children less than 12 months and children 1 through 3 years. One comment said that we should continue to allow labeling information on foods for infants less than 7 months, such as infant cereals, or, at a minimum, allow such labeling to remain voluntary.

(Response) We agree, in part, with the comments that recommended mandatory nutrition labeling for infants less than 12 months. We decline to revise the age range for infants to infants less than 12 months because using that age range would leave a 1 month gap as the age for children 1 through 3 years represents 13 through 48 months. We also agree that nutrition labeling on foods represented or purported to be for infants less than 7 months old such as infant cereals should continue to be mandatory. We proposed the age category for labeling of infants 7 through 12 months to be consistent with the age ranges used in the IOM's age-specific DRI recommendations as well as current breastfeeding recommendations for the first 6 months of life (79 FR 11933). Optimally, infants should begin eating complementary foods at around 6 months of age (AAP Section on Breastfeeding 2012, WHO Complementary feeding 2010); however, some infants are being introduced to foods and beverages before then (siega-Riz JADA 2010). To ensure that nutrition labeling includes products for infants and allow for flexibility in timing of complementary food, we have amended § 101.9(j)(5)(i) and (ii) to refer only to ''infants'' as infants through 12 months of age rather than infants less than 12 months (as suggested by the comment) or ''infants 7 through 12 months'' of age as we had proposed. (We have made similar edits in § 101.9(c), (c)(7), (c)(8), (d)(1), (e), and (f) to refer to ''infants through 12 months of age.'')

We note that, while nutrition labeling is mandatory for food for children less than 4 years, we are not establishing DVs for infants less than 7 months of age. Therefore, nutrition information on foods purported for infants less than 7 months would not reflect DVs for that age group.

(Comment 442) One comment said that labeling of foods for infants 7 through 12 months and children 1 through 3 years is overdue and important. The comment said, however, that separate labeling for these two ages is not necessary and could be confusing, so the comment recommended that we use a population approach to set single values for 7 months through 3 years.

Another comment noted that the proposed new age range to set labeling requirements for these foods (infants 7 through 12 months and children 1 through 3 years of age) did not take into account the definition of ''young children'' given in different Codex standards (*e.g.,* 074–1981 Rev. 1–2006) whereby ''young children'' are ''persons from the age of more than 12 months up to the age of 3 years (36 months).''

(Response) We disagree with the comment suggesting an age range of 7 months through 3 years of age. Providing one label for infants and children 7 months through 3 years of age is inappropriate because growth and nutrient needs differ for infants through 12 months of age and children 1 through 3 years of age (beginning at the start of the 13th month through the end of 48th month of age). These differences in growth and development between infants and young children are reflected in the age categories established by the IOM (79 FR 11879 at 11933).

As for the comment noting that we did not take into account the definition of ''young children'' used in certain Codex texts, we note that our age range of children 1 through 3 years of age includes ''persons from the age of more than 12 months up to the age of 36 months.'' We also note that our age range aligns with the age specific category used in the IOM's DRI recommendations for the purposes of establishing DRVs and RDIs for this subpopulation. Our purpose of establishing a DRV or RDI for use in nutrition labeling is distinct from a purpose related to defining the age range when infants and young children are fed processed cereal-based complementary foods (CODEX STAN 074–1981, REV.1–2006). Furthermore, while certain Codex standards such as the Standard for Processed Cereal-based Foods for infants and young children (CODEX STAN 074–1981, REV.1–2006) provide minimum and maximum levels for the composition of processed cereal-based complementary foods, we note that the Codex Guidelines on Nutrition Labelling (CAC/GL 2–1985) (Ref. 121) do not provide Nutrient Reference Value—Requirements that are comparable to our proposed DRVs and RDIs for children 1 through 3 years.

(Comment 443) Some comments asked that we require the declaration of cannabinoid content, nutritional values, and/or health risks pertaining to the consumption of tetrahydrocannabinol (THC) and/or marijuana edibles for all consumers, in particular, children under the age of 4 years as well as pregnant and lactating women.

(Response) We decline to revise the rule as suggested by the comment. We note that section 403(q)(2)(A) of the FD&C Act authorizes the inclusion of nutrients on the label or labeling of food for purposes of providing ''information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.'' General labeling requirements of products containing THC and/or marijuana edibles is outside the scope of this rule. Therefore, we are making no changes in response to this comment.

2. Mandatory Declaration of Calories and Statutorily Required Nutrients

Currently, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. For foods, other than infant formula, represented or purported to be for infants and children less than 2 years, the declaration of certain statutorily required nutrients, which include calories from fat, saturated fat, and cholesterol, is not required or permitted (§ 101.9(j)(5)(i)).

a. Declaration of saturated fat and cholesterol. In the preamble to the proposed rule (79 FR 11879 at 11934), we tentatively concluded that, except for the declaration of calories from fat, the declaration of statutorily required nutrients that include saturated fat and cholesterol on the label of foods represented or purported to be specifically for infants 7 through 12 months and children 1 through 3 years of age should be mandatory because: (1) The declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act, and we have no basis on which to not require or permit their declaration as discussed previously; and (2) these nutrients are essential in fostering growth and maintaining good health during a critical stage of human development and physiology and, therefore, their mandatory declaration can assist in maintaining healthy dietary practices. We proposed to remove § 101.9(j)(5)(i) and revise and redesignate current § 101.9(j)(5)(ii) as § 101.9(j)(5)(i).

Similarly, foods consumed by pregnant and lactating women must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. Women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy and lactation. In the preamble to the proposed rule (79 FR 11879 at 11934), we tentatively concluded that, except for the declaration of calories from fat, the declaration of statutorily required nutrients should be mandatory because the declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act and we have no basis on which to not require or permit their declaration as discussed previously. Thus, we proposed to require the mandatory declaration of calories, and the amount of total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein for foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, and permit the declaration of calories from saturated fat such that the declaration of these nutrients on foods for these populations would be subject to the same requirements applicable to foods for the general population.

(Comment 444) Several comments supported the declaration of saturated fat and cholesterol on labeling for infants and children 1 through 3 years old and agreed such labeling will help maintain healthful dietary practices. In response to our request for information on whether consumers may be confused by these changes, one comment said that its products have been labeled for children under 2 years as well as for children less than 4 years of age on the market for many years. The comment noted that these dual label formats include the declaration of both saturated fat and cholesterol and the company has received no comments or concerns about the inclusion of this information on its labels from either consumers or health care professionals. The comment said that declaring saturated fat and cholesterol in addition to *trans* fat on infant foods will be more helpful in

food selection than having *trans* fat alone. The comment said declaring saturated fat, cholesterol, and *trans* fat will provide more information on the fat composition of foods and their relationship to chronic disease risk. The comment also noted that some children as young as 12 months, with a family history of obesity, dyslipidemia, or CVD, may benefit from a diet lower in saturated fat and that having saturated fat on food labels can assist families in choosing foods that are lower in saturated fat while maintaining total fat intakes.

Another comment said we should not finalize the rule until we had conducted appropriate research, including consumer testing, to better understand the impacts of declaring saturated fat and cholesterol on the labels of products represented or purported to be specifically for infants and children 1 through 3 years of age and to determine if an explanatory footnote would assist in improving consumer understanding when accompanying any relative declaration. The comment also noted that relevant empirical research is not available to determine whether the declaration of saturated fat and cholesterol will result in restricted intakes for infants and children ages 1 through 3 years old. One comment would revise the rule to include a voluntary footnote stating that ''total fat should not be limited in the diets of children less than 2 years unless directed by a physician'' or similar wording to provide dietary guidance to parents and other caregivers to help assure total fat is not restricted in the diet of young children.

(Response) We acknowledge that products dual labeled for children under 2 and children less than 4 years of age include the declaration of both saturated fat and cholesterol. We agree that declaration of saturated fat and cholesterol provides more nutrition information and can help consumers make informed choices and maintain a healthy diet, and the final rule requires the declaration of saturated fat and cholesterol on Nutrition Facts labeling for infants and children 1 through 3 years of age.

As for the comment regarding consumer testing, we disagree that consumer testing is necessary before we can require the declaration of saturated fat and cholesterol on Nutrition Facts labels for infants and children 1 through 3 years of age. Section 403(q) of the FD&C Act lists total fat, saturated fat, and cholesterol as nutrients required on nutrition labeling. These nutrients are essential for growth and development, thus their mandatory declaration can assist consumers in maintaining healthy dietary practices (79 FR 11879 at 11934). We considered the Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents which suggest a diet with saturated fat less than 10 percent of calories and cholesterol intake less than 300 mg/day can safely and effectively reduce the levels of total and LDL cholesterol in healthy children (Ref. 250). This type of diet may have similar effects when started in infancy and sustained throughout childhood into adolescence (Ref. 250).

We acknowledge, in general, that total fat should not be limited in the diets of young children less than 2 years of age unless directed by a health professional. In response to the comment noting that research is unavailable on whether declaration of saturated fat and cholesterol will result in restricted intakes for infants and children, we intend to monitor fat and cholesterol intakes in these age groups and will consider whether to revisit our requirements for this labeling, as appropriate.

We also decline to include a voluntary footnote. We intend to monitor fat intakes and educate consumers on changes to the labeling of foods for infants through 12 months of age and children 1 through 3 years of age.

b. Percent DV declaration. In the preamble to the proposed rule (79 FR 11879 at 11935), we explained that, under our preexisting regulations, the percent DV declaration is not permitted on the food label for foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years (which includes infants and children less than 2 years) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (§ 101.9(j)(5)(ii)). Percent DV is required for protein and vitamin A, vitamin C, iron, and calcium. We tentatively concluded that it is appropriate to require declarations of percent DV for those nutrients for which we are establishing a DRV or RDI for infants 7 through 12 months, for children 1 through 3 years of age, and for pregnant and lactating women (except for a % DV for protein for pregnant and lactating women), and this change would be reflected in redesignated § 101.9(j)(5)(i).

(Comment 445) One comment would retain a requirement for the mandatory declaration of percent DV for protein on infant foods.

In contrast, another comment would not require the mandatory declaration of the percent DV for protein on labels of foods for children aged 1 through 3 years. The comment cited dietary intake data suggesting that protein intakes are above 40 grams per day and from high quality sources. Another comment recommended allowing for the use of the PDCAAS for determining the percent DV for protein for all population groups, including infants. The comment asked us to clarify the acceptability of PDCAAS for determining protein quality for foods for infants and specify the specific amino acid pattern that should be used (*i.e.,* IOM pattern) and to reference the pattern by Table number.

(Response) The final rule requires the mandatory declaration of percent DV for protein on foods for infants though 12 months of age and children 1 through 3 years of age. While the evidence suggests that protein intake is adequate and of high quality, the level and quality of protein present in a food remain an important consideration in food selection for infants because infant diets are derived from a limited number of foods. Calculating the percent DV for protein incorporates a measure of protein quality. Thus, the percent DV declaration is a useful tool to indicate protein quality to the consumer. Because of the importance of adequate high quality protein in the diets of infants and young children, we conclude that the percent DV declaration for protein for infants though 12 months of age and children 1 through 3 years of age should remain mandatory.

We disagree with the comment asking that we allow for the use of the PDCAAS to determine protein quality for infants. The PDCAAS allows evaluation of food protein quality based on the needs of humans as it measures the quality of a protein based on the amino acid requirements (adjusted for digestibility) of a 2- to 5-year-old child (considered the most nutritionally demanding age group), not infants (Ref. 251). Protein quality is important during infancy for growth and development. We established the protein efficiency ratio (PER) as the method of determining protein quality (see 79 FR 7934 at 8022) for infants based on recommendations from the 1991 WHO Protein Quality report. A protein source may contain the necessary amino acids, but they may be in a form that an infant cannot digest and absorb. The PER method, unlike chemical measures of protein composition, provides an estimate of the bioavailability or amount absorbed, of the protein.

(Comment 446) One comment said that, if the percent DV for protein remains mandatory, we should provide

an exemption from the mandatory declaration of percent DV for protein for foods intended for infants and children aged 1 through 3 years that declare less than 1 gram of protein per serving, such as fruits, because these foods contain an insignificant amount of protein and are not expected to contribute meaningfully to protein intake. The comment also would revise the rule to allow the optional declaration of ''0% DV'' instead of the phrase ''not a significant source of protein'' on infant foods with a protein quality of less than 40 percent of casein as measured by PER or less than 40 percent by PDCAAS or other comparable method. The comment explained that these options will help save label space, especially on small packages, while still providing meaningful information on protein quantity relative to the DV.

(Response) We decline to revise the rule as suggested by the comment. While we recognize that the protein quantity of some foods, such as fruits, may be small, we consider the mandatory declaration of percent DV to provide important information on protein quality to the consumer. In establishing mandatory declaration of percent DV for protein on foods intended for infants through 12 months of age and children aged 1 through 3 years and associated statements of ''less than 1 g of protein per serving'' or ''not a significant source of protein,'' we considered that: (1) Protein is of critical importance in maintaining good health because it supplies essential amino acids and is a principal source of calories along with fat and carbohydrate; and (2) calculating the percent DV for protein incorporates a measure of protein quality. Thus, the percent DV declaration is a useful tool to indicate protein quality to the consumer.

While label space on small packages may be a concern, we decline to make the change requested by the comment that would allow the optional declaration of ''0% DV'' instead of the phrase ''not a significant source of protein'' on infant foods with a protein quality of less than 40 percent of casein as measured by PER or less than 40 percent by PDCAAS or other comparable method. As explained in part II.I and in our response to comment 445, we concluded that the PDCAAS was the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants through 12 months of age. We established the PER as the method of determining protein quality for infants because infants cannot digest and absorb all forms of protein; thus, PDCAAS or another comparable method that scores the amino acid profile of the specific food protein after it has been digested is not appropriate.

3. Declaration of Non-Statutory Nutrients Other Than Essential Vitamins and Minerals

In the preamble to the proposed rule (79 FR 11879 at 11935), we stated that foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from saturated fat and the amount of polyunsaturated fat and monounsaturated fat (§ 101.9(j)(5)(i)), whereas soluble fiber, insoluble fiber, and sugar alcohols can be declared voluntarily. Polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols can be declared voluntarily on the label of foods represented or purported to be specifically for children 2 through 4 years of age, and pregnant and lactating women.

For foods represented or purported to be specifically for children 1 through 3 years of age and pregnant and lactating women, we considered whether to propose the mandatory or voluntary declaration of non-statutory nutrients. In the preamble to the proposed rule (79 FR 11879 at 11935), we said that most advisory consensus and policy reports on which we rely for the general population apply to children 2 years of age and older and pregnant and lactating women, unless noted otherwise (*e.g.,* 2010 DGAC and health claims (§ 101.14(e)(5)).

a. Voluntary declaration of calories from saturated fat, and the amount of polyunsaturated and monounsaturated fat. Our preexisting regulations, at § 101.9(j)(5)(i), state that foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age must bear nutrition labeling with certain, specific exceptions. Among the exceptions, the label is not to include polyunsaturated fat or monounsaturated fat.

The proposed rule would remove the restriction regarding the declaration of polyunsaturated fat and monounsaturated fat on foods represented or purposed to be specifically for children less than 2 years of age. In the preamble to the proposed rule (79 FR 11879 at 11935 through 11936), we explained that, for infants 7 to 12 months, there are no specific recommendations provided about calories from saturated or polyunsaturated or monounsaturated fat. We also stated there is some evidence to suggest that reduction of total and LDL cholesterol levels can occur with reducing saturated fat intake to less than 10 percent of calories, beginning in infancy and sustained throughout childhood into adolescence, that there is no evidence to suggest that infants 7 through 12 months of age would be different than children 1 through 3 years of age, and that there is no basis to continue to provide an exception that does not permit the declaration of calories from saturated fat, or polyunsaturated and monounsaturated fats on foods represented or purported to be specifically for infants and children less than 2 years of age.

(Comment 447) One comment argued the declaration of alpha linoleic acid (ALA) on foods for infants and children 7 months to 3 years of age should be considered for voluntary labeling using the AI as the basis for a DRV. The comment noted that much of the evidence for a health benefit of n-3 fatty acids derives from studies on infants, and labeling of ALA is consistent with FDA's criteria of encouraging health dietary practices. Another comment recommended that we examine NHANES data for ALA consumption to determine whether there is a public health risk from inadequate dietary intake.

(Response) We decline to amend the rule to permit the voluntary labeling of ALA on labels or labeling for foods intended for infants though 12 months of age and children 1 through 3 years of age and to use the AI for ALA to establish a DRV.

We agree with promoting healthy dietary practices in this subpopulation; however, well-established evidence for ALA and disease risk reduction in adulthood and infancy is lacking (Ref. 29). As discussed in part II.F.4, we decided that, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of α-linolenic acid as well as other n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Because the declaration of ALA is not permitted on labeling, a DRV for this nutrient is unnecessary.

We disagree with the analysis of NHANES data for ALA intake to determine public health risk from inadequate dietary intake. An analysis of dietary intake data alone does not meet our criteria of public health significance. Moreover, an analysis of ALA intakes from NHANES data cannot determine inadequacy of dietary intake

because an EAR has not been established for ALA. EARs, not AIs, are used for assessing the statistical probability of adequacy or nutrient intakes of groups of people (79 FR 11879 at 11885).

(Comment 448) One comment noted that we proposed mandatory labeling of the quantitative amount of some nutrients (*trans* fatty acids for which there is no DRI) on foods for infants aged 7 through 12 months and children aged 1 through 3 years. The comment said we should provide for the voluntary declaration of docosahexaenoic acid (DHA) on these foods to encourage healthy dietary practices.

(Response) We decline to revise the rule as suggested by the comment. Our regulations, at § 101.9(c)(2)(ii), require the declaration of *trans* fat on nutrition labeling for people of all ages because the consumption of *trans* fats may affect their risk of CHD; therefore, the presence or absence of *trans* fat in a food product is a material fact that consumers need to know to make healthy choices and allow them to reduce risk of CHD. *Trans* fat continues to be a nutrient with public health significance because of its well-established role in chronic disease through its effect on blood cholesterol levels (79 FR 11879 at 11896). However, DHA lacks well-established evidence for its role in chronic disease as well as growth or neural development (IOM Macro report). As discussed in part II.F, voluntary labeling of DHA is not permitted because of the lack of well-established evidence for DHA's role in chronic disease risk and lack of a quantitative intake recommendation (79 FR 11879 at 11898).

(Comment 449) One comment cited a 2011 IFIC survey suggesting that 45 percent of consumers were already eating foods containing n-3 fatty acids to benefit cognitive development, especially in children and 39 percent were somewhat likely to begin eating n-3 fatty acids for this health benefit in the next 12 months. The comment said that continued allowance of ALA nutrient content claims, absent a voluntary declaration of DHA, increases the likelihood that consumers may purchase foods for a benefit that the food will not supply. The comment also said that allowing polyunsaturated fat labeling of foods for children younger than 2 years without allowance for labeling of individual polyunsaturated fatty acids creates a scenario where polyunsaturated fat values, inflated by ALA, may mislead consumers actually seeking DHA.

(Response) The comments did not provide, and we are not aware of, data or information to support the claim that consumers seeking to consume DHA would be misled by the voluntary declaration of polyunsaturated fats or an ALA nutrient content claim on labeling for children less than 2 years of age. Therefore, we are not making changes in response to this comment.

We acknowledge the 2011 IFIC survey conclusions suggesting that consumers eating foods containing n-3 fatty acids are somewhat likely to begin eating these foods to benefit cognitive development. We also recognize that total polyunsaturated fats in foods include both n-6 and n-3 polyunsaturated fatty acids and the n-3 polyunsaturated fatty acids content may include ALA and DHA.

However, we are unable to determine, based on the information provided in the comment, if some consumers seeking to consume DHA may be confused or misled by the declaration of total polyunsaturated fats or the ALA nutrient content claim. Furthermore, we are unable to determine if consumers understand that ALA may be converted to DHA. Without knowledge of the conversion from ALA to DHA, consumers would not be able to distinguish between the level and type of n-3 fatty acids in the food.

Thus, the final rule removes the restriction regarding the declaration of calories from saturated fat, polyunsaturated fat, and monounsaturated fat on foods represented or purposed to be specifically for infants through 12 months of age and children 1 through 3 years of age.

b. Voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols. In the preamble to the proposed rule (79 FR 11879 at 11936), we stated that, while quantitative intake recommendations are lacking for soluble fiber, insoluble fiber, and sugar alcohols, there is well-established evidence for the role of these nutrients in chronic disease risk, risk of a health-related or a beneficial physiological endpoint (*i.e.,* CHD, improved laxation, or dental caries). We also said that there is no evidence to suggest that the role of these nutrients would be different among infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women compared to the general population. As a result, we did not propose any changes to the provisions for the voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols on the label of foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women.

We did not receive comments on this topic, so no changes to the rule are necessary.

c. Mandatory declaration of trans fat. In the preamble to the proposed rule (79 FR 11879 at 11936), we stated that *trans* fat must be declared on the Nutrition Facts label and that our regulations do not provide exceptions for foods represented or purported to be specifically for infants, young children, or pregnant and lactating women. We noted that cardiovascular disease is known to begin in childhood (id.). Thus, we tentatively concluded that declaration of *trans* fat continues to be necessary to assist consumers in maintaining health dietary practices, including among infants, young children, and pregnant and lactating women, and we did not propose any changes to the mandatory declaration of *trans* fat on the label of foods represented or purported to be specifically for infants, children 1 through 3 years of age, or pregnant and lactating women.

Trans fat declaration is voluntary when the total fat content of a food is less than 0.5 grams (§ 101.9(c)(2)(ii)). In addition, if a manufacturer does not declare the *trans* fat content because total fat amount is less than 0.5 grams, then the statement ''Not a significant source of *trans* fat'' must be placed at the bottom of the table of nutrient values.

We did not receive comments on this topic and have finalized this provision without change.

d. Mandatory declaration of added sugars. Our preexisting regulations do not provide for the declaration of added sugars on the Nutrition Facts label, but the proposed rule would require the mandatory declaration of added sugars on the Nutrition Facts label. Additionally, in the **Federal Register** of July 27, 2015 (80 FR 44303), we published a supplemental proposed rule that would, among other things, establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars and require the declaration of the percent DV for added sugars on the label.

(Comment 450) Several comments supported mandatory declaration of added sugars. One comment stated that sugar is used as a means to attract children, and this practice should be discouraged.

Another comment opposed the mandatory labeling of added sugars for infants and children aged 1 through 3 years and pregnant and lactating

women. The comment argued that scientific consensus is lacking for the health effects of added sugars alone versus sugars as a whole and recommended careful consideration of the totality of the scientific evidence, as well as consideration of compliance and other technical issues. The comment also noted that consumer testing is also highly important prior to any determination relative to added sugars being made.

(Response) We disagree that added sugars should not be required on the label for infants and children aged 1 through 3 years and pregnant and lactating women. We discuss in part II.H.3 our rationale for requiring the declaration of added sugars on the label for the general population. We are also basing an added sugars declaration on labeling for infants, children 1 through 3 years of age, pregnant women, and lactating women on the need to provide consumers with information to construct a healthy dietary pattern that meets the dietary recommendations for added sugars.

In response to the comment about the totality of evidence for the health effects of added sugars, we discuss in part II.H.3 that rather than basing a declaration of added sugars on an association with risk of chronic disease, a health-related condition, or a physiological endpoint, we are considering a declaration of added sugars in the context of how it can assist consumers in maintaining healthy dietary practices by providing information to help them limit consumption of added sugars, and to consume a healthy dietary pattern. We have established that there is public health significance of added sugars through other evidence related to a healthy dietary pattern low in sugar-sweetened foods and beverages that is associated with reduced risk of CVD, through consumption data showing that Americans are consuming too many calories from added sugars, through evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and through evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children.

The comment did not explain what compliance and other technical issues merit further consideration. In response to the comment noting the importance for consumer testing of a declaration of added sugars, we have received several comments on this topic and discuss responses in part II.H.3.g.

While the declaration of added sugars is mandatory, we are not establishing a DRV for added sugars for infants through 12 months. Dietary recommendations for infants through 12 months suggest introducing complementary foods such as infant cereal, vegetables, fruits, meat, and other protein-rich foods modified to a texture appropriate (*e.g.,* strained, pureed, chopped, etc.) for the infant's developmental readiness one at a time. A DRV for added sugars for infants through 12 months is not necessary as the infant diet is comprised primarily of breast milk and/or infant formula as well as complementary foods. As the food introduced does not comprise the majority of the infant diet, a DRV is not necessary to compare added sugars in the context of a daily diet. Mandatory declaration of added sugars for infants through 12 months of age can help consumers limit the added sugars in the limited complementary foods that are being introduced individually.

(Comment 451) One comment would modify the definition of added sugars to exclude ingredients that are inherent in the food or are present for purposes other than sweetening the food and that this modified definition should apply for adults and children between 7 months to 3 years of age, and pregnant and lactating women.

(Response) We received many comments on the definition of added sugars and, in part II.H.3.n, discuss ingredients that are inherent in the food, such as naturally occurring sugars, and the intended purpose of sweetening. The comment did not explain why a regulatory definition for added sugars should be different for infants, children 1 through 3 years of age, and pregnant women, and lactating women, so we decline to revise the rule as suggested by the comment.

e. Voluntary declaration of fluoride. Our preexisting regulations do not provide for the declaration of fluoride on the Nutrition Facts label of any foods. The proposed rule would allow voluntary declaration of fluoride on the labeling of foods for the general population, and we also tentatively concluded that the declaration of fluoride on foods represented or purported to be specifically for children 1 through 3 years of age and pregnant and lactating women can assist in maintaining healthy dietary practices. We stated, in the preamble to the proposed rule (79 FR 11879 at 11937 through 11938), that evidence on dental caries is lacking for infants 7 through 12 months of age, but we did not expect the role of fluoride in the protection against dental caries to be different from other age groups. Therefore, proposed § 101.9(c)(5) would permit the voluntary declaration of fluoride on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women.

We did not receive comments on this topic and have finalized the provision to permit the voluntary declaration of fluoride on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, pregnant women, and lactating women.

4. Declaration of Essential Vitamins and Minerals

Our preexisting regulations require the declaration of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label, and there are no specific exceptions to this requirement for foods represented or purported to be specifically for infants and children less than 2 years and children less than 4 years of age, and pregnant and lactating women. In the preamble to the proposed rule (79 FR 11879 at 11937), we explained that the AIs for essential vitamins and minerals (and RDAs for iron and zinc) for infants 7 through 12 months of age are based on the average intake of nutrients that infants consumed from breast milk, complementary foods, and/or supplements with the understanding that these sources provided sufficient amounts of the nutrients to meet the infant's daily needs. The AIs (as well as the RDAs for iron and zinc) for infants were not based on endpoints related to chronic disease risk, or a health-related conditions or health-related physiology. Furthermore, because the AI represents intakes that are considered adequate and are based on average nutrient intakes from breast milk, foods, and/or supplements, the presence of an AI indicates that there is not a public health concern about adequate intake of that nutrient. So, rather than determine public health significance for a nutrient during infancy based on an AI for infants, we considered the importance of the nutrient in establishing healthy dietary practices during infancy for later in life, as well as the relevant available information for children 1 through 3 months of age that may also be applicable to infants. For nutrients with an RDA for infants 7 through 12 months of age (*i.e.,* iron and zinc), we considered the factors for mandatory and voluntary labeling described in section I.C to determine whether to propose mandatory or voluntary labeling for the nutrient.

For the declaration of essential vitamins and minerals for children 1

through 3 years of age and pregnant and lactating women, we said, in the preamble to the proposed rule (79 FR 11879 at 11937) that we would use the same considerations, based on the same rationale as we set forth and proposed for the general population, because scientific and policy considerations are generally the same and the DGA recommendations apply to Americans 2 years of age and older. We also explained that, while NHANES data were collected in lactating women, we did not include these data in our analysis because the sample size of lactating women was small, and we could not reliably estimate mean intake and status of this population (id.). However, we stated that the conclusions made about nutrient inadequacy during pregnancy are applied to lactating women since the needs of essential vitamin and minerals are increased for both pregnant and lactating women, and we proposed to remove the provision in § 101.9(c)(8)(i) that requires separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant and lactating women.

We did not receive comment on this topic and are removing the provision in § 101.9(c)(8)(i) regarding separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant and lactating women.

a. Mandatory declaration of calcium and iron. We did not propose any changes to the mandatory declaration of calcium on foods for the general population. In the preamble to the proposed rule (79 FR 11879 at 11937), we stated that the AI for calcium for infants 7 through 12 months of age is based on average calcium consumption of these nutrients, rather than chronic disease risk, health related-condition, or physiological endpoints and that, for children 1 through 3 years of age and pregnant and lactating women, the RDAs for calcium are based, in part, on bone health.

Our analysis of NHANES 2003–2006 data estimated that infants ages 7 to 12 months have usual calcium intakes above the AI and that about 12 percent of children 1 through 3 years of age had usual intakes of calcium below the EAR, based on intakes from conventional foods only (see 79 FR 11879 at 11937). We said, in the preamble to the proposed rule (id.), that promoting the development of eating patterns that are associated with adequate calcium intake later in life is important given that calcium intakes are inadequate for the majority of the population. Intakes of calcium, which is necessary for growth and bone development, are inadequate among children. Similar to the general population, approximately 20 percent of pregnant women consumed less than the EAR for calcium from conventional foods as well as from conventional foods and supplements. Consequently, we tentatively concluded that calcium is a nutrient of public health significance for children 1 through 3 years of age and for pregnant and lactating women and that, because calcium is important for growth and development, calcium is of public health significance for infants 7 through 12 months of age.

With respect to iron, we stated, in the preamble to the proposed rule (id.) that, while the EAR and RDA are based on daily iron requirements and not directly on chronic disease risk, iron deficiency is associated with delayed normal infant motor function (*i.e.,* normal activity and movement) and mental function (*i.e.,* normal thinking and processing skills) and that our analysis of NHANES 2003–2006 data estimated that about 18 percent of infants ages 7 through 12 months have usual iron intakes below the EAR, based on intakes from conventional foods only and 4 percent of infants ages 7 through 12 months have usual iron intakes below the EAR based on intakes from conventional foods and supplements. For children 1 through 3 years of age, about 1 percent of children have usual iron intakes below the EAR, based on intakes from conventional foods only and 0.4 percent of children have usual iron intakes below the EAR based on intakes from conventional foods and supplements. While total iron intakes appear adequate, the prevalence of iron deficiency in children ages 1 to 2 years has been reported to be 14.4 percent and the prevalence of iron deficiency anemia in children younger than 5 years has been reported to be 14.9 percent (see 79 FR 11879 at 11937). We also stated that inadequate iron intakes during pregnancy are of public health significance because of the adverse effects for both the mother and the fetus (such as maternal anemia, premature delivery, low birth weight, and increased perinatal infant mortality) and that our analysis of data collected by NHANES 2003–2006 estimated that 5 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and 4 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and supplements (see 79 FR 11879 at 11937). Among pregnant women aged 12 to 49 years, 25 percent were iron deficient and 13 percent had iron deficiency anemia. While intakes appear adequate for most individuals, the prevalence of iron deficiency and iron deficiency anemia indicates that iron deficiency is of public health significance for pregnant women. Therefore, we tentatively concluded that iron is a nutrient of public health significance for lactating women as well.

Thus, we proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of calcium and iron on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women.

We did not receive any comments with respect to mandatory declaration of calcium and iron for these populations, and so, other than replacing ''infants 7 to 12 months'' with ''infants through 12 months,'' we have finalized the provisions without change.

b. Mandatory declaration of vitamin D and potassium. We proposed to require the declaration of vitamin D on foods for the general population. With respect to infants, we stated, in the preamble to the proposed rule (79 FR 11879 at 11938), that the AI for vitamin D for infants was based on maintenance of serum 25(OH)D concentrations at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (30 to 50 nmol/L) in order to meet the needs of the majority of the infants and support bone accretion and that DRIs (EAR and RDA) for vitamin D were established at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (40 to 50 nmol/L) to maintain bone health for children 1 through 3 years of age and pregnant women. Although serum 25(OH)D data were not available in NHANES 2003–2006 for infants ages 7 to 12 months, we noted that our analysis of NHANES 2003–2006 dietary data showed that 28.7 and 33.6 percent of infants ages 7 to 12 months have usual vitamin D intakes above the AI from conventional foods and conventional foods plus supplements, respectively (see 79 FR 11879 at 11938).

Our analysis of NHANES 2003–2006 data showed that about 3 percent of children 1 through 3 years of age had serum 25(OH)D levels below 40 nmol/L, while an analysis of NHANES 2005–2008 dietary data showed that, assuming minimal sun exposure, about 82 percent of these children had usual vitamin D intakes below the EAR from

conventional foods only and 66 percent had usual intakes below the EAR from conventional foods and supplements (see 79 FR 11879 at 11938). For pregnant women, 15 percent had serum 25(OH)D levels below 40 nmol/L, while about 88 percent of pregnant women had usual vitamin D intakes below the EAR from conventional foods only and 48 percent had usual intakes below the EAR from conventional foods and supplements (id.). We tentatively concluded that vitamin D has public health significance in children 1 through 3 years of age and pregnant women based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health and that vitamin D is of public health significance for infants 7 through 12 months of age based on its importance for growth and development during infancy.

We also proposed, at proposed § 101.9(c)(8)(ii), to require the declaration of potassium on foods for the general population. The AI for the general population is set at a level to maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones, but for infants, the AI is based on average potassium intake from breast milk and/or complementary foods (id.). Our analysis of NHANES 2003–2006 showed that 99 percent of infants ages 7 to 12 months have usual potassium intakes above the AI and that only 7 percent of children 1 through 3 years of age and 4 percent of pregnant women had usual potassium intakes above the AI from conventional foods or conventional foods plus dietary supplements, indicating that the adequacy of intakes is very low. We acknowledged, in the preamble to the proposed rule (79 FR 11879 at 11938) that, as a result of a FDAMA notification for a health claim about potassium, blood pressure, and stroke, foods may bear the following claim ''Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke,'' on the label or labeling of any food product that meets the eligibility criteria described in the notification and meets the general requirements for a health claim (§ 101.14(e)(6)). This health claim pertains to the general population 2 years of age and older. Thus, because potassium is important in the risk reduction of these chronic diseases for children 2 years of age and older, we tentatively concluded that potassium is of public health significance to children 1 through 3 years of age, pregnant women, and lactating women and that, because of the benefits of adequate potassium intake in lowering blood pressure, data indicating low likelihood of potassium adequacy, and importance of establishing healthy dietary practices for later life, potassium is a nutrient of public health significance for infants 7 through 12 months of age, children 1 through 3 years of age, pregnant women, and lactating women. Thus, we proposed to require the labeling of vitamin D and potassium on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, or pregnant and lactating women based on the quantitative intake recommendations for vitamin D and potassium and the public health significance of these nutrients and did not provide for any exceptions for these subpopulations from the general requirement for declaration of vitamin D and potassium in proposed § 101.9(c)(8)(ii).

We did not receive comments regarding potassium and these subpopulations, so, other than replacing ''infants 7 to 12 months'' with ''infants through 12 months,'' we have finalized those provisions without change.

(Comment 452) One comment questioned the need for mandatory disclosure of vitamin D on the Nutrition Facts panel. The comment cited dietary intake data from food, beverages and supplements that suggests at least 75 percent of children ages 1 through 3 years have adequate intakes of vitamin D, not including sun exposure (Ref. 252). The comment said that mandatory declaration of vitamin D is not of value because relatively few foods have naturally occurring vitamin D, limitations on vitamin D addition to foods already exist, and vitamin D added to foods is already required on labeling. In addition, according to the comment, labeling can not necessarily help consumers achieve adequate intakes of vitamin D because it is not expected that all the required vitamin D will be provided by foods or supplements. Another comment noted that its products have many labels with very little label space and that using this label space for a declaration of 0 percent DV for vitamin D will limit its ability to provide other label information including information on other nutrients present in the products at significant levels.

(Response) We disagree with comments arguing against the mandatory declaration of vitamin D. We have determined that vitamin D is a nutrient of public health significance (79 FR 11879 at 11921 and 11938). The comment cited data that assessed usual intakes using the AI for vitamin D established in 1997 (Ref. 253). The IOM has since established an EAR for vitamin D (Ref. 38). Our analysis of NHANES data compared to the EAR showed 66 percent of children 1 through 3 years of age had inadequate intake of vitamin D from foods and supplements (79 FR 11879 at 11938).

We also disagree that mandatory declaration of vitamin D, including the declaration of zero percent DV, is not of value because few foods have naturally occurring vitamin D. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11938) and part II.L, we identified vitamin D as a nutrient of public health significance for children 1 through 3 years of age based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (Ref. 198). Our analysis also shows that vitamin D intakes and status remain inadequate in the general population (79 FR 11879 at 11922). While limited label space may present challenges, the consideration for the mandatory declaration of vitamin D on the label is whether it will help consumers maintain healthy dietary practices.

While we acknowledge that some, but not all, vitamin D needs can be met by the body's exposure to sunlight, we determined the mandatory declaration of vitamin D based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (see part II.L). The mandatory declaration of vitamin D is intended to help consumers maintain healthy dietary practices and make healthy choices in context of a daily diet. The mandatory declaration of vitamin D also provides information to consumers about what foods are good sources of vitamin D and what foods do not contain vitamin D. Therefore, we have finalized this provision without change.

c. Voluntary declaration of vitamin A and vitamin C. We proposed to no longer require the declaration of vitamin A and vitamin C on foods for the general population. With respect to subpopulations, we noted, in the preamble to the proposed rule (79 FR 11879 at 11939) that our analysis of data from NHANES 2003–2006 showed that less than 2 percent of children 1 through 3 years of age had usual vitamin A intakes below the EAR from conventional foods or conventional foods plus dietary supplements and that, while 36 percent of pregnant women had usual intakes below the EAR from conventional foods and 22 percent had usual intakes below the

EAR for conventional foods plus dietary supplements, only 1 percent of these women had serum vitamin A levels that were considered to be indicative of a vitamin A deficiency. Furthermore, our analysis of data from NHANES 2003–2006 showed that neither vitamin A nor vitamin C is considered to have public health significance for children 1 through 3 years of age and pregnant women. Therefore, we tentatively concluded that vitamin A and vitamin C are not of public health significance among infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, but we proposed to permit, but not require, the declaration of vitamin A and vitamin C on foods represented and purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women. As for other voluntary nutrients, the declaration of these nutrients would be required when these nutrients are added as nutrient supplements or claims are made about them (proposed § 101.9(c)(8)(ii)).

We did not receive comments regarding the voluntary declaration of vitamins A and C for subpopulations, so, other than replacing ''infants 7 to 12 months'' with ''infants through 12 months,'' we have finalized that provision without change.

d. Voluntary declaration of other vitamins and minerals. For the general population, we proposed to permit the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline (proposed § 101.9(c)(8)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11939), we said that vitamins and minerals other than iron, calcium, vitamin D and potassium for infants either have DRIs that are not based on chronic disease risk, heath-related conditions, or health-related physiological endpoints or are not shown to have public health significance due to the prevalence of a clinically relevant nutrient deficiency. For infants 7 to 12 months, children 1 through 3 years of age, and pregnant and lactating women, we tentatively concluded that the essential vitamins and minerals, other than iron, calcium, vitamin D and potassium, do not have public health significance and there is no basis for the declaration of these nutrients to be different from that proposed for the general population. Thus, proposed § 101.9(c)(8)(ii) would allow the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, pregnant women, or lactating women, under the requirements of this section, unless they are added to foods as a nutrient supplement or if the label or labeling makes a claim about them, in which case the nutrients would have to be declared.

We did not receive comments regarding the voluntary declaration of vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, copper, manganese, chromium, molybdenum, and chloride on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, pregnant women, or lactating women. Therefore, other than replacing ''infants 7 to 12 months'' with ''infants through 12 months,'' we have finalized these provisions without change.

(Comment 453) One comment requested we reconsider mandatory declaration of vitamin E on nutrition labeling for children 1 through 3 years of age. The comment said that about 63 percent of children 12 to 24 months and 37 percent of children 24 to 48 months have vitamin E intakes below the EAR (Ref. 252). The comment also noted that encouraging an adequate intake of vitamin E in the diets of young children may encourage adequate consumption of foods with higher levels of vegetable fat.

(Response) We agree that vitamin E intakes are below the EAR and disagree that mandatory declaration of vitamin E is needed. Our analysis of NHANES data also has shown that intakes of children 1 through 3 years of age are below the EAR (79 FR 11879 at 11944). However, low intakes of vitamin E have not been associated with clinically relevant nutrient deficiency (Ref. 246). Therefore, consistent with the factors for mandatory or voluntary declaration of non-statutory nutrients (79 FR 11879 at 11889 and 11918, and part II.D), we have determined that vitamin E is not a nutrient public health significance for children 1 through 3 years of age and the general population.

The comment did not provide evidence to suggest that mandatory declaration of vitamin E may encourage adequate intake and consumption of foods with higher levels of vegetable fat, and we are not aware of any evidence to support that proposition. Therefore, we are not making changes in response to this comment.

(Comment 454) One comment supported the voluntary declaration of choline for pregnant and lactating women. The comment noted that choline has a role in preventing neural tube defects in infants and high intakes improve placental function and ease babies' response to stress during pregnancy. Another comment suggested that some nutrients should be considered for mandatory labeling, *e.g.,* choline and selenium as public health concerns. The comment also recommended that choline be considered for mandatory labeling on foods for pregnant and lactating women. The comment explained that mandatory labeling on foods in general, should be driven by the interest to reduce the risk of chronic diseases in adulthood, and should be revisited for foods for 7 months through 3 years to emphasize the role of nutrients in development.

(Response) We disagree that the declaration of choline and selenium should be mandatory. As the comment suggested, we have considered the relationship of nutrients and chronic disease risk, health-related conditions, or a health-related physiological endpoints (*i.e.* growth and development) in infants, children, and pregnant and lactating women to determine its mandatory or voluntary declaration on labeling. Based on our analysis of dietary intakes, we found no evidence of inadequate intakes of choline and selenium in these subpopulations. We also found no evidence for a substantial prevalence of chronic disease, health-related condition, or nutrient deficiency with clinical significance linked to choline and selenium in these subpopulations. Therefore, consistent with the factors for mandatory or voluntary declaration of these types of non-statutory nutrients (see part II.D), we have determined that choline and selenium are not nutrients of public health significance for infants through 12 months of age, children 1 through 3 years of age and pregnant and lactating women and have finalized the provision regarding voluntary declaration.

5. DRVs and RDIs for Infants Through 12 Months of Age

Our preexisting regulations do not include DRVs or RDIs for nutrients for infants, except for an RDI of protein of 14 grams. However, the proposed rule would establish a DRV or RDI for certain nutrients, and we explained, in the case

of polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, sugar alcohols, sodium, and fluoride, why we were not proposing to establish a DRV.

a. General comments.

(Comment 455) One comment recommended considering dietary intake data and public health need in addition to quantitative intake recommendations to determine appropriate RDIs for vitamins and minerals to be established for infants 7 months through 12 months of age and children 1 through 3 years of age. Another comment recommended that menu modeling and intake survey data should be a consideration in the establishment of certain DRVs as they provide insight on whether a DV is achievable, without compromising intake of another food group or nutrient and whether they align with dietary recommendations.

(Response) We agree dietary intake data and public health significance are important considerations in determining appropriate RDIs for vitamins and minerals. We consider public health significance in the context of developing RDIs for vitamins and minerals to refer to the existence of ''well-established'' scientific evidence from U.S. consensus reports that there is a relationship between a nutrient and chronic disease risk, a health-related condition, or a health-related physiological endpoint and where the intake of such nutrient is of general importance in the general U.S. population, *e.g.,* where intakes are generally too low or too high among the U.S. population. Thus, we established RDIs for vitamins and minerals based on the DRIs set by the IOM that reflect the most current science regarding nutrient requirements and associated disease risk, health-related condition, or health-related physiological endpoints (79 FR 11879 at 11926). While the DRI reports also consider dietary intake data, we also have analyzed more recent dietary intake data for these age groups (79 FR 11879 at 11944).

We acknowledge the comment suggesting that menu modeling and intake survey data could be a consideration in the establishment of certain DRVs. Dietary recommendations based on menu modeling may aim to achieve nutrient requirements, but are not the sole determining factor for establishing all DRVs. We agree that menu modeling can be considered in choosing a reference point for daily intake that is realistically achievable and practical in light of the current food supply and consumption patterns.

b. Calories. The preamble to the proposed rule (79 FR 11879 at 11939) stated that we have not established a reference calorie intake for infants. We noted that there is no quantitative intake recommendation for calories for infants and that we were not aware of scientific data and information on which we could rely to establish such a level (id.). Thus, we did not propose to establish a reference calorie intake level for infants 7 to 12 months.

We did not receive comments on this issue. Consequently, the final rule does not establish a reference calorie intake for infants though 12 months of age.

c. Total fat. Regarding total fat, the IOM set an AI of 30 grams/day for fat for infants 7 through 12 months of age based on the average intake of human milk and complementary foods. The AI provides a basis on which we can determine an appropriate DRV for total fat for infants 7 through 12 months, so we proposed to amend § 101.9(c)(9) to include a DRV of 30 grams for fat for infants 7 through 12 months of age.

We did not receive comments regarding the proposed DRV for infants, so the final rule establishes a DRV of 30 grams for fat for infants though 12 months of age.

d. Saturated fat, trans fat, cholesterol, dietary fiber, and sugars. Regarding saturated fat, *trans* fat, cholesterol, dietary fiber, and sugars, there are no quantitative intake recommendations from U.S. consensus reports available with respect to infants. Thus, we did not propose to establish DRVs for these nutrients for infants 7 through 12 months of age.

We did not receive comments on our decision not to establish DRVs for saturated fat, *trans* fat, cholesterol, and dietary fiber for infants. Thus, the final rule does not establish DRVs for infants though 12 months of age for these nutrients.

(Comment 456) One comment recommended establishing a DRV for sugars for infants and children and suggested that we work with the IOM to establish a DRV for sugar for this population.

(Response) We decline to establish a DRV for sugars for infants though 12 months of age and children 1 through 3 years of age. As discussed in part II.H.2, we are not aware of data or information related to a quantitative intake recommendation for sugars that we could use as the basis for a DRV for total sugars. The IOM reviewed the evidence on this topic in the Macronutrient report (IOM, 2002) and did not provide quantitative intake recommendations for infants and children.

e. Polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. For polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols, there are no quantitative intake recommendations from U.S. consensus reports available with respect to infants. Thus, we did not propose to establish DRVs for these nutrients for infants 7 through 12 months of age.

We did not receive comments on our decision not to establish DRVs for polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. Thus, the final rule does not establish DRVs for infants though 12 months of age for these nutrients.

f. Total carbohydrates. For total carbohydrates, the IOM set an AI of 95 grams/day for carbohydrates for infants 7 through 12 months of age based on the average intake of human milk and complementary foods; the AI provides a basis on which we can determine an appropriate DRV for total carbohydrate for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation. Therefore, we proposed to amend § 101.9(c)(9) to establish a DRV of 95 grams for total carbohydrate for infants 7 through 12 months of age.

We did not receive comments regarding the proposed DRV of 95 grams for total carbohydrates for infants. Consequently, the final rule adopts the DRV of 95 grams for total carbohydrates for infants though 12 months of age.

g. Protein. For protein, the DV for protein for infants is an RDI, rather than a DRV. The preexisting RDI for infants is 14 grams/day for infants, but, in the preamble to the proposed rule (79 FR 11879 at 11940), we said we would revise the RDI to rely on current quantitative intake recommendations and that, in 2002, the IOM established an RDA for infants 7 through 12 months of 1.2 grams/kilogram/day based on nitrogen balance studies and using a reference body weight of 9 kilograms. The value 1.2 grams/kilogram/day × 9 kg equals 10.8 grams/day or a rounded value of 11 grams/day, yet we also noted that protein intakes are well above the current and proposed RDI. Mean protein intake for infants 6 to 11 months of age was 22 grams/day, well above the RDA of 11 grams/day. Thus, we proposed to revise § 101.9(c)(8)(iv) to establish an RDI of 11 grams for protein for infants 7 through 12 months of age.

We did not receive comments on our proposed RDI of 11 grams for infants, so the final rule, at § 101.9(c)(7)(iii) and (c)(8)(iv), establishes a RDI for protein of 11 grams for infants though 12 months of age.

h. Sodium. For sodium, we noted, in the preamble to the proposed rule (79 FR 11879 at 11940), that the IOM did not set a UL for sodium for infants 7 through 12 months of age due to insufficient data on adverse effects of chronic overconsumption in this age group. Thus, we did not propose a DRV for sodium for infants 7 through 12 months of age.

We did not receive comments regarding a DRV for sodium for infants. Thus, the final rule does not establish a DRV for sodium for infants though 12 months of age.

i. Fluoride. For fluoride, although the IOM set an AI for fluoride, the AI for infants 7 through 12 months is close to the EPA benchmarks for total fluoride intake. Additionally, we did not propose a DRV for fluoride for use in the labeling of foods for the general population because of a concern about excess intakes associated with dental fluorosis, and so, in the proposed rule, we tentatively concluded that a DRV for fluoride is not warranted for infants 7 through 12 months. Thus, we did not propose to establish a DRV for fluoride for infants 7 through 12 months of age.

We did not receive comments regarding establishment of DRVs for fluoride for infants. Thus, the final rule does not establish DRVs for fluoride for infants though 12 months of age.

j. Other vitamins and minerals. For vitamins and minerals, we reviewed current quantitative intake recommendations for vitamins and minerals for infants to determine appropriate RDIs for vitamins and minerals to be established in regulations for infants 7 through 12 months of age. In the preamble to the proposed rule (79 FR 11879 at 11940), we explained that we considered it important to establish RDIs for infants 7 through 12 months of age because infants in this age range transition from a diet of mostly breast milk and infant formula to infant cereal and baby foods, and labeling foods for this subpopulation with percent DV declarations can help parents make nutritious food choices. The DRIs (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. We considered it appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for infants. We also stated that the IOM established DRIs based on scientific knowledge that update and supersede previous RDA recommendations. Consequently, we proposed to amend § 101.9(c)(8)(iv) to include a listing of RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants 7 through 12 months of age.

We did not receive comments regarding our proposed RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants. Thus, the final rule adopts these RDIs for infants though 12 months of age without change.

(Comment 457) One comment would have us retain a DV for iron of 15 mg for infants given the importance of adequate iron in the diets of infants and young children and the prevalence of iron deficiency in children. The comment noted that published data reported 12 percent of infants aged 6 to 11 months have iron intakes from food, beverages, and supplements below the EAR (Butte 2010) and our analysis of NHANES data showed that 17.8 percent of infants aged 7 to 12 months have iron intakes from conventional foods only below the EAR.

(Response) We decline to revise the rule as suggested by the comment. We recognize the importance of adequate iron in the diets of infants. We acknowledge the dietary intake data and prevalence of iron deficiency for infants cited by the comment and point out that our analysis of NHANES data showed that 3 percent of infants aged 7 to 12 months have iron intakes below the EAR from food, beverages, and supplements. While we evaluated intakes, we consider that the DRI is the appropriate basis for establishing the DV for iron for infants because the DRI reports and its set of nutrient reference values are comprehensive reviews and applications of nutrition science research (79 FR 11879 at 11885).

(Comment 458) One comment questioned how a decrease in the DV for iron would affect iron fortification of foods for infants. The comment said that such a decrease in the DV could cause manufacturers to reduce iron fortification of products for this population group.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, any evidence to suggest that decreasing the DV for iron would impact iron fortification of foods for infants. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on potential changes in fortification of products. We recognize the importance of adequate iron intake in the diets of infants and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

(Comment 459) One comment asked that we use the current DV of 5 mg for zinc for infants as the DV for infants because previous RDA panels have recommended intakes of up to 10 mg for children 1 through 3 years of age and now recommend a RDA of 3 mg for infants and children 1 through 3 years of age. The comment also cited a study by Walravens et al. 1989 (Ref. 254) referenced by the IOM confirming the factorial approach and questioned the IOM's use of the Walraven baseline data minus 2 standard deviations to support for the EAR and suggested that reported dietary intake data, instead of standard deviations, maybe a more appropriate basis for EAR. The comment stated that lowering the DV to 3 mg/day may affect the availability and level of zinc fortification in foods and reduce intake levels without a full understanding of the potential impact in this sensitive population.

(Response) We decline to revise the rule as suggested by the comment. We are changing the DVs to reflect the most recent comprehensive reviews and applications of nutrition science research provided by current DRI reports and its set of nutrient reference values (see 79 FR 11879 at 11885). Modifying the reference value for zinc provided by these consensus reports is not warranted based on the scientific evidence to support the DRI.

We also disagree that using reported dietary intake data may be a more appropriate basis for the EAR infants. We note that the IOM established the EAR for zinc using a factorial approach and did not base the EAR on the growth data from the Walravens study (Ref. 226). We decline to comment on the IOM's rationale for the calculation used in confirming the factorial approach using the growth data cited by the Walraven study. We decline to speculate on how consumers may interpret % DV for zinc resulting from a recommended dietary pattern and whether they may inappropriately limit zinc intake. The comment did not provide, and we are not aware of, any evidence to suggest how consumers will react to the changes in percent DV as a result of changes to the DVs and whether they would inappropriately limit zinc intake. We recognize the importance of adequate zinc intake in

the diets of infants and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

We also have no evidence to suggest how that decreasing the DV for zinc would impact zinc fortification of foods for infants and decline to speculate on how availability and level of zinc fortification may change. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements and not on potential changes in the fortification of products.

6. DRVs and RDIs for Children 1 Through 3 Years of Age

With respect to children 1 through 3 years of age, our preexisting regulations do not include DRVs or RDIs, except an RDI for protein of 16 grams for children less than 4 years of age. In the preamble to the proposed rule (79 FR 11879 at 11940 through 11941), we explained that we reviewed scientific evidence and current recommendations, as well as comments in response to the 2007 ANPRM to consider establishing DRVs and RDIs for nutrients for this subpopulation and to consider revisions to the current RDI for protein.

a. General comments.

(Comment 460) Several comments supported establishing DVs for children 1 through 3 years (13 through 48 months) that are consistent with the IOM's DRI recommendations for children 1 through 3 years age ranges.

In contrast, one comment suggested setting DVs specific for 4- to 8-year-old children because, according to the comment, setting a single DV that groups 4- to 8-year-old children with adults could lead to excessive intakes of some fortified vitamins and minerals and potentially increase the risk of adverse health effects from ingesting too much. The comment pointed out that the updated DVs for two nutrients, vitamin A and niacin, are the same as or higher than the IOM Tolerable Upper Intake Levels (ULs) for 4-to-8-year-olds.

Other comments suggested establishing RDIs and DRVs for children 4 to 13 years of age because product labeling based on RDIs for adults, in most cases, exceed the nutritional needs for children 4 to 13 years of age. The comments also noted that setting RDIs for children would provide an opportunity for more companies to formulate children's products to age-specific RDAs (rather than adult values which may not be appropriate for children's nutritional needs) and communicate the information to consumers via product labeling. One comment recommended that declarations of percent DV should be required for products targeted to children 4 through 13 years of age that contain nutrients for which this age-specific DRV or RDI is established.

(Response) We decline to revise the rule as suggested by the comments. While we recognize that nutritional needs of children aged 4 to 8 or 4 to 13 years are different from adults, we disagree with establishing RDIs for children aged 4 to 8 or 4 to 13 years due to concerns about excessive intake of nutrients above the UL or recommended intakes for these age groups. As noted in the preamble to the proposed rule (79 FR 11879 at 11928) and the accompanying memorandum to the file rule (Ref. 199), intakes of vitamins and minerals generally do not exceed the ULs under current RDIs that are based on a population coverage approach, except for zinc, vitamin A (preformed), iodine and folic acid among children 4 to 8 years old. In these few instances where total usual intakes of vitamins and minerals by children aged 4 to 8 years exceed corresponding ULs, we have determined that such intakes are not of public health significance.

With respect to the comment regarding niacin, the UL for niacin applies to niacin obtained from fortified foods and/or supplements and is based on flushing (burning, tingling sensation and reddening flush primarily on skin, arms and face) which is not considered a serious adverse effect. The UL for children was set by extrapolating downward from the UL for adults. While niacin intakes from fortified foods and dietary supplements may exceed the UL for children aged 4 to 8 years old (Refs. 194–195), no data were found to suggest that children have increased susceptibility to flushing effects from excess intake (Ref. 249).

We also disagree with establishing RDIs and DRVs for children 4 to 13 years of age and mandatory declaration of percent DV for products targeted to children 4 through 13 years of age to provide an opportunity for companies to formulate children's products to age-specific RDAs rather than adult values which may not be appropriate for children's nutritional needs. We recognize that RDAs for adults may be higher than the RDAs of children 4 through 8 years of age and 9 through 13 years of age. RDIs are intended to help persons to understand the relative significance of nutrients in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate. While RDIs are not precise values for certain age and sex groups, they function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods.

b. Calories. With respect to calories, we stated, in the preamble to the proposed rule (79 FR 11879 at 11940 through 11941), that several comments to the 2007 ANPRM supported establishing a DV for calories specifically for young children 1 through 3 years of age and that we considered it appropriate to establish a reference calorie intake level for children 1 through 3 years of age because we proposed to set DRVs using quantitative intake recommendations that are based on calories (*e.g.,* total fat, saturated fat, and dietary fiber). Because recommendations from the IOM, AHA, AAP, and the 2010 DGA for caloric intake range from 800 to 900 calories/day for children 1 year old, approximately 1,000 calories/day for children 2 years of age, and from 1,000 to 1,200 calories/day for children 3 years of age, we used an average of the range of these caloric intake recommendations (800 to 1,200 calories/day), *i.e.,* 1,000 calories/day, as a reasonable reference calorie intake level and proposed to amend § 101.9(c)(9) to provide a reference calorie intake level of 1,000 calories/day for children 1 through 3 years of age.

(Comment 461) One comment supported the reference calorie intake of 1,000 calories/day for children 1 through 3 years of age.

(Response) We agree with the reference calorie intake of 1,000 calories/day for labeling represented or purported to be for children 1 through 3 years of age. Thus, the final rule, at § 101.9(c)(9), establishes a reference calorie intake of 1,000 calories/day for children aged 1 through 3 years.

c. Total fat. In the preamble to the proposed rule (79 FR 11879 at 11941), we noted that there is no DRV for total fat for children ages 1 through 3 years, but a comment to the 2007 ANPRM recommended that 35 percent of the recommended 1,050 calories or 41 grams/day of fat be used to as the DRV for fat because it is the midpoint of the AAP/AHA recommendation and the IOM Acceptable Macronutrient Distribution Range (AMDR) for 1 through 3 year olds. We agreed that 35 percent of calories from fat for children 1 through 3 years of age serves as an appropriate basis on which to set the DRV for total fat and would be consistent with AHA and AAP recommendations that 30 to 40 percent

of calories consumed by children 12 to 24 months of age and 30 to 35 percent of calories consumed by children 24 through 48 months of age should come from fat. Therefore, we tentatively concluded that 35 percent of total calories from fat (*i.e.,* 39 grams using the proposed reference calorie intake level of 1,000 calories/day) is an appropriate DRV for total fat for children 1 through 3 years of age, and we proposed to amend § 101.9(c)(9) to establish a DRV of 39 grams for fat for children 1 through 3 years of age.

(Comment 462) One comment would increase the DRV for total fat for children 1 through 3 years of age to 41 grams, given the importance of an adequate intake of total fat in this population for healthy development and growth. The comment noted that this level of total fat would be 37 percent of total calories from fat (based on 1,000 calories/day reference calorie intake level) which is within the AMDR of 30 to 40 percent total calories from fat. The comment cited dietary intake data suggesting that 23 percent (12 to 23 months) and 47 percent (24 to 48 months) of children are below the AMDR. The comment noted that it is important for the total fat DV to help encourage adequate fat intake.

(Response) We decline to increase the DRV for total fat. In the preamble to the proposed rule (79 FR 11879 at 11941), we determined that 35 percent of calories from fat, based on a 1,000 calorie/day reference calorie intake level, is an appropriate basis for the DRV for total fat because it aligns with the AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 through 24 months of age and 30 to 35 percent of calories consumed by children 24 through 48 months of age should come from fat and is consistent with our proposed approach to setting the DRV for total fat for the general population (Ref. 255). We acknowledge the dietary intake data suggesting the total fat intake of children is below the AMDR. This calculation yields a DRV of 39 grams.

We disagree that the purpose of the total fat DV is to encourage fat intake. The DVs are intended to help persons to understand the relative significance of nutrients in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate.

Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 39 grams for total fat for children aged 1 through 3 years.

d. Saturated fat, trans fat, and cholesterol. For saturated fat, *trans* fat, and cholesterol, we stated, in the preamble to the proposed rule (79 FR 11879 at 11941), that there are no DRVs for children 1 through 3 years of age. Based on the scientific evidence in the 2010 DGA to support that Americans 2 years of age and older consume less than 10 percent of calories from saturated fat and less than 300 mg/day of cholesterol, we tentatively concluded that it would be appropriate to set a DRV of 10 grams for saturated fat, based on 10 percent of total calories from saturated fat and using the proposed reference calorie intake level of 1,000 calories/day, which equals 11 grams, rounded down to 10 grams, and a DRV of 300 mg for cholesterol for children 1 through 3 years of age. We proposed to amend § 101.9(c)(9) to establish a DRV of 10 grams for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age. We declined to propose a DRV for *trans* fat because the scientific evidence from the IOM and the 2010 DGA did not provide any specific appropriate levels of intake.

(Comment 463) One comment recommended using the DRV of 12 grams for saturated fat for children 1 through 3 years of age. The comment noted that this value represents 10.7 percent of calories from saturated fat based on a 1,000 calorie diet and is consistent with the diets of about 25 percent of children between 12 and 47 months, an indication that this level of intake is achievable.

(Response) We decline to change the DRV for saturated fat as suggested by the comment. In establishing the DRV for saturated fat, we considered that cardiovascular disease can begin in childhood and the scientific evidence in the 2010 DGA that support Americans 2 years of age and older consuming less than 10 percent of calories from saturated fat (79 FR 11879 at 11941). We disagree that the DRV for saturated fat should be based on dietary intake data that suggest that a level of 12 grams is achievable. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on levels of intakes that are achievable. Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 10 grams for saturated fat for children aged 1 through 3 years. Additionally, on our own initiative, we have replaced ''saturated fatty acids'' in the table with ''saturated fat'' for consistency in how we refer to saturated fat. We also have replaced ''Unit of measurement'' with ''Unit of measure'' in the table for consistency with the introductory sentence to § 101.9(c)(9).

We did not receive comments regarding our tentative decision not to establish a DRV for *trans* fat or the proposed DRV of 300 mg for cholesterol for children aged 1 through 3 years. Thus, the final rule establishes a DRV of 300 mg for cholesterol for children aged 1 through 3 years and does not establish a DRV for *trans* fat.

e. Polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. For polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, and sugar alcohols, we stated, in the preamble to the proposed rule (79 FR 11879 at 11941), that there are no DRVs for children 1 through 3 years of age. We recognized the essential nature of α-linolenic acid in the diet, but we said that, for children 1 through 3 years of age, DRIs or other data and information were not available on which we could rely to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, and sugar alcohols (id.). Therefore, we tentatively concluded that there was no basis for setting DRVs for these nutrients and did not propose DRVs for polyunsaturated fat, including n-3 or n-6 polyunsaturated fatty acids, monounsaturated fat, sugars, added sugars, soluble fiber, insoluble fiber, or sugar alcohols for children 1 through 3 years of age.

We did not receive comments on our tentative decision not to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, and sugar alcohols. Thus, the final rule does not establish DRVs for children 1 through 3 years of age for these nutrients.

(Comment 464) Some comments agreed with not defining DVs for added sugars. One comment recommended establishing a DRV for added sugar for children.

(Response) We received many comments on defining a DRV for added sugars and explain, in part II.H.3.o, that we are establishing a DRV for added sugars for children and adults 4 years of age and older of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. For the reasons discussed in part II.H.3.o, we are also establishing a DRV of 25 grams of added sugars for children 1 through 3 years of age based on food pattern modeling. Using the 1,000 calorie intake reference amount for children 1 through 3 years of age and the DRV of no more than 10 percent of total calories, the DRV for children 1 through 3 years of age is 25 grams (1,000

calories × 0.1 = 100 calories and 100 calories ÷ 4 calories per gram for carbohydrates = 25 grams). Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 25 grams for added sugars for children ages 1 through 3 years of age.

f. Total carbohydrates. In the preamble to the proposed rule (79 FR 11879 at 11941), we said that, for total carbohydrates, there is not a DRV for children 1 through 3 years of age. We noted, however, that we were proposing a DRV for total carbohydrate for the general population based on the percentage of calories in a 2,000 calorie diet remaining after the sum of the DRV for fat (30 percent) plus the DRV for protein (10 percent) have been subtracted and that we considered this method to be appropriate for setting a DRV for total carbohydrate for children 1 through 3 years of age (id.). We also stated that total calories (100 percent) minus the proposed DRV for total fat (35 percent of calories) and the proposed DRV for protein (5 percent of calories) equals 60 percent of calories from total carbohydrate. A value of 60 percent of total calories from total carbohydrates also falls within the IOM AMDR recommendation of 45 to 65 percent of calories from carbohydrates for children 1 through 3 years of age. Therefore, we tentatively concluded that an appropriate DRV for total carbohydrate is 60 percent of calories (*i.e.,* 150 grams using the proposed reference calorie intake level of 1,000 calories/day), and we proposed to amend § 101.9(c)(9) to set a DRV of 150 grams for total carbohydrate for children 1 through 3 years of age.

We did not receive comments regarding the proposed DRV of 150 grams for children 1 through 3 years of age, so the final rule adopts this DRV without change.

g. Dietary fiber. In the preamble to the proposed rule (79 FR 11879 at 11941), we stated that there is not a DRV for dietary fiber for children 1 through 3 years of age, but we agreed with a comment to an ANPRM that an AI of 14 grams/1,000 calories for dietary fiber for children 1 through 3 years of age should be used to set a DRV for dietary fiber to be consistent with how other proposed DRVs are being set. Additionally, because we proposed a reference calorie intake level of 1,000 calories/d for this subpopulation, we proposed to amend § 101.9(c)(9) to establish a DRV of 14 grams for dietary fiber for children 1 through 3 years of age.

We did not receive comments regarding the proposed DRV of 14 grams for fiber for children 1 through 3 years of age. Thus, the final rule adopts this DRV without change.

h. Protein. Under our preexisting regulations, at § 101.9(c)(7)(iii), the RDI for protein for children younger than 4 years of age was based on the 1989 RDA for protein of 16 grams/day. Taking into account current recommendations and protein intakes, we noted, in the preamble to the proposed rule (79 FR 11879 at 11942), that protein intakes are well above the current RDI, with the mean protein intake for children 12 to 23 months of age being 44 grams/day, well above the RDA of 13 grams/day, and the midpoint of the AMDR of 5 to 20 percent calories from protein (*i.e.,* 12.5 percent of calories from protein or 31 grams/day). The protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories, and the RDA is approximately 5 percent of calories. Given the proposed reference calorie intake level and the approaches used for the proposed DRVs for fat and carbohydrate that are based on percent of calories, we tentatively concluded that, as with the general population, the DV for protein for children 1 through 3 years of age should be a DRV, rather than an RDI (using the RDA) and that a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories which equals 12.5 grams or, when rounded up, 13 grams. We proposed to amend § 101.9(c)(7)(iii) and (c)(9) to establish a DRV for protein of 13 grams for children 1 through 3 years of age.

(Comment 465) One comment recommended retaining the current DV of 16 grams for protein or using 10 percent of calories from protein. The comment noted that children 24 to 47 months have 13 to 19 percent of energy intakes from protein, respectively. The comment said that the proposed DV of 13 grams appears to be low relative to the protein that would be expected to be contributed from a diet that supplies the appropriate servings of foods from the recommended food groups, including milk, meat/poultry and beans and other legumes.

(Response) We decline to retain a DV of 16 grams for protein. In the preamble to the proposed rule (79 FR 11879 at 11942), we discussed a comment to the 2007 ANPRM recommending the DV for protein be maintained at 16 grams. We declined to keep the DV for protein at 16 grams, in part, because protein intakes are well above the current RDI. Mean protein intake for children 12 to 23 months of age was 44 grams/day, well above the RDA of 13 grams/day and the midpoint of the AMDR of 5 to 20 percent calories from protein (*i.e.,* 12.5 percent of calories from protein or 31 grams/day, which we rounded up to 13 grams). The protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories and the RDA is approximately 5 percent of calories. Thus, a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories which equals 12.5 grams or, when rounded up, 13 grams, and the final rule, at § 101.9(c)(7)(iii) and (c)(9), establishes a DRV for protein of 13 grams for children 1 through 3 years of age.

i. Sodium. In the preamble to the proposed rule (79 FR 11879 at 11942), we noted that, for the general population, we proposed to establish a DRV based on the UL for sodium and that there is no DRV for sodium for children 1 through 3 years of age. We also noted that the IOM derived the UL for children 1 through 3 years of age by extrapolation from the adult UL of 2,300 mg/day based on observational studies showing that blood pressure increases with age into adulthood and the recognition that risk factors for CVD, such as high blood pressure and atherosclerosis, occur in childhood (id.). We proposed to amend § 101.9(c)(9) to establish a DRV of 1,500 mg for sodium for children 1 through 3 years of age.

We did not receive comments regarding the DRV of 1500 g for sodium for children 1 through 3 years of age. Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 1,500 mg for sodium for children 1 through 3 years of age.

j. Fluoride. There is not a DV for fluoride for children 1 through 3 years of age. In the preamble to the proposed rule (79 FR 11879 at 11942), we said that, although the IOM recognized fluoride as a trace mineral that is important for public health by setting an AI based on evidence of its role in reducing the risk of dental caries, we tentatively concluded that a DRV should not be established for fluoride. The proposed rule did not contain a DRV for fluoride for children 1 through 3 years of age.

We did not receive comments regarding the establishment of DRVs for fluoride for children 1 through 3 years of age. Thus, the final rule does not establish a DRV for fluoride for children 1 through 3 years of age.

k. Other vitamins and minerals. In the preamble to the proposed rule (79 FR 11879 at 11942 through 11943), we stated that the IOM's quantitative intake recommendations (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for children 1 through 3 years of age. We explained that the RDA, when available, is the best estimate of an intake level that will meet the nutrient goals of practically all consumers who would use the Nutrition Facts label and that,

while AIs have less certainty than RDAs, AIs represent goals for nutrient intake for individuals and provide the best estimate based on current science for use in setting RDIs for such nutrients (see id.). Therefore, using the RDAs and AIs, we proposed to amend § 101.9(c)(8)(iv) to establish RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for children 1 through 3 years of age.

We did not receive comments regarding our proposed RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, selenium, copper, manganese, chromium, molybdenum, and chloride for children 1 through 3 years of age. Thus the final rule adopts these RDIs for children 1 through 3 years of age without change.

(Comment 466) One comment said that a DV for potassium of 3,000 mg for children aged 1 through 3 years is unrealistic and may promote an unbalanced diet. The comment said that the DV for potassium should be calculated using a 1,000 calorie diet instead of the 1,372 calorie factor used by the IOM for 1 through 3 year olds. The comment requested a DV of 2,300 mg given the reference caloric intake of 1,000 for children ages 1 through 3 years.

Another comment expressed concern that, with a DV of 3,000 mg, several foods products would no longer be considered a ''good source'' of potassium.

(Response) We decline to establish a DV of 2,300 mg for potassium, and we disagree with the comment regarding foods that would no longer be considered as a ''good source'' of potassium. In the preamble to the proposed rule (79 FR 11879 at 11942), we discussed how we had considered comments to the 2007 ANPRM suggesting that we use 1,800 or 2,000 mg/day potassium as the basis for the RDI for potassium; we said that it would be inconsistent with the approach for the general population. Selecting a number other than a RDA or AI, when there is one, is inconsistent with our approach for establishing DVs. We rely on the DRI reports and its set of nutrient reference values for establishing the DVs because they are comprehensive reviews and applications of nutrition science research. We acknowledge that current potassium intakes are below the proposed DV of 3,000 mg. However, we disagree that the DV for potassium may promote an unbalanced diet. Dietary sources of potassium are found in all food groups, notably in vegetables and fruits, and milk and milk products (Ref. 30). Promoting the development of healthy eating patterns that will be associated with adequate potassium intake later in life is important because chronic conditions such as elevated blood pressure, bone demineralization, and kidney stones likely result from inadequate potassium intakes over an extended period of time, including childhood (Ref. 256).

We disagree that DVs should be set based on realistic intakes or eligibility to make a nutrient content claim. The DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on levels of intakes that are achievable or eligibility to make nutrient content claims.

(Comment 467) One comment would have us retain a DV for iron of 10 mg of children 1 through 3 years given the importance of adequate iron in the diets of infants and young children and the prevalence of iron deficiency in children. The comment noted that dietary intake data in children aged 12 to 24 months suggests that children may be consuming less heme iron than assumed in the determination of the IOM EAR so the EAR may be too low to achieve the requirement of absorbed iron. However, the comment did not provide an amount or percentage of heme iron being consumed from current intakes and also cited data from published and unpublished sources.

(Response) We decline to revise the rule as suggested by the comment. We recognize the importance of adequate iron in the diets of infants and young children. As for the statement that children may be consuming less heme iron than assumed in the IOM's determination of the EAR, as the comment provided data from one published study reflecting dietary intake data from 2002 and did not provide estimates of the heme iron consumed or total iron absorbed, we cannot determine from the information provided by the comment that the EAR may be too low to achieve the requirement of absorbed iron.

Furthermore, selecting a number other than a RDA or AI is inconsistent with our approach for establishing DVs. We rely on the DRI reports and its set of nutrient reference values for establishing the DVs because they are comprehensive reviews and applications of nutrition science research (79 FR 11879 at 11885).

(Comment 468) One comment questioned how a decrease in the DV for iron would affect iron fortification of foods for toddlers. The comment said that such a decrease in the DV could cause manufacturers to reduce iron fortification of products for this population group.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, any evidence to suggest that decreasing the DV for iron would impact iron fortification of foods for toddlers. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on potential changes in fortification of products. We recognize the importance of adequate iron intake in the diets of young children and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

(Comment 469) One comment asked that we use the current DV of 5 mg for zinc for infants as the DV for children 1 through 3 years of age because previous RDA panels have recommended intakes of up to 10 mg for children 1 through 3 years of age and now recommend a RDA of 3 mg for infants and children 1 through 3 years of age. The comment also cited a study by Walravens et al. 1989 (Ref. 254) referenced by the IOM confirming the factorial approach and questioned the IOM's use of the Walravens baseline data minus 2 standard deviations to support for the EAR and suggested that reported dietary intake data, instead of standard deviations, maybe a more appropriate basis for EAR. The comment said that the zinc consumption from a recommended dietary pattern for children 1 through 3 years of age would be at least 6 mg, or 200 percent of the proposed DV and that consumers would likely be confused by these high amounts per serving and could take steps to inappropriately limit zinc intake. The comment stated that lowering the DV to 3 mg/day may affect the availability and level of zinc fortification in foods and reduce intake levels without a full understanding of the potential impact in this sensitive population.

(Response) We decline to revise the rule as suggested by the comment. We are changing the DVs to reflect the most recent comprehensive reviews and applications of nutrition science research provided by current DRI reports and its set of nutrient reference values (see 79 FR 11879 at 11885).

We also disagree that using reported dietary intake data may be a more appropriate basis for the EAR children 1 through 3 years of age. We note that the IOM established the EAR for zinc using a factorial approach and did not base the EAR on the growth data from the Walravens study (Ref. 226).

The comment did not provide, and we are not aware of, any evidence to suggest how consumers will react to the changes in percent DV as a result of changes to the DVs and whether they would inappropriately limit zinc intake. We recognize the importance of adequate zinc intake in the diets of young children and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

We also have no evidence to suggest how that decreasing the DV for zinc would impact zinc fortification of foods for toddlers and decline to speculate on how availability and level of zinc fortification may change. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements and not on potential changes in the fortification of products.

7. DRVs and RDIs for Pregnant Women and Lactating Women

The proposed rule would establish certain DRVs and RDIs for pregnant women and lactating women.

a. Calories. The proposed rule would use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (§ 101.9(c)(9)). In the preamble to the proposed rule (79 FR 11879 at 11943), we explained that the calorie needs for pregnant women and lactating women are similar to the general population, and few products are purported for pregnant and lactating women. Thus, because the reference calorie intake for the general population is 2,000, we proposed to use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (§ 101.9(c)(9)).

We did not receive comments on our proposed 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women. Thus, we have finalized the provision without change on this point. However, on our own initiative, we have made a grammatical change to the rule's mention of ''pregnant and lactating women'' to refer, instead, to ''pregnant women and lactating women.'' We have made this change to clarify that the rule is referring to two groups (pregnant women and lactating women) instead of one group.

b. Total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber. For total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber, we explained, in the preamble to the proposed rule (79 FR 11879 at 11943), that the quantitative intake recommendations for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women are generally similar to the general population. Thus, we tentatively concluded that the DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women should remain the same as for the general population, and so we proposed to amend § 101.9(c)(9) to establish DRVs for pregnant and lactating women using the proposed DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber.

We did not receive comments on our proposal to establish DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women based on the DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber. Thus, we have finalized these provisions without change.

c. Trans fat, polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, sugars, added sugars, and sugar alcohols. For *trans* fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, and sugar alcohols, in the preamble to the proposed rule (79 FR 11879 at 11943), we said that we did not propose DRVs for these nutrients for the general population because of a lack of quantitative intake recommendations. Because quantitative intake recommendations are lacking for these nutrients for pregnant and lactating women, we did not propose to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, or sugar alcohols for pregnant and lactating women.

We did not receive comments on our proposal not to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, insoluble fiber, soluble fiber, sugars, or sugar alcohols for pregnant and lactating women. Thus, the final rule does not establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, insoluble fiber, soluble fiber, sugars, or sugar alcohols for pregnant and lactating women.

However, with respect to added sugars, we received many comments on defining a DRV for added sugars for children and adults 4 years of age and older and explain, in part II.H.3.o, that we are establishing a DRV for added sugars for children and adults 4 years of age and older of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. For the reasons discussed in part II.H.3.o, we also are establishing a DRV for added sugars for pregnant women and lactating women of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. Thus, the final rule at § 101.9(c)(9), establishes a DRV of 50 grams for added sugars for pregnant women and lactating women.

d. Protein. Our preexisting regulations, at § 101.9(c)(7)(iii), establish RDIs of 60 grams of protein for pregnant women and 65 grams of protein for lactating women based on the highest 1989 RDAs for pregnant and lactating women. In the preamble to the proposed rule (79 FR 11879 at 11943), we noted that the IOM established 71 grams/day protein as the RDA for pregnant and lactating women based on the needs for maternal and fetal development and human milk production. Because the RDA for protein during both pregnancy and lactation is the same, and given that most foods represented or purported to be specifically for pregnant women are also represented or purported to be specifically for lactating women, we tentatively concluded that it would be appropriate to establish a single RDI of 71 grams applicable to both pregnant and lactating women and that the DV for protein for pregnant and lactating women should remain an RDI (using the RDA) instead of a DRV because the DRV approach used to calculate protein for the general population based on 10 percent of 2,000 calories, which equals 50 grams of protein/day, falls short of the recommended protein needs of pregnant and lactating women of 71 grams/day. Thus, we proposed to amend § 101.9(c)(7)(iii) to establish an RDI of 71 grams for protein for pregnant and lactating women.

We did not receive comments on the proposed RDI of 71 grams for protein for pregnant and lactating women. Thus, we have finalized this provision without change.

e. Fluoride. For fluoride, we did not propose to establish a DRV for pregnant or lactating women because we were not proposing a DRV for fluoride in the general population.

We did not receive comments regarding the establishment of a DRV for fluoride for pregnant and lactating

women. Thus, the final rule does not establish a DRV for fluoride for pregnant and lactating women.

f. Vitamins and minerals. For vitamins and minerals, in the preamble to the proposed rule (79 FR 11879 at 11943), we considered it appropriate to establish RDIs for pregnant and lactating women for vitamins and minerals that have DRIs, using population-coverage RDAs and AIs, instead of population-weighted EARs. We proposed to establish a single set of RDIs intended for both pregnant women and lactating women because nutrient needs during pregnancy and lactation are similar. Thus, we proposed to amend § 101.9(c)(8)(iv) to establish RDIs as set forth previously for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for pregnant and lactating women.

We did not receive comments with respect to these DRVs and RDIs for pregnant and lactating women, and so we have finalized these provisions without change.

P. Dietary Supplements

Our preexisting regulations specific to dietary supplement nutrition labeling appear in § 101.36. Many requirements in § 101.36 are consistent with the requirements for the nutrition labeling of conventional foods in § 101.9, and there are references throughout § 101.36 to requirements established in § 101.9.

The proposed rule would amend both the content and format of the Supplement Facts label to correspond to the Nutrition Facts label.

1. Mandatory Dietary Ingredients

Our preexisting regulations, at § 101.36(b)(2), provide information on dietary ingredients that have an RDI or a DRV as established in § 101.9(c)(8)(ii) and (c)(9). These dietary ingredients are known as the ''(b)(2)-dietary ingredients.'' Of these 15 nutrients, vitamin A, vitamin C, calcium, and iron must be listed in the Supplement Facts label for a dietary supplement when the quantitative amount by weight exceeds the amount that can be declared as zero in the nutrition labeling of foods in accordance with § 101.9(c). Section 101.36(b)(2) states that any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), must not be declared (*e.g.,* amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). The regulation also requires, in § 101.36(b)(2), that calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, other carbohydrate, and § 101.9(c)(8)(iv) or (c)(9) vitamins and minerals other than vitamin A, vitamin C, calcium, and iron may be declared, but they must be declared when they are added to the product for purposes of supplementation, or when a claim is made about them.

We proposed to update the list of (b)(2)-dietary ingredients to maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9. Therefore, proposed § 101.36(b)(2)(i) would: (1) No longer require declaration of vitamin A, vitamin C, or Calories from fat; (2) require vitamin D and potassium; (3) require the declaration of added sugars; and (4) retain the other (b)(2)-dietary ingredients as mandatory declarations. We also proposed to amend § 101.36(b)(2)(i), (b)(2)(i)(B)(1), and (b)(2)(iii)(G) to remove the requirement for declaration of ''Calories from fat.''

We did not receive comments on these proposed changes to the Supplement Facts label, and so, with the exception of replacing ''sugars'' with ''total sugars'' in § 101.36(b)(2)(i), we have finalized the provisions without change.

We note that we did receive comments, in general, on removing the declaration of vitamins A and C and on requiring the declaration of vitamin D and potassium; we discuss those comments in part II.L.2 and II.L.3. We also received comments on removing the requirement for declaration of ''Calories from fat;'' we discuss those comments in part II.E.1.

2. Folate and Folic Acid

The preamble to the proposed rule (79 FR 11879 at 11947) explained that folate is a nutrient found in conventional foods, whereas folic acid is the synthetic form of folate that is added to fortified conventional foods and dietary supplements. Because of the difference in bioavailability between naturally occurring folate and synthetic folic acid, we proposed to:

- Amend § 101.9(c)(8)(v) such that the term ''folate'' would be used in the labeling of conventional foods that contain either folate alone or a mixture of folate and folic acid;
- amend § 101.36(b)(2)(i)(B) and (b)(2)(i)(B)(2) to specify that ''folic acid'' is the term used to declare folic acid content of dietary supplements; and
- remove ''folate'' and ''folacin'' from the list of synonyms that may be used to declare folic acid on the Supplement Facts label.

(Comment 470) Many comments opposed allowing only the use of the term ''folic acid'' on dietary supplements. The comments said that dietary supplements can contain folate.

(Response) As discussed in part II.N.3.b, the final rule requires that the Supplement Facts label declare folate in mcg DFE, a percent DV based on mcg DFE, and that the mcg of folic acid be stated in parenthesis when folic acid is added as a nutrient supplement to a dietary supplement. In doing so, there will be consistency with the use of the term folate in labeling of both conventional foods and dietary supplements. In addition, the mcg DFE reflects the fact that folic acid is more bioavailable than folate and is the basis of the DV. By requiring the declaration of the mcg DFE folate, a percent DV based on mcg DFE, and the mcg of folic acid in parentheses on dietary supplements when folic acid is added as a nutrient supplement, consumers will be aware of the type and amount of folate or folic acid in the dietary supplement.

The final rule also removes ''folacin'' from the list of synonyms that may be used for folate in the Nutrition Facts label in § 101.9(c)(8)(v) and the Supplement Facts label in § 101.36(b)(2)(i)(B)(2)). In addition, the final rule removes the term ''folic acid'' from the list of synonyms that may be added in parentheses immediately following ''folate'' on the Nutrition Facts label in § 101.9(c)(8)(v) or in place of the term ''folate'' on the Supplement Facts label in § 101.36(b)(2)(B)(2) because we are now requiring that the terms ''folate'' and ''folic acid'' be included, when declared, on both the Nutrition and Supplement Facts label.

3. Units of Measure

The proposed rule would amend § 101.9(c)(8)(iv) to replace ''IU'' for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E. The proposed rule would quantify and declare folate and folic acid in ''mcg DFE'' instead of ''mcg.'' For consistency in nutrition labeling of foods and dietary supplements, the proposed rule also would amend § 101.36(b)(2)(i)(B)(3) to require that, when β-carotene is included in parentheses following the percent statement for vitamin A, it should be declared using ''mcg'' (representing mcg RAE) as the unit of measure. In addition, under § 101.36(b)(2)(ii)(B), the

proposed units of measure for vitamin D, vitamin E, and folate in § 101.9(c)(8)(iv) would be used in the declaration of vitamin D, vitamin E, and folic acid in the Supplement Facts label.

(Comment 471) Some comments disagreed with our proposal to replace ''IU'' for the RDIs for vitamin A, vitamin D, vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E.

(Response) We address these comments in part II.N.4. The final rule, at § 101.9(c)(8)(iv), revises the units of measure to be mcg RAE for vitamin A, mcg for vitamin D (with the allowance of voluntary declaration of IUs), and mg α-tocopherol for vitamin E, and § 101.36(b)(2)(ii)(B), therefore, adopts the same units of measure for vitamin D, vitamin E, and folate.

Additionally, we did not receive comments on the proposed changes to the declaration of β-carotene at § 101.36(b)(2)(i)(B)(3), so we have finalized that provision without change.

(Comment 472) One comment said we should adopt a unit of measure for fluoride of mg per liter (mg/L) rather than mg/servings.

(Response) We address this comment in part II.K.3. The final rule does not adopt mg/L as the unit of measure for fluoride.

(Comment 473) The proposed rule, at § 101.36(b)(2)(ii)(A), would state that amounts must be expressed in the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium. One comment said we should permit the use of additional units of measure for dietary ingredients to allow for use of more appropriate units of measure when metric weight is not the most accurate way to express the quantity of the dietary ingredient. The comment gave examples of ''colony forming unit'' (CFU) for probiotics and enzyme assay units (*e.g.* HUT, PC, SU, ALU) for enzymes. Another comment would amend § 101.36(b)(2)(ii)(A) to state ''these amounts shall be expressed in metric or other appropriate units of measure.''

(Response) We decline to permit the use of additional units of measure for dietary ingredients. The comment provided the examples of CFUs for probiotics and enzyme assay units for enzymes; however, the broader change suggested in the comment, by including ''other appropriate units of measure,'' would allow for the use of units of measure for dietary ingredients other than just probiotics and enzyme assay units.

We recognize that manufacturers are using a number of different units of measure for probiotics, enzymes, and other dietary ingredients. We need to fully evaluate each unit of measure for dietary ingredients to determine if it is appropriate for use on the Supplement Facts label, and if there are any implications to allowing for the use of such units of measure on the label. Because of the complexity of these labeling concerns, we plan to issue information related to this subject at a later date. We have, therefore, finalized § 101.36(b)(2)(ii)(A) without change.

4. Order of Nutrients Declared on the Label

For dietary supplements, § 101.36(b)(2)(i)(B) specifies that vitamins and minerals must be declared in a specific order on the Supplement Facts label. The proposed rule would add choline to the list of ordered nutrients in § 101.36(b)(2)(i)(B) and that, when declared, choline must follow potassium on the label.

We proposed to amend § 101.9(c)(5) to provide for the voluntary declaration of fluoride, unless a claim about fluoride, in which case fluoride would be mandatory on the label. We inadvertently did not propose to add fluoride to the list of ordered nutrients for declaration on the Supplement Facts label in § 101.36(b)(2)(i)(B).

We did not receive any comments on the proposed addition of choline to the list of nutrients on the Supplement Facts label. Therefore, the final rule adds choline to the list of nutrients in § 101.36(b)(2)(i)(B) and requires it to appear after pantothenic acid on the label because choline is a vitamin and pantothenic acid is the last vitamin in the list of nutrients provided in § 101.36(b)(2)(i)(B). In addition, the final rule specifies that calcium and iron shall be declared after choline on the label because choline will now be declared after pantothenic acid on the label.

As for fluoride, to enable manufacturers to know where to declare fluoride on the Supplement Facts label, we are adding fluoride to the end of the list of nutrients in § 101.36(b)(2)(i)(B) such that, when it is declared, it should be placed below potassium on the Supplement Facts label.

5. Subpopulations

The preamble to the proposed rule (79 FR 11879 at 11947) indicated that, to maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9, we would revise portions of § 101.36 pertaining to labeling requirements for foods, other than infant formula, that are represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women. The proposed rule would amend § 101.36(b)(2)(iii) to state that the percent of the DV of all dietary ingredients declared under § 101.36(b)(2)(i) must be listed, except that the percent DV for protein may be omitted as provided in § 101.9(c)(7) and that no percent DV is to be given for subcomponents for which DRVs have not been established.

When the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, our existing regulations require that a symbol be placed next to the percent DV declaration for these nutrients that refers the consumer to a statement at the bottom of the label that says ''Percent Daily Values are based on a 2,000 calorie diet.'' This statement is only accurate for products meant for children and adults that are 4 years of age and older. In the preamble to the proposed rule (79 FR 11879 at 11947), we explained that the proposed DRVs for total fat, total carbohydrate, dietary fiber, and protein for children 1 through 3 years of age are based on a 1,000 calorie diet, so, when a product that is represented or purported to be for children 1 through 3 years of age contains a percent DV declaration for total fat, total carbohydrate, dietary fiber, or protein, the proposed rule would require, in § 101.36(b)(2)(iii)(D), that a symbol be placed next to the percent DV declaration that refers the consumer to a statement at the bottom of the label that says ''Percent Daily Values are based on a 1,000 calorie diet.''

The proposed rule also would amend § 101.36(b)(2)(iii)(E) to change the categories of infants and children less than 4 years of age to infants 7 through 12 months of age and children 1 through 3 years of age, and, because we are proposing DRVs for various nutrients for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women, amend § 101.36(b)(2)(iii)(F) such that the requirement for an asterisk noting that a DV has not been established would be applicable to foods for these subpopulations only when a DRV has not been established for a nutrient (*i.e.,* for saturated fat, cholesterol, or dietary fiber for dietary supplements that are represented or purported to be for use by infants 7 through 12 months).

We did not receive comments specific to subpopulations and the proposed changes to § 101.36, and so, except as described in our response to comment 474, we have finalized those provisions without change. As discussed in our

response to comment 441, we are using the terminology ''infants through 12 months of age'' throughout § 101.36. As discussed in part II.O.7.a, we also have decided to use the terminology ''pregnant women and lactating women'' rather than ''pregnant and lactating women'' to clarify that the rule is referring to two groups (pregnant women and lactating women) instead of one group.

6. Footnote

The Supplement Facts label can bear a footnote stating that the percent Daily Values are based on a 2,000 calorie diet. In the preamble to the proposed rule (79 FR 11879 at 11947 through 11948), we noted that we intended to modify the footnote on the Nutrition Facts label and to conduct consumer studies related to the footnote on the Nutrition Facts label. We also noted that the footnote for the Supplement Facts label differs from the footnote for Nutrition Facts label, yet we expected that consumers who buy dietary supplements would be more interested in information about the amount of specific micronutrients contained in dietary supplements and would be less focused on the caloric reference value used in determining the percent DV for macronutrients (id.). We said that, based on the results of the consumer study, we would consider whether it is necessary to make corresponding changes to the footnote used on the Supplement Facts label when certain macronutrients are declared, and we invited comment on whether we should change the footnote on the Supplement Facts label to be consistent with the footnote on the Nutrition Facts label.

(Comment 474) One comment said there should be no footnote on the Supplement Facts label. The comment said that consumers do not receive their nutrition solely from a supplement, so, according to the comment, there is no need to refer to total calories. In addition, because all nutrition calculations are being made from the 2,000 calorie total, the comment said that the information provided by the footnote is already standardized across industry, so the footnote is unnecessary.

(Response) We decline to remove the footnote from the Supplement Facts label. Our preexisting regulations, at § 101.36(b)(2)(iii)(D), require manufacturers to declare the footnote ''Percent Daily Values are based on a 2,000 calorie diet'' only when total fat, saturated fat, total carbohydrate, dietary fiber, or protein are declared. The final rule amends § 101.36(b)(2)(iii)(D)) to include added sugars in the list of macronutrients to be consistent with the final requirement to include a declaration for added sugars in the nutrition label. As with the declaration of the footnote statement on the Nutrition Facts label, the footnote statement on the Supplement Facts label provides context for the consumer and enables the consumer to better judge how the nutrients in the supplement contributes towards the total daily diet. Therefore, we decline to remove the footnote statement from the Supplement Facts label.

When the food is purported to be for children 1 through 3 years of age, the final rule requires footnote to state that ''Percent Daily Values are based on a 1,000 calorie diet'' because a 1,000 calorie reference caloric value is used when calculating percent DVs for children 1 through 3 years of age. Therefore, the final rule amends § 101.36(b)(2)(iii)(D) to require the footnote statement ''Percent Daily Values are based on a 2, 000 calorie diet'' on the Supplement Facts label when the percent DV for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars is declared on the label, and to require the footnote statement ''Percent Daily Values are based on a 1,000 calorie diet'' if the product is represented or purported to be for use by children 1 through 3 years of age and, if the percent DV is declared for total fat, total carbohydrate, dietary fiber, protein, or added sugars.

7. Miscellaneous Comments

Several comments raised other issues regarding dietary supplements and labeling.

(Comment 475) One comment said that the current method of labeling dietary supplements causes confusion regarding which micronutrients, especially vitamins and minerals, are added to a product as opposed to those that are naturally occurring within the product. The comment suggested that the terminology ''naturally occurring'' be used when nutrients are naturally present in ingredients or products, and that other terms, such as ''added,'' be used when ingredients containing micronutrients have been added to a product.

Another comment objected to the nomenclature we proposed for the declaration of certain vitamins and minerals, suggesting the limitations in nomenclature are unconstitutional under the First Amendment (citing *Pearson* v. *Shalala,* 164 F.3d 650 (D.C. Cir. 1999); *reh'g, en banc, denied,* 172 F.3d 72 (D.C. Cir. 1999)) and stating that the nomenclature prevents the dissemination of information helpful to the public in evaluating health implications of supplements. For example, the comment stated that calling tocotrienols vitamin E is not accurate because these forms of vitamin E differ from other forms of vitamin E. The comment also noted that the proposed rule does not distinguish between different forms of vitamin K, selenium, vitamin B_{12}, vitamin B_6, and vitamin B_3 for purposes of identifying on the label the actual ingredient that is contained in a dietary supplement product. The comment suggested that the identification of the actual form of vitamin B_3 that is included in the product is essential because of the physiological differences between these forms. For example, vitamin B_3 could be identified as niacin or niacinamide; and similarly, vitamin B_{12} could be methylcobalamin or cyanocobalamin; vitamin B_6 could be pyridoxal 5-phosphate or pyridoxine; vitamin K could be phylloquinone or menaquione; selenium could be selenomethionine or sodium selenite or selenocysteine. The comment also cited references to suggest selenium in different forms has been reported to have different effects. Furthermore, the comment noted that the name of a nutrient ingredient in a dietary supplement may be a structure/function claim because the form of the molecule determines its function. For example, the comment stated that gamma-tocopherol denotes a particular structure of vitamin E that has a particular function because of its structure.

(Response) With respect to the comment related to added versus naturally occurring micronutrients in dietary supplement products, we decline to revise the rule as suggested by the comment. In dietary supplement products, when terms such as ''naturally occurring'' are used to refer to micronutrients in dietary supplements, they may imply that there is an inherent difference in nutritional quality of the vitamin depending on its source. We are not aware of any evidence that this is the case. Typically, ''added'' nutrients are synthetic forms of the nutrient. As stated in § 101.9(k)(4), a food is misbranded if its labeling suggests or implies that a natural vitamin is superior to an added or synthetic vitamin.

With respect to the comment objecting to the nomenclature we proposed for the declaration of certain vitamins and minerals, the comment seems to misunderstand our requirements for the declaration of vitamins and minerals and for structure or function claims. We provide for the truthful, nonmisleading labeling of

nutrients in their varying forms on dietary supplements in § 101.36(b) and (d) and § 101.9(c). Our regulation (21 CFR 101.36(b)(2)) provides for the labeling on the nutrition label of dietary ingredients with RDIs such as vitamins or minerals listed in § 101.9(c)(8)(iv), with the exception of vitamin B_3. We discussed, in the preamble to the proposed rule (79 FR 11879 at 11925) and also in part II.M (Reference Daily Intakes for Vitamins and Minerals), the reference intakes for vitamins and minerals listed in the Nutrition Facts and Supplement Facts panels that are identified in § 101.9(c)(8)(iv). The RDIs for vitamins and minerals are based on the IOM RDAs or AIs. In some cases, the RDA is based on the form of a vitamin or mineral recognized to meet human requirements (*i.e.,* the α-tocopherol form of vitamin E) and the AI is based on intakes of a specific form of the vitamin or mineral (*i.e.,* phylloquinone form of vitamin K). With the exception of vitamin B_3, we note that § 101.9(c)(8)(iv) lists the common and usual names of vitamins and minerals. The dietary supplement label requirements at § 101.36(d) provide for labeling of the source ingredient that supplies a dietary ingredient (*i.e.* niacin, vitamin $B_{12,}$ vitamin B_6, vitamin K, and selenium) within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words ''as'' or ''from,'' *e.g.,* ''Calcium (as calcium carbonate).'' When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). In addition, dietary ingredients, such as menaquinone, that are ''other dietary ingredients'' within the meaning of § 101.36(b)(3) must be declared by their common or usual name when they are present in a dietary supplement in accordance with that section. Thus, the forms of vitamins and minerals contained in dietary supplements such as niacinamide; methylcobalamin or cyanocobalamin; pyridoxal 5-phosphate or pyridoxine; phylloquinone or menaquione; and selenomethionine, sodium selenite, or selenocysteine may be identified, as appropriate, in the Nutrition Facts label or the ingredient statement.

Although we do not recognize the term vitamin B_3 and instead list niacin in § 101.9(c)(8)(iv), the term ''vitamin B_3'' if identified in labeling, other than in the Nutrition Facts label, must be truthful and not misleading. Furthermore, we disagree that we are requiring misinformation by calling tocotrienols vitamin E and lumping these forms of vitamin E together. As we discuss in part II.M, we established the RDI for vitamin E based on α-tocopherol § 101.9(c)(8)(iv). In § 101.36, we provide for dietary ingredients, such as tocotrienols for which we have not established RDI's or DRV's and that are not subject to regulation under paragraph (b)(2) of this section, as ''other dietary ingredients'' in § 101.36(b)(3). If other statements are made about ''other dietary ingredients,'' the statements must be consistent with the all applicable statutory and regulatory requirements.

To the extent the comment suggests that our regulations limit the information about the form of a nutrient on the label, we disagree. Although we have specific requirements related to nomenclature for the nutrient declarations, there are ways to convey the source of the nutrient in labeling, and thus, we do not restrict information about the source of the nutrient, provided the information presented is consistent with our statutory and regulatory requirements.

With respect to the comment that the name of a nutrient may be a structure or function claim, a structure or function claim is described in section 403(r)(6)of the FD&C Act. Such a claim is a statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function (section 403(r)(6)(A) of the FD&C Act). Gamma-tocopherol is a name for a particular form of tocopherol. While the molecular form of a vitamin may result in a particular function, the name of the form does not describe the role of the dietary ingredient in affecting the structure or function in humans nor does it describe a documented mechanism by which the dietary ingredient acts to maintain such structure or function. Thus, structure or function claims are permitted for dietary ingredients provided they meet the applicable statutory and regulatory requirements for such claims.

(Comment 476) One comment said there is confusion whether nutrient declarations on the Supplement Facts label represent only the added nutrients or the total amount of a nutrient based on analysis of the finished product in products where either micronutrients have been added or botanical ingredients are present that are natural sources of particular micronutrients. The comment suggested we could resolve the issue by ensuring that, where micronutrients are listed on the Supplement Facts and/or Nutrition Facts label, the information reflects those micronutrients that are typically present at the end of the shelf-life period in the finished product, taking into account industry-accepted overages/tolerances.

(Response) The Supplement Facts label provides the nutrition information for nutrients that have a RDI or a DRV as established in § 101.9(c). A (b)(2)-dietary ingredient may only be listed if it is a quantitative amount by weight that exceeds the amount that can be declared as zero in § 101.9(c). We are aware that micronutrients are sometimes added to naturally occurring micronutrients. The value declared on the label should be the value that is supported by data that factors in variability generally recognized for the analytical method used for the finished dietary supplement product for the level involved. We disagree that the label declaration should be based on a shelf-life period because the Dietary Supplement Good Manufacturing Practices regulations do not require an expiration date, shelf-life date, or ''best if used by'' date (see 72 FR 34752 at 34912 and 34856). Therefore, not all products would have a shelf-life date that could be used when determining what the final value should be.

(Comment 477) Several comments opposed decreasing the RDIs for vitamins and minerals because of the impact on the dietary supplement industry. The comments also stated that decreasing the RDIs for vitamins and minerals makes it difficult for consumers to get therapeutic dosages of vitamins and minerals in one supplement.

(Response) We address these comments in part II.M.

8. Compliance Requirements for Dietary Supplements

Compliance for dietary supplements is currently determined in accordance with § 101.9(g)(1) through (g)(8), except that the sample for analysis must consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The regulation also says that the criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) are applicable to other dietary ingredients.

The proposed rule would require manufacturers to declare added sugars on the Supplement Facts label under § 101.36(b)(2)(i). It would also require manufacturers to make and keep records to verify the amount of dietary fiber,

soluble fiber, insoluble fiber, added sugars, vitamin E, and folate, under certain circumstances for foods (79 FR 11879 at 11956). The proposed rule, at § 101.9(g)(10) and (g)(11), also would establish recordkeeping requirements for foods that contain a mixture of dietary fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of naturally occurring and added sugars, foods that contain added sugars that are reduced through non-enzymatic browning and/or fermentation, foods that contain a mixture of *all rac*-α-tocopherol and RRR-α-tocopherol, and foods that contain a mixture of folate and folic acid.

The same records requirements in § 101.9(g)(10) and (g)(11) also should apply to dietary supplements. Therefore, the final rule revises § 101.36(f)(1) to include the recordkeeping requirements for specific nutrients under § 101.9(g)(10) and (g)(11).

Manufacturers of dietary supplements may request an alternative means of compliance or additional exemptions under § 101.36(f)(2) when it is technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of the regulation. This allowance is the similar to what is made for conventional foods under § 101.9(g)(9). Therefore, the final rule, at § 101.36(f)(2), does not refer to § 101.9(g)(9).

Q. Format

Under our preexisting regulations (see, *e.g.,* § 101.9(d) through (f) and (j)), nutrition information must be presented on food labels in a specific format. The elements of format related to the Nutrition Facts label include such features and graphic design principles as the type style (*i.e.,* font) and size of the type (*i.e.,* point); use of boldface, lines, and bars; arrangement of information in one or more columns; column headings; presence of a footnote and use of a symbol (such as an asterisk) to designate a footnote; and whether nutrition information is listed as a percentage or in absolute (*i.e.,* quantitative) amounts. The elements of format also include the alignment of information; whether indentations are used in listing nutrient data; and the use of white space (or negative space) where no image or text exists. The format may differ from package to package according to the amount of space on the package that is available for labeling, as described and detailed in the relevant sections in this document.

The original format of the Nutrition Facts label was informed by a number of factors, including consumer research that we conducted; consideration of the environment in which consumers typically use the label (*i.e.,* grocery stores); the diversity of consumers (*i.e.,* with respect to education, age, socioeconomic status, etc.) for whom the label is intended; and comments and data received on this issue in response to rulemaking activities conducted in the 1990s. Research studies consistently confirmed that simple formats are easier to comprehend and require less consumer effort than complex information formats. A simple format is one that minimizes clutter and best meets the NLEA requirements that nutrition information should enable the public to readily observe and comprehend such information. In addition, a simple format allows consumers to search for accurate nutrition information with minimum effort, and provides information in a succinct manner that maximizes understanding (79 FR 11879 at 11948).

In the preamble to the proposed rule (79 FR 11879 at 11948), we explained that we were not proposing an extensive reformatting of the Nutrition Facts label. We further explained that we were proposing to make changes based on graphic design principles (such as alignment, consistency, repetition, and contrast), highlight key nutrients and key information, and remove or modify parts of the label to assist consumers in maintaining healthy dietary practices. In brief, we proposed the following changes to the format of the Nutrition Facts label: (1) Increasing the prominence of calories and serving size; (2) reversing the order of the ''Serving Size'' declaration and the ''Servings Per Container'' declaration and increasing the prominence of ''Servings Per Container;'' (3) right-justifying the quantitative amounts of the serving size information; (4) changing the phrase ''Amount Per Serving'' to ''Amount Per ____'' with the blank filled in with the serving size; (5) removing the declaration of ''Calories from fat;'' (6) modifying the presentation of the ''% DV'' information by changing its position to the left of the name of the nutrient on certain labels and separating it from the list of nutrients with a vertical line; (7) declaring ''Added Sugars'' as an indented listing directly beneath the listing for ''Sugars''; (8) declaring the quantitative (or absolute) amounts (in addition to percent DVs) of mandatory vitamins and minerals and, when declared, voluntary vitamins and minerals; (9) requiring dual column labeling under certain conditions; (10) modifying the footnote; (11) requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular (*i.e.,* semi-bold) type; (12) adding a horizontal line directly beneath the ''Nutrition Facts'' heading; and (13) replacing the listing of ''Total Carbohydrate'' with ''Total Carbs.'' We also invited comments on other issues related to the Nutrition Facts label format, including the use of an alternative format design or requiring the use of a specific font.

The preamble to the proposed rule also discussed certain modifications to be applied to other label formats to maintain consistency with the proposed Nutrition Facts label. These other modifications would pertain to formats for packages of products that contain two or more separately packaged foods that are intended to be eaten individually (*e.g.,* variety packs of cereals and snacks) or that are used interchangeably for the same type of foods (*e.g.,* round ice cream containers (§ 101.9(d)(13)); formats that apply to subpopulations (§ 101.9(e) and (j)(5)); the simplified format (§ 101.9(f)); the tabular display on packages that do not have sufficient continuous vertical space (§ 101.9(d)(11)(iii)); and the tabular display (§ 101.9(j)(13)(ii)(A)(*1*)) and linear display (§ 101.9(j)(13)(ii)(A)(*2*)) for small packages.

Additionally, in the **Federal Register** of July 27, 2015 (80 FR 44303), we proposed text for the footnotes to be used on the Nutrition Facts label and proposed to require the declaration of the percent DV for added sugars on the Nutrition Facts label. In a separate notice published in the **Federal Register** of July 27, 2015 (80 FR 44302), we reopened the comment period for the proposed rule for inviting public comments on two consumer studies: One using an experimental design methodology (the format study) and one using eye-tracking methodology (the eye-tracking study). The purpose of these studies was to examine the combined effects of most of the changes outlined in the proposed rule in their totality; however, both studies also examined certain individual changes, selected on the basis of priorities and resources available at that time.

1. General Comments

To make a determination about the final format for the Nutrition Facts label, we considered many factors including: Comments we received about the proposed label format in response to our proposed rule (79 FR 11879), the supplemental proposed rule (80 FR 44303) and the reopening of the comment period (80 FR 44302); graphic design principles; and results from consumer research conducted by ourselves and others. This is similar to the approach we took when determining the original Nutrition Facts label formats. At that time, our decisions about format elements drew on information collected from a variety of sources including focus groups and a professional package design firm, in addition to label research conducted by FDA and other organizations (57 FR 32060).

(Comment 478) Several comments stated that neither the results of our consumer studies nor those submitted by outside parties support the proposed label changes and that our proposed changes do not improve consumer understanding of nutrition information on the label over the current label format. One comment said that the proposed format changes do not offer ''enhanced value'' to the consumer that would justify a change from the preexisting label format.

(Response) The consumer studies that we conducted focused mainly on comparing the Current, Proposed, and Alternative formats in their totality. We found that overall consumer preferences, understanding, or perceptions of product healthfulness (as indicated by the label) were comparable among the Current, Proposed, and Alternative label formats. In this final rule, we are making minor changes, such as highlighting certain specific features and characteristics of the label, to enhance the information or for other reasons. Our consumer research provided important information and insights about consumer perceptions, judgments, and understanding that will be useful in informing our future consumer education efforts. We acknowledged in our 1993 nutrition labeling final rule that various considerations (*i.e.,* in addition to consumer research) would bear on the selection of a final nutrition label format. We previously said that an essential criterion would be how well a format conveyed information that Congress expected a nutrition label to provide, such as information that would allow people to decide whether to buy a product or to understand the relative significance of the food in the context of the daily diet (58 FR 2079 at 2115). In the consumer studies we conducted to determine the format for the original Nutrition Facts label, no single format emerged as being superior in every aspect that was investigated. We subsequently worked with graphic design experts to develop the new label, drawing on research that considered not only comprehension, but also legibility and literacy (Ref. 257).

(Comment 479) One comment described a study designed to investigate the extent that consumers are able to quickly notice and understand label information, as they would during grocery shopping (Ref. 258). The study compared consumer reactions to FDA's current and proposed versions of four different Nutrition Facts label formats, each portraying a different food product, so that a total of eight different labels were examined. The current and proposed label formats, and the foods depicted, were: Standard format for single-serve yogurt; tabular format for frozen vegetables; dual-column label for breakfast cereal (per serving and with ½ cup skim milk); and a dual-column label for a multi-serving snack mix package (per serving and per container). The comment recommended that we not implement the proposed changes in format for the Nutrition Facts label because, according to the comment, the study indicated that participants perceived few differences between the current and proposed label formats.

(Response) The results of this study are difficult to interpret because a number of details were not provided. Among other things, the comment did not adequately describe or explain the demographic characteristics of the participants, the statistical methods that were used, how the survey instrument was validated, how the participants were selected and the study was administered, and why 90 percent confidence levels were chosen to indicate significant differences rather than the conventional 95 percent confidence interval. In addition, the manner in which some questions were worded could have affected the responses, and the full range of response options was not presented. Furthermore, the proposed snack mix label appeared to be inconsistent in how the ''per serving'' and ''per container'' values were listed for various nutrients. Although the label indicated ''3½ servings per container'' for some nutrients (*e.g.,* calories, carbohydrates, sodium, protein) the amounts that were listed on the label suggested that there were 4 servings per container, and the amount of dietary fiber shown on the label indicated there were only 2½ servings per container. Therefore, we are not able to rely on the results of this study to inform our decisions regarding Nutrition Facts label formats.

(Comment 480) Several comments said that we should not move forward with the proposed nutrition label format changes without conducting further consumer research.

(Response) We disagree with comments suggesting that we should not finalize this rulemaking until we conduct further consumer research (see, also, our response to comment 6). We considered consumer research studies and public comments, and we also relied on graphic design principles (such as contrast, proximity, alignment, consistency, etc.) in deciding how the various Nutrition Facts label formats should appear in finalizing the requirements for the label format.

2. Increasing the Prominence of Calories and Serving Size

The ability to determine the caloric content of packaged foods is important for all consumers, especially those who are trying to control their total caloric intake and manage their weight. Our preexisting regulations require ''Calories'' to be declared in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). While calorie information is mandatory on the Nutrition Facts label, modifying the Nutrition Facts label to give more prominence to calories may benefit consumers in weight control and maintenance, as noted by the OWG in its final report entitled ''Calories Count'' (Ref. 127).

In the preamble to the proposed rule (79 FR 11879 at 11849 and 11948 through 11949), we explained that the OWG recommended, in part, that we issue an ANPRM to solicit comments on how to give more prominence to calories on the food label. The OWG suggested possible changes to the Nutrition Facts label, such as increasing the prominence of ''Calories'' and ''Serving Size,'' providing a percent DV for calories, and eliminating the ''Calories from fat'' declaration, which may detract from the emphasis on total calories. The OWG recommended that we obtain information on the effectiveness of these options on consumer understanding and behavior related to calorie intake (Ref. 127). In response to the 2005 ANPRM, several comments supported increasing the prominence of calories on the Nutrition Facts label. These comments suggested

various approaches for doing so and pointed out the need for additional research to fully understand the effects of potential label changes on consumer understanding and behavior (Ref. 26).

We considered available data from consumer research and comments received in response to the ANPRMs and conducted our own research on food labels. We tentatively concluded that the proposed changes to the number of calories per serving and the number of servings per container would result in these declarations serving as an anchor to the Nutrition Facts label by focusing the reader's attention to this information and therefore would assist consumers to effectively use this information in the Nutrition Facts label (Ref. 259). The proposed rule would revise § 101.9(d) to increase the type size for ''Calories'' and the numeric value for ''Calories'' and also would require the numeric value for calories be highlighted in bold or extra bold type to draw attention to this information, emphasize the importance of calories on the label, and maintain consistency with the bolded declaration for ''Calories.''

We also expressed a tentative view that the Supplement Facts label should have a format similar to the format being proposed for the Nutrition Facts label with respect to increasing the prominence of information for calories. We invited comment on whether any changes we proposed to the Nutrition Facts label also should be required for certain products with Supplement Facts labels, and if so, under what conditions and for which dietary supplement products should such labeling be required.

(Comment 481) Most comments supported our proposal to increase the prominence of the calories declaration, indicating that giving more emphasis to calories on the Nutrition Facts label would likely benefit consumers in helping them to monitor their caloric intake and make healthier food choices. Several comments suggested that increasing the prominence of calories would help focus consumer attention on their total caloric intake because the information on the label would be more visible, readily accessible, and hard to ignore. Many comments noted that the larger, bolder font would draw attention to the calorie content of the product, encourage consumers to consider this information when selecting a product or deciding how much to eat, and help them to grasp the relative significance of a particular food in the context of their daily diet. Other comments said that increasing the prominence of calories also would help consumers compare products when shopping and perhaps encourage them to pay more attention to labels in general. Several comments pointed out that increasing the type size and visibility of calories would be especially helpful to people with impaired vision, including many older adults and diabetics, and even people with normal vision would benefit if shopping in a dimly lit grocery store. The comments said that, although information about other nutrients is important, information on calories is particularly important because of the prevalence of obesity and the association between obesity and chronic diseases and disabilities. The comments agreed that enlarging the calories information and making it bolder would be an important step, not only in fighting obesity, but also in controlling diabetes.

Although most comments acknowledged the importance of calories and supported increasing the prominence to some extent, many comments opposed declaring the calorie information in a type size substantially larger than that of other information on the label. Many comments expressed concerns that the proposed format overemphasized calories at the expense of other nutrients declared on the label, and several comments suggested that the calorie information was ''disproportionately large'' or consumed too much label space. Other comments included suggestions for improving the overall design and balance of the label by adjusting the relative type sizes for ''Calories,'' the numeric value for calories, and other nutrition information on the label, including the ''Nutrition Facts'' heading. A few comments stated that there was no need to increase the prominence of calories because the Nutrition Facts label already provides calorie information and that increasing the prominence may not provide any additional benefits.

Several comments said that there is no convincing data that enlarging the calorie information would help consumers choose healthier products and that additional consumer research would be essential for determining a format that improves consumer understanding of calorie information in the Nutrition Facts label. One comment pointed out that, although the FDA consumer study cited in the proposed rule failed to demonstrate that increasing the font size for calories lead to healthier choices, we nevertheless decided to proceed with our proposal to increase the prominence of calories on the label. The comment further stated that, because FDA's own consumer research suggested that a larger font size does not improve consumer awareness of the calorie information, we must provide another justification to increase the font size.

Many comments also expressed concerns that overemphasizing calories could have the unintended consequence of suggesting that information about calories is much more important than information about other nutrients appearing on the label. For example, some comments said that the proposed Nutrition Facts label could give the impression that calorie counting is the most important consideration in managing health, when, in fact, reducing the risk of chronic diseases and other health-related conditions goes well beyond caloric intake. Other comments said that consumers might evaluate and compare food or beverage products based solely on their caloric content and choose the option having the fewest calories, without considering the product's total nutrient profile. Consequently, this could inadvertently result in consumers avoiding nutrient dense foods as recommended by the Dietary Guidelines for Americans.

Several comments expressed concerns that making the calorie declaration so prominent could affect consumer use and understanding of other information on the Nutrition Facts label. For example, comments suggested that, because the ''Amount per ____ (serving)'' declaration is relatively small compared to the proposed ''Calories'' and ''____servings per container'' declarations, consumers may mistakenly associate the numeric value for ''Calories'' with the contents of the entire container, rather than with only one serving. Several comments emphasized that consumer research is needed to further investigate formats that would facilitate consumer understanding of this label information and ensure that the format does not result in consumers misinterpreting the calories information. One comment suggested that as part of a consumer test, the ''Amount per ____'' (*i.e.,* serving size) listing and the numeric value for ''Calories'' could be shown in equal type sizes.

(Response) We agree that giving more prominence to calories by increasing the type size and bolding of the ''Calories'' declaration and the numeric value for ''Calories'' would emphasize the importance of calories on the Nutrition Facts label.

We disagree with the comments suggesting it is not necessary to increase the prominence of the calorie declaration or that the numeric value for calories should not be larger than the word ''Calories,'' because, as we explain later in this response, emphasizing this

information has potential benefits to consumers who read the label. However, we agree that the 24 point type size that was proposed for the numeric value for ''Calories'' on most label formats (excluding small packages and dual column labels using the tabular format) could be considered too large and that adequate prominence could still be achieved by slightly reducing the type size. Therefore, the final rule, at § 101.9(d)(i)(iii), requires a type size of 22 point for the numerical value for ''Calories,'' (excluding labels for smaller packages that have a total surface area available to bear labeling of 40 square inches or less) and a type size of 16 point for the word ''Calories'' on all label formats (excluding labels on smaller packages, with a total surface area available to bear labeling of 40 square inches or less and all tabular displays) and highlighting both pieces of information in bold or extra bold type. The requirements for smaller packages require a type size of no smaller than 14 point for the numerical value for ''Calories'' for the tabular display for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear display as shown in § 101.9(j)(13)(ii)(A)(*2*), a type size of no smaller than 10 point for the word ''Calories'' for the tabular displays as shown in § 101.9(d)(11)(iii) and (e)(6)(ii) and for the tabular display for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear display as shown in § 101.9(j)(13)(ii)(A)(*2*). These type sizes will be sufficiently large to emphasize the importance of calories on the label and draw attention to this information while decreasing the size to address issues raised in the comments as well as accommodating size constraints for packages with a total surface available to bear labeling of 40 square inches or less (see our response to comment 517).

We disagree with the comments suggesting that emphasizing calories would detract from information about other nutrients on the label, or would result in consumers avoiding nutrient dense foods. No evidence was submitted in support of these comments, and we are unaware of any data that emphasizing the calories declaration would encourage consumers to always choose the lower calorie option, result in poor nutritional practices, or lead to adverse health consequences. Although we also are unaware of any consumer studies demonstrating that increasing the prominence of calories information on the Nutrition Facts label would either help or hinder consumer use and understanding of this information, we explained in the preamble to the proposed rule (79 FR 11879 at 11949) that existing data from studies on warning label and drug label formats have demonstrated that increasing the prominence of label information such as warning statements increases consumer attention to such information. Furthermore, the OWG report suggested that we consider increasing the font size for calories on the Nutrition Facts label because of the critical importance of caloric balance in relation to overweight and obesity (Ref. 127). Similar to graphic design principles underlying the appearance of warning labels, increasing the prominence of calories would be expected to draw consumer attention to this information. The OWG report recommend mainitaining a healthy body weight and calorie balance is key factor for managing body weight. The OWG report concluded that obesity is positively associated with adult morbidity and mortality and has become a pervasive and urgent public health problem in the United States. The OWG report also emphasized the medical and health related costs that result from high rates of overweight and obesity. Moreover the 2015–2020 DGA does not alter these conclusions and corroborates these findings. We agree with the OWG report's recommendations and conclusions particularly emphasizing calories, but we are sensitive to concerns about over-emphasizing the calories declaration on the label. An important goal in addressing concerns regarding nutrient density is education. Nutrition education, especially around the Nutrition Facts label should be multifactorial and highlight the importance of calories, but also the other nutrients that can affect health and chronic disease. Therefore, the final rule requires a smaller type size for the number of calories on all labels than what we had originally proposed (*i.e.,* 22 point rather than 24 point for all displays except those for smaller packages), and even further decreased type size (14) requirements are permitted for small packages with a total surface area available to bear labeling of 40 square inches of surface area or less as described in § 101.9(j)(13)(ii)(A)(*1*) and (*2*).

(Comment 482) A few comments expressed concerns that excessively focusing on calories and drawing too much attention to the caloric content of a food product would likely have a negative impact on individuals who are at risk for an eating disorder, or who are already struggling with an eating disorder.

(Response) The comments did not submit data or other evidence to show that eating disorders could be triggered or exacerbated by enlarging the ''Calories'' declaration on the Nutrition Facts label. We are unaware of the existence of such an association and remain convinced that the potential public health benefits of increasing the prominence of ''Calories'' would outweigh the risk of a possible negative impact on individuals struggling with eating disorders.

(Comment 483) One comment stated that, because dietary supplement labels often contain a large amount of information on a small label, increasing the prominence of calories information would likely be difficult because of a lack of space. The comment stated that an increased prominence for ''Calories'' on Supplement Facts labels should be required only if consumption of the dietary supplement would make a major contribution to daily caloric intake (*e.g.,* 50 or more calories per serving). However, the comment noted that, in most cases, dietary supplement products contribute insignificant amounts of calories to the overall diet.

(Response) In the preamble to the proposed rule, we invited comments on whether any of the changes being proposed for the Nutrition Facts label should also apply to products with Supplement Facts labels that list calories and/or other macronutrients (79 FR 11879 at 11949). We did not propose increasing the prominence of calories on labels of dietary supplement products and did not display the calories information in a larger and bolder type size in any of the labels illustrated in the proposed rule in § 101.36(e)(11) and § 101.36(e)(12). We agree with the comment that many dietary supplement products may contribute a negligible amount of calories. Therefore, the final rule does not require that information about calories be displayed in a larger type size or be highlighted in bold or extra bold type or other highlighting on any Supplement Facts labels.

(Comment 484) Several comments pointed out that increasing the font size for ''calories'' and ''serving size'' on the Nutrition Facts label would affect the size of the percentage juice declaration that manufacturers are required to make on juice products. Under § 101.30(e)(2), the percent of juice declaration must be in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, or the title for Nutrition Facts. Because information about ''Calories'' is not included among these exceptions, the type size of the juice declaration would have to be at least as large as the type size of the numeric value for ''Calories.''

Therefore, according to the comments, increasing the size of the ''Calories'' information would mean increasing the size of the percent juice declaration significantly. The comments further suggested that we revise § 101.30(e)(2) to clarify that the percent juice declaration does not have to be larger than the information about ''Calories'' or ''Serving size.''

(Response) We inadvertently omitted the corresponding correction to § 101.30(e)(2) to include ''Serving size,'' ''Calories,'' and the numerical value for ''Calories'' in the list of exceptions for declarations in larger type to avoid requiring a type that would be too large for the declaration of the amount of juice. Therefore, we have made a technical correction in the final rule and revised § 101.30(e)(2) to state that the title phrase ''Nutrition Facts, the declaration of ''Serving size,'' ''Calories,'' and the numerical value for ''Calories'' appearing in the nutrition information must be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, or universal product code.

(Comment 485) One comment said we should not require the calories information listed on labels of food products intended for infants and young children to have the same prominence as the calories information on product labels intended for people 4 or more years of age. The comment stated that decisions about food choices that are made for infants and young children should not be based on the number of calories per portion, but rather on the overall nutrient profile of the food. The comment explained that, by relying too much on a food's caloric content, parents may inadvertently restrict healthful foods or make inappropriate food choices for their young children and infants. The comment also said that, according to nutrition experts, children in this age range should be encouraged to self-regulate caloric intake and that parents and caregivers should feed children in response to the child's hunger and fullness cues rather than on the basis of a preconceived number of calories they believe the child should consume.

(Response) We agree with the comment that food choices for infants through 12 months of age and children 1 through 3 years of age should focus primarily on a food's overall nutrient profile rather than on the number of calories per serving (Refs. 260–261). The IOM report advocated feeding children in response to their hunger and fullness cues, rather than providing foods for children based on the number of calories in a serving of the product. However, the IOM report also emphasized the importance of parents establishing healthful eating habits for their children early in life. The IOM report stated that children who consume a diet that restricts energy-dense foods high in sugar, fat, and salt, but that is rich in nutrient-dense foods, are less likely to become overweight or obese. Thus, although the IOM report did not explicitly recommend restricting children's foods based on calorie content, it suggested that parents and caregivers should at least be aware of the amount of calories (and other nutrients) in the foods they give their children, especially those over 2 years of age, in order to begin establishing good eating habits.

The comment did not provide evidence that parents would restrict foods or make inappropriate food choices for their young children and infants based solely on the food's caloric content. We acknowledge that parents and caregivers would likely consider a variety of factors when making decisions about what to feed their young children and that increasing the prominence of calories information on the labels of foods intended for young children does not necessarily mean that parents would restrict these foods. Therefore, we do not consider it necessary for the calories information on products for infants through 12 months of age and children 1 through 3 years of age to differ from that required on Nutrition Facts label formats for foods intended for individuals 4 years of age and older. To maintain consistency in label formats, the final rule requires that the calories information on labels of foods intended for infants through 12 months of age and children 1 through 3 years of age be displayed prominently, as indicated in the label mockups shown in § 101.9(j)(5)(i) and (ii).

3. Changing the Order of the ''Serving Size'' and ''Servings Per Container'' Declarations and Increasing the Prominence of ''Servings Per Container''

Our preexisting regulations specify that information on serving size, consisting of a statement of the serving size (§ 101.9(d)(3)(i)) and the number of servings per container (§ 101.9(d)(3)(ii)), must immediately follow the identifying heading of ''Nutrition Facts.'' In addition, ''Serving Size'' and ''Servings Per Container'' must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)).

In the preamble to the proposed rule (79 FR 11879 at 11949), we explained that, with respect to the Nutrition Facts label, an important consumer need is to identify the number of servings per container of a packaged food. Therefore, we proposed placing ''Servings Per Container'' above ''Serving Size'' to help consumers find the number of servings per container with less effort than is now needed. We also proposed that listing ''____ servings per container'' with the blank filled in with the actual number of servings directly beneath the ''Nutrition Facts'' heading, and highlighting it in bold or extra bold type, would help increase awareness that the information presented in the Nutrition Facts label does not refer to the contents of the entire package when the label indicates that there is more than one serving per container. We explained that listing ''Serving size'' in the same proximity to where the actual nutrient information is located on the label (rather than directly beneath the Nutrition Facts heading as in our preexisting regulations, § 101.9(d)(3)) would help consumers understand that this nutrient information pertains to the particular serving size that is declared. (According to the graphic design principle of proximity, items that are positioned closer together are perceived to be more closely related (Ref. 262)). Thus, we tentatively concluded that reversing the order of the declarations of ''Servings Per Container'' and ''Serving Size'' would help consumers more readily observe and comprehend the nutrition information appearing in the Nutrition Facts label, allow consumers to search for information with a minimum of effort, and assist consumers in their food purchasing decisions and in maintaining healthy dietary practices. We proposed to redesignate § 101.9(d)(3)(i) as § 101.9(d)(3)(ii), redesignate § 101.9(d)(3)(ii) as § 101.9(d)(3)(i), and to make changes in how the serving size information is capitalized on the label so that no capital letters are used, except for the first letter in ''Serving size.'' We also proposed to require that the declaration of ''____servings per container'' (with the blank filled in with the actual number of servings) be highlighted in bold or extra bold type and be in a type size no smaller than 11 point (except for the tabular and linear displays for small packages) (proposed § 101.9(d)(3)(i)), and that the information for ''Serving size'' be in a type size no smaller than 8 point (except for the linear display for small packages) (proposed § 101.9(d)(3)(ii)).

We did not propose similar changes for serving size information for dietary supplements. In the preamble to the

proposed rule (79 FR 11879 at 11950), we said that, when taking dietary supplements, consumers need to know how much of the product to take (*e.g.,* 1 capsule, 2 tablets, 1 packet) and that this information, which is currently provided in the ''Serving Size'' line of the Supplement Facts label, is more important for the consumer to know than the number of servings (*e.g.,* 100 tablets) contained in the package.

(Comment 486) Many comments supported changing the order of the ''Serving Size'' and ''Servings Per Container'' declarations because the comments felt that this change would make the label easier to read and understand. The comments said consumers would be better able to compare products when shopping and make better buying decisions, which could ultimately lead to improved health for themselves and their families. Other comments suggested that the proposed changes could help consumers understand that nutrition information on the label is based on the serving size, which could increase awareness of the amount of food actually being consumed. In addition, comments said that the proposed change could help consumers monitor their caloric and nutrient intakes, compare products more easily, eat more moderate portions, and more easily grasp the relative significance of a food product in the context of their daily diet.

Other comments said that reversing the order of serving size and the number of servings per container, especially in combination with increasing the prominence of information about calories, would make the relationship between the ''Calories'' and ''Serving size'' declarations clearer, lead to a better understanding of the calories information, and improve the flow of the label.

In contrast, several comments opposed changing the order and said we should continue to list ''Serving size'' above ''____ servings per container.'' The comments suggested that information about a product's serving size was more important than the number of servings per container because the label's information is based on the serving size declaration. Many comments that opposed reversing the order of serving size and servings per container expressed a preference for us to increase the prominence of serving size instead. The comments said that putting the ''Serving size'' declaration in bold print and increasing its type size would emphasize its importance and increase awareness that the nutrition information on the label is based on the serving size.

(Response) As we explained in the preamble to the proposed rule (79 FR 11879 at 11949), reversing the order in which ''Serving Size'' and ''Servings Per Container'' are listed would place the serving size information in closer proximity to where the actual nutrient information is located on the Nutrition Facts label. According to graphic design principles (*i.e.,* the principle of ''proximity''), this would increase the perception that the serving size is closely related to the nutrition information that follows directly below it, and thus provide necessary context for helping consumers understand that this nutrition information pertains to the particular serving size that is declared. If the order of the ''Serving Size'' and ''Servings Per Container'' declarations was preserved as in our preexisting regulations and as preferred by some comments, the relationship between the nutrition information and the serving size might be less clear. Although some comments suggested that we put the serving size declaration in bold print rather than shift its position, it is unlikely that bold print, alone, would provide the necessary context for helping consumers to understand the association between serving size and the nutrient information because these pieces of information in the preexisting regulation would be lacking in proximity, and the contrast between the ''Serving size'' declaration and the ''Nutrition Facts'' heading directly above it would be reduced if both were in a bold or extra bold font. We address the comments concerns regarding increased emphasis of ''serving size'' instead of ''servings per container'' in our response to comment 488.

Therefore, the final rule, at § 101.9(d)(3)(ii), requires that ''serving size'' be placed below ''__Servings per container.'' The final rule also requires the information to be highlighted in bold or extra bold and be in a type size no smaller than 10 point, except the type size must not be smaller than 8 point for the information for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and (*2*). Displaying both pieces of information related to serving size adjacent to each other should help consumers understand how the serving size relates to the nutrition information on the label and use the label to plan and maintain healthy dietary practices. It is important for consumers to understand the serving size and realize how it relates to the rest of the label's nutrition information.

(Comment 487) Many comments supported inserting the actual number of servings at the beginning of ''servings per container'' statement because this could help consumers identify more readily the number of servings in a package and help consumers decide how many people a particular food item could serve or feed. The comments said that consumers would have a better idea of the total number of calories in the package as well as the number of calories they would actually consume if they eat the entire contents of a multi-serving package.

(Response) We agree with the comments, and so the final rule, at § 101.9(d)(3)(i), requires the actual number of servings at the beginning of the ''servings per container'' statement.

(Comment 488) Many comments agreed that increasing the prominence and visibility of ''servings per container'' would enable consumers to notice and use this information. The comments further stated that individuals who did not previously or regularly use the label might begin to do so and that increasing the prominence of the ''servings per container'' declaration would not only be ''eye catching'' and ''hard to ignore,'' but also would be helpful to people with poor vision or those who shop in dimly lit grocery stores.

Some comments suggested increasing the size and prominence of the ''Serving Size'' declaration, as well as that of ''servings per container.'' One comment acknowledged that one intention of the proposed rule is to help consumers more easily recognize multi-serving packages, but said there was no valid justification for making the ''____ servings per container'' information more prominent than the ''Serving size'' declaration. Another comment suggested that increasing the prominence of both calories and serving size could be especially important on labels of some sugar-sweetened beverages, particularly on products that may contain more than one serving, but are often consumed during one eating occasion.

Several other comments opposed increasing the prominence of ''servings per container'' because, according to the comments, ''serving size'' is the more important piece of information. The comments would emphasize ''Serving size'' in a larger and bolder font. Many comments said that making the serving size information easier for consumers to see and understand was important for properly interpreting the calorie information (in addition to increasing the prominence of ''Calories'') and is also ''what consumers are used to'' seeing. Several comments said that the proposed font size of the ''____ servings per container'' statement was so large

that consumers might mistakenly think that the number of calories listed in the ''Calories'' declaration on the label pertained to the entire package; *i.e.,* to all of the servings that appear in the ''____'' space. Another comment suggested reducing the type size for ''____ servings per container'' to a size smaller than the ''Amount per ____'' statement. One comment suggested that the relative differences in type sizes in the listings for the number of servings per container, the amount per serving, and the numeric value for ''Calories'' could result in consumers mistakenly associating the number of calories with the total package because the ''Amount per ____'' is relatively small compared to the other declarations. One comment said that giving increased prominence to ''Serving size'' would be a reasonable way to implement the recommendations of the OWG's Calories Count report and would be consistent with existing research data suggesting a lack of attention to this listing.

(Response) The comments reflect the need to consider how much emphasis to provide for the ''Serving size'' declaration compared to the ''____ servings per container'' declaration. We agree with the comments that the serving size information was not prominent enough in our proposal and that consumers could potentially associate the calorie and nutrition information on the label with the ''servings per container'' declaration since it was more prominent compared to the serving size declaration. We also agree that the ''servings per container'' declaration should be more prominent and visible than on the preexisting label so consumers will be able to use this information if they consume all or a larger portion of a multi-serving container. Increasing the prominence of the ''Serving size'' information by bolding and slightly increasing the font size will emphasize the importance of the information and, along with its placement, would assist consumers in better understanding how to use the Nutrition Facts label to interpret accurately the calories and nutrient information on the label that is directly below the ''Serving size'' declaration. To provide prominence to ''Serving size,'' however, we need to reduce the prominence of ''servings per container.'' According to graphic design principles (*e.g.,* contrast), alternating a larger and bolder type style with a smaller, regular type style on successive lines of the Nutrition Facts label will provide maximum visibility and optimal highlighting to the information that we wish to emphasize on the label (Ref. 262). Contrast is a graphic design principle that uses opposing elements (such as bolding) to differentiate objects in the same field of view, or to intensify the effect between objects that would otherwise look similar (Ref. 263). Thus, we are providing contrast in the first three lines of the Nutrition Facts label in the final rule (*i.e.,* the Nutrition Facts heading, the ''____ servings per container'' declaration, and the ''Serving size'' declaration) by alternating the use of bold font with non-bold font for this information. We also realize that enlarging the ''____ servings per container'' declaration through bolding may pose space challenges if the word ''about'' is used in this statement, which is allowed under § 101.9(b)(8)(i).

Therefore, the final rule requires that the ''Serving size'' declaration, and the quantitative information associated with this declaration, be listed in a type size no smaller than 10 point (except on labels of smaller packages with a total surface area available to bear labeling of 40 square inches or less and all tabular formats where a type size of 9 point type is permissible due to space constraints) and be highlighted in bold or extra bold type. Additionally, if a product has a ''Serving size'' declaration with too many characters to fit in the provided space allocated for the ''Serving size''declaration, then a type size of 8 point is permissible for any size package (§ 101.9(d)(3)(ii)). To reduce the prominence of the ''____ servings per container'' declaration, we are requiring that ''____ servings per container'' be listed in a regular type in a type size no smaller than 10 point (except on labels of smaller packages with a total surface area available to bear labeling of 40 square inches or less (§ 101.9(j)(13)(ii)(A)(*1*) and (*2*)) where a type size of 9 point is permissible due to space constraints) directly beneath the Nutrition Facts heading, followed directly below by the ''Serving size'' declaration in bolder font.

(Comment 489) One comment referred to a study suggesting that many consumers do not look at serving size information, but otherwise do refer to the Nutrition Facts label and ingredients list, as evidence that the serving size declaration needs to be made more prominent. Other comments suggested that we should more closely review previous consumer research studies or conduct additional studies to determine the effects of displaying ''Serving size'' and ''servings per container'' information more prominently, and determine the potential implications of increasing the prominence and changing the location of the ''____ servings per container'' information on the Nutrition Facts label.

(Response) We disagree with the comment suggesting that many consumers do not look at serving size information, but otherwise do refer to the Nutrition Facts label and ingredients list. The comment apparently misinterpreted a published abstract (Ref. 264) of a study that investigated consumer perceptions and use of the serving size information, ingredient list, health claim information, and the Nutrition Facts label in general, particularly with regards to the extent that each of these impact purchasing decisions. The study, which drew on data from the 2005–2006 and 2007–2008 NHANES, was recently published in its entirety (Ref. 265). In contrast to what the comment said, the abstract stated that the study participants were more likely to use the Nutrition Facts label (in general) and the ingredient list in particular than information about serving size and health claims. In addition, according to data from the NHANES 2009–2010 cycle, approximately 64 percent of respondents (16+ years of age) reported at least ''sometimes'' using the serving size information on the food label when deciding to buy a food product, and 31 percent of the respondents reported that they used the serving size information either ''always'' or ''most of the time'' (Ref. 266).

As for the comments suggesting that we need to evaluate consumer research and conduct further research in regards to switching the order and increasing the prominence of ''Serving size'' and ''servings per container,'' we address these issues in our responses to comments 478 and 480. We also note that we are finalizing the requirement to include, directly below ''Nutrition Facts,'' the ''servings per container'' declaration followed by the ''Serving size'' declaration. As we explain in our response to comment 488, the location of ''Serving size'' to where ''servings per container'' was formerly located places it in closer proximity to the nutrient information that pertains to the serving size of the product.

(Comment 490) One comment said that ''____ servings per container'' is irrelevant information because the nutrition information on the label refers to the amount of nutrients and calories in a single serving. The comment would have the Nutrition Facts label emphasize the size of a serving (*i.e.,* the serving size) rather than the number of servings that are in the container.

(Response) The declaration of ''____ servings per container'' provides important information to the consumer

about how the information on calories and nutrients for one serving of food relate to the entire package of food. Consumers may consume more than one serving and need to know how the portions consumed relate to their total daily dietary intake. Therefore, we decline to revise the rule as suggested by the comment. However, we have revised § 101.9(d)(3) to clarify that both the ''____ servings per container'' and ''Serving size'' declarations are components of the serving size information required on the label.

(Comment 491) Other comments opposed increasing the prominence of ''__ servings per container'' because, in combination with other proposed changes, it would increase the space requirements for the Nutrition Facts label. One comment said that, because of space limitations on the label, we should not require the words ''per container'' to be included in the ''____ servings per container'' statement. The comment further said that ''per container'' is not needed for consumers to identify the number of servings in the package. The comment cited data from an online consumer research study (Ref. 267) to assert that 98 percent of the study participants correctly identified the number of servings per package and the serving size when the label did not include the words ''per container,'' while 92 percent of respondents who viewed the proposed Nutrition Facts label (*i.e.,* ''____ servings per container'') were able to correctly identify this information.

(Response) We note in our response to comment 488 that we are requiring that ''____ servings per container'' be listed in a type size no smaller than 10 point (except on labels of smaller packages with a total surface available for labeling of 40 square inches or less, where the type size will be no smaller than 9 point) and in regular font in order to provide adequate contrast to the prominent information displayed directly above and below it (*i.e.,* the ''Nutrition Facts'' heading and ''Serving size'' information, respectively). We disagree that the words ''per container'' should not be required to be included in the ''____ servings per container'' statement because ''per container'' would provide context and a frame of reference for the number of servings. Furthermore, the comment did not provide adequate details about its study design, methodology, and statistical analyses, and did not include data that would enable us to appropriately evaluate the survey results. Including the words ''per container'' would remove any potential ambiguity between servings per container and the serving size information, which would help clarify the number of servings to which the label refers. Although the survey findings reported in the comment indicated that respondents did not need to see ''per container'' on the label to correctly interpret information about serving size and the number of servings per container, it is difficult to evaluate the results without any data. Therefore, we decline to change our longstanding practice of including ''per container'' as part of the ''servings'' declaration, as this information is intended to help consumers accurately identify the number of servings in a package.

(Comment 492) Many comments suggested that we explain that nutrition information is based on the serving size listed in the Nutrition Facts label or conduct an education program to help consumers understand that the label serving size is not a recommendation but is based on actual food intake data. Some comments also asked us to explain the difference between serving size and portion size. One comment stated that, because some consumers use the terms ''serving size'' and ''portion size'' interchangeably, we should clarify the label by either: (1) Denoting the serving size provided as a ''typical'' serving size; or (2) including a footnote to clarify that ''the serving size is based upon the amount typically consumed, and is not a recommended portion size.'' Other comments said it was important to educate consumers that, if one eats more than one serving of a food product, the amount of calories consumed will increase proportionally.

(Response) We recognize the importance of providing consumers with more in-depth information about the meaning of the serving size and intend to make this a key component of our future nutrition education efforts for consumers. However, we decline to revise the rule to add a footnote to the Nutrition Facts label to indicate that the serving size is based on what is typically consumed, rather than what is recommended. Manufacturers can include a truthful and not misleading statement explaining the meaning of serving size elsewhere on the product label.

4. Right-Justifying the Quantitative Amounts Declared in the ''Serving Size'' Statement

In the preamble to the proposed rule (79 FR 11879 at 11950), we said that we tentatively concluded, based on design considerations, that the label statement for ''Serving size'' in both household units (*e.g.,* cups, tablespoons, teaspoons, pieces or slices, as explained in § 101.9(b)(5)) and gram amounts must be right-justified on the same line that ''Serving size'' is listed. Under our preexisting regulations at § 101.9(d)(12), this numerical information is stated immediately adjacent to the ''Serving Size'' declaration. By keeping the proposed ''Serving size'' declaration left-justified while right-justifying the corresponding numerical values, the proposed change would create white space on the Nutrition Facts label that would result in a less cluttered appearance, heightened focus and emphasis, and improved readability (Ref. 268). This design feature would provide enhanced emphasis to the information about serving size, allowing this information to be more noticeable and thereby facilitating its access and use by consumers.

(Comment 493) Some comments addressed the issue of right-justifying the quantitative amounts declared in the ''Serving size'' statement. One comment suggested that moving the serving size information to the right-hand side of the Nutrition Facts label would help emphasize the information, create white space leading to a less cluttered appearance, and would allow the eye to ''flow across the information.'' Another comment said that the proposed change would make it easier for readers to find the values for calories, serving size, number of servings per container, and percent Daily Values if all of these values were consistently placed in the same right-hand side of the label.

One comment opposed to right-justifying the serving size quantitative information on the Supplement Facts label. The comment said that because the ''Serving size'' declaration must be left-justified, the quantitative information for serving size should appear near this declaration, rather than on the other side of the panel where it would be separated by a large white space. The comment added that this may be a particular concern for dietary supplement products that use dual column labeling (*e.g.,* with columns for ''Per Serving'' and ''Per Day'').

(Response) Keeping the ''Serving size'' declaration left-justified, while requiring the corresponding numerical value be right-justified, provided that adequate space is available, will make this information more noticeable and facilitate its access and use by consumers. Although we did not propose to right-justify quantitative amounts in the ''Serving size'' declaration in the Supplement Facts label, we agree that it would not be appropriate to do this. The ''Supplement Facts'' title in the Supplement Facts label requires more

space than the ''Nutrition Facts'' title in the Nutrition Facts label and (unless impractical) must span the full width of the label (§ 101.36(e)(1)). Also, the Supplement Facts label is less likely than the Nutrition Facts label to be situated on the narrow side panel of a package. Therefore, because Supplement Facts labels are often wider than Nutrition Facts labels, right-justifying the serving size amount might leave too much white space between the words ''Serving size'' and the quantitative amount. It may not be apparent on some Supplement Facts labels that the quantitative amount per serving listed on the far right side of the label would refer to the serving size declaration, which would be left-justified. With dietary supplements in particular, it is important that consumers understand the serving size unit (*e.g.,* 1 tablet, 1 capsule) to minimize the possibility of taking an excessive amount of the product. The serving size amount also is important so that consumers can understand and follow instructions on dietary supplement labels for the suggested use of the product, which explain how, when, or how much of the product to take daily and (if applicable) the amount not to exceed. Therefore, the final rule only requires that quantitative amounts declared in the ''Serving size'' statement be right-justified on Nutrition Facts labels, provided that adequate space is available, and not on Supplement Facts labels.

5. Changing the ''Amount Per Serving'' Statement

Our preexisting regulations require the Nutrition Facts label to include a subheading designated as ''Amount Per Serving'' and to separate this subheading from the serving size information by a bar (§ 101.9(d)(4)) and highlight the subheading in bold or extra bold type or other highlighting (§ 109(d)(1)(iv)). The proposed rule would change the ''Amount Per Serving'' declaration to ''Amount per _____'', with the blank filled in with the actual serving size expressed in household units. We also proposed increasing the type size of this information and, to heighten contrast with the calories information, using semi-bold rather than bold or extra bold highlighting. We explained, in the preamble to the proposed rule (79 FR 11879 at 11950), that these changes would make it easier for label users to understand what the nutrition information in the Nutrition Facts label refers to, because it would eliminate the need to first locate the ''Serving size'' declaration to see what the serving size unit is. Because studies suggest that consumers often find serving size information difficult to interpret (Ref. 9) we stated that specifying the actual serving size in the ''Amount per _____'' declaration would likely help consumers to more readily observe and comprehend the nutrition information that is displayed in the label.

(Comment 494) Some comments supported the proposed change and said that replacing ''Amount Per Serving'' with ''Amount per _____'' would reinforce the concept of serving size and help people realize how many calories are actually in a serving of the product. One comment said it was reasonable for the label to include duplicate information (*i.e.,* in both the ''Serving size'' and ''Amount per _____'' declarations) about what constitutes a serving because it is important for consumers to understand that the nutrition information on the label is based on the serving size. Another comment suggested that both the ''Serving size'' and ''Amount per _____'' declarations should be bolded to increase their visibility.

Many comments disagreed with the proposed change and said it would make the serving size information repetitive, create unnecessary clutter, and impose additional space constraints on the label. One comment said that including duplicative information about serving size would be distracting and ''slow down'' the comprehension process, especially if the serving size is listed as a fraction (*e.g.,* ⅔ cup). Another comment suggested that listing the serving size in the ''Amount per _____'' statement is unnecessary because our proposal to reverse the order of ''Serving size'' and ''Servings Per Container'' and make the ''____ servings per container'' information more prominent already allows the serving size to be more easily identified. The comment said that only the ''Serving size'' declaration should be used to indicate the amount of food contained in a serving, and that doing so would maintain consistency with the current Nutrition Facts label.

Another comment suggested improving the clarity of the label by moving the ''Amount per _____'' declaration directly above the list of percent Daily Values, listing the serving size after ''Calories '' (*i.e.,* ''Calories per _____''), and using the same type size for the ''Serving size'' and ''Amount per _____'' declarations. Another comment said that changing ''Amount Per Serving'' to ''Amount per _____'' should be voluntary for dietary supplement labels, but if the change is made mandatory, then manufacturers should have the option of using the abbreviation ''Amt Per _____'' on Supplement Facts labels when extra space is required for the quantity statement (*e.g.,* ''2 capsules'').

(Response) We recognize there are multiple viewpoints and potential advantages and disadvantages with respect to listing the actual serving size in the blank space of the ''Amount per _____'' declaration. We acknowledge that inserting the serving size in the blank space would essentially repeat the value for serving size that is listed directly above this statement. We further agree that this information would be duplicative and add to the amount of numerical information already present on the label. Therefore, we will retain the preexisting requirement to declare ''Amount per serving'' directly above the ''Calories'' declaration rather than finalize a change to declare ''Amount per _____'' with the blank filled in with the actual serving size expressed in household units. We also will retain the preexisting requirement to list ''Amount per serving'' in bold or extra bold type or other highlighting and in a type size no smaller than 6 point rather than finalize a change in type size and contrast.

With respect to the comment that said changing ''Amount Per Serving'' to ''Amount per _____'' should be voluntary for dietary supplement labels, we did not propose this change for the Supplement Facts label. Consequently, there is no need to provide the option of using the abbreviation ''Amt Per _____'' on Supplement Facts labels as the comment requested.

6. Declaration of ''Calories From Fat''

The proposed rule would eliminate the requirement for declaring ''Calories from fat'' on the label.

Most comments supported removing the requirement for declaring ''Calories from fat,'' and we discuss those comments in part II.E.1.

7. Presentation of Percent DVs

Our preexisting regulations at § 101.9(d)(7) establish the format for listing nutrients with DRVs on the Nutrition Facts label, including the quantitative amount by weight and percent DV. The preamble to the proposed rule (79 FR 11879 at 11950 through 11951) explained that, when we established the requirements for percent DV declaration, we considered that the information would help consumers evaluate the nutrient characteristics of a single product (*e.g.,* how high or low a particular product is in certain nutrients or the extent to which it contributes toward daily nutritional goals) and help

consumers make choices between products. We also explained that consumer research back in 1992 indicated that the percent DV information improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet and helped consumers to verify the accuracy of front panel claims (*id.*).

The proposed rule would use ''% DV'' rather than ''% Daily Value'' as the column heading above the nutrient listings to provide consistency among the different label formats and to maintain the alignment of this heading over the DV column. For most labels, the proposed rule also would list percent DVs in a column to the left of the names of the nutrients and their quantitative amounts, with a thin vertical line separating the % DV column from the list of nutrients. On dual column labels and on labels using the aggregate display, we proposed to list the names of nutrients to the left of the % DV columns and the quantitative (weight) amounts of each nutrient to the right of the % DV column, to use thin vertical lines to separate the information in the ''% DV'' column from the information in the column containing the quantitative weights, and to use the same style of thin vertical lines to separate each of the dual columns and aggregate display columns from each other.

We also invited comment on alternative terms that may be more readily understandable than Daily Value, such as Daily Guide or Daily Need; whether the word ''percent'' (or the % symbol) needs to precede whatever term is used in the column heading where the percent DVs are listed or if this would be redundant because the ''%'' symbol is already included next to the numerical values listed in this column; and the appropriate placement of percent DVs in the labeling of foods for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women (*id.* at 11961).

(Comment 495) Some comments supporting our proposal said that moving the percent DVs to the left would draw attention to this information and help people realize its importance. Some comments said that, because we read from left to right, people would be less likely to skip over the percent DVs. Furthermore, because the information would be more noticeable, consumers might find it more quickly and use it more often to judge the percent DV of a specific nutrient and to compare products when shopping, leading to healthier food choices. Other comments said that shifting the percent DV column to the left would be ''eye catching,'' create a cleaner design, and make the label more logical, better organized, and easier to read and comprehend. It also would improve the simplicity and visual clarity of the label, as recommended by the IOM.

Many comments that opposed placing the percent DV column on the left side of the label said that, because we read from left to right, consumers would see the percent DV before knowing to which nutrient the value referred. The comments said it is more logical to list an item first and then its value. Some comments said that moving the percent DV information to the left of the nutrient name would be counter-intuitive and confusing to consumers. One comment included data from a study it had commissioned; the study indicated that, when the percent DV was on the left side of the label, there was no advantage in consumer comprehension of this information. The study found that a higher percentage of respondents answered a question about Daily Values correctly when the percent DV information was on the right versus the left side of the label (Ref. 269). Another comment noted that the proposed label would be awkward to read because consumers would need to first find the name of the nutrient in the middle of the label.

Several comments agreed with the concern we expressed in the preamble to the proposed rule, that giving more prominence to the percent DV by listing it first could potentially make the Nutrition Facts label appear less user-friendly particularly to frequent users who are accustomed to its current format and could draw attention away from nutrients that do not have a DV (79 FR 11879 at 11951). Another comment said that shifting the percent DV to the left could hinder, rather than assist, individuals with lower levels of health literacy and numeracy in understanding the label.

Several comments said that moving the percent DV information to the left might cause layout problems for certain formats, such as dual-column labels, because of the difficulty in aligning the column headings with the information in the columns, and in differentiating the columns. Other comments expressed concerns that placing percent DVs on the left would be distracting because consumers are mainly interested in the quantitative values of nutrients and tend to look for that information rather than the percent DVs. Other comments said that increasing the focus on percent DVs would be misguided because the percent DVs are not relevant to people who do not eat 2,000 calories per day; moving the percent DVs to the left would make the label look ''foreign'' and would be an unnecessary change having no benefits; and shifting the location of the percent DVs would not help consumers understand the information any better than they currently do. Many comments said that, because people are generally confused by the meaning of percent DV and do not know how to properly use this information, percent DVs should not be given a more prominent placement on the left side of the Nutrition Facts label. Several comments said it was premature to shift the percent DVs to the left based solely on theoretical design principles, and that we should not do this unless research data become available demonstrating that this change would assist consumers in maintaining healthy dietary practices.

(Response) We acknowledge that the conventional way to display data would be to list the percent DV after the name of the nutrient, as shown in the preexisting Nutrition Facts label format, and that shifting the percent DVs to the left might present layout challenges with certain formats. We also note that the results of our consumer research study were equivocal, as we found that no significant benefit was achieved by shifting the percent DV column to the left side of the Nutrition Facts label (Ref. 270).

We have no evidence that the placement of the percent DV information on the left would result in less comprehension by consumers who do not understand the meaning of percent DV, as suggested by some comments. Nevertheless, we have reconsidered how percent DV should be presented and have decided to retain the preexisting requirement to list the percent DV information on the right side of the label.

We anticipate that an increased focus on percent DV through the introduction of a new footnote and enhanced consumer education efforts could help consumers who currently have some difficulty understanding percent DV become more comfortable using the percent DV information. Furthermore, we may study this issue, and other issues involving the DV, in the future.

(Comment 496) Several comments suggested that the term ''Daily Need'' would be more helpful to consumers than ''Daily Value.'' Another comment suggested using the term ''Daily Requirement'' because it would be ''more in keeping with a DRV calculation.'' The comment cautioned that the term ''Need'' may have a

negative perception because it conveys a ''personal tone'' and therefore may be seen as prescriptive or patronizing. An additional comment suggested using ''% Ref'' instead of ''% DV.''

(Response) In the preamble to the proposed rule, we said that we had previously provided our rationale for choosing the term Daily Value in the format final rule (58 FR 2079 at 2124, January 6, 1993) and had explained why we considered ''need'' and ''requirement'' to be misleading terms that might complicate nutrition education efforts. Although one comment suggested the use of the term ''% Ref.'' (which we interpret as meaning % Reference) instead of % DV, the comments, in general, did not suggest alternative terms or provide data or information to support why an alternative term would be more appropriate or preferable. Thus, we continue to believe that the term Daily Value is generally understood by consumers to be a point of reference (see 58 FR 2079 at 2125) and will continue to use Daily Value as an appropriate single term to refer to all reference values in the Nutrition Facts label.

(Comment 497) Many comments opposed the use of the abbreviated term % DV, and suggested that spelling out the term Daily Value would be clearer and easier to comprehend, eliminate possible confusion about the meaning of DV, and not require an explanatory footnote. Some comments stated that, while abbreviating Daily Value would save space, the abbreviation would not be helpful if consumers did not understand the abbreviation, especially when consumer research has shown that the term Daily Value is not well understood. One comment noted that if ''% Daily Value'' was abbreviated to ''% DV,'' we might replace a concept that is already obscure with a shorthand designation that would be even more obscure to consumers.

Another comment suggested that consumer research is needed to evaluate the impact that changing % Daily Value to % DV would have on consumer use and understanding of this information. Some comments supported using ''%'' rather than spelling out ''percent'' because, according to the comments, it would decrease the amount of clutter on the label, and the term ''percent'' requires more label space without providing additional information or benefits to consumers. Another comment questioned whether either ''percent'' or the ''%'' symbol should be used on the label because the comment said that many consumers have difficulty understanding the concept of percent.

(Response) We acknowledge that the term % DV is spelled out on most labels (with the exception of some small packages) and therefore the term ''% Daily Value'' should be familiar to consumers. We also acknowledge that it would be desirable for the Nutrition Facts label to be able to ''stand alone'' as a source of information to assist consumers in maintaining healthy dietary practices, and that the label should be self-explanatory insofar as possible. By spelling out the words Daily Value instead of abbreviating them, the meaning of the nutrition information presented on the Nutrition Facts label would be less ambiguous to consumers, alleviate the need to explain the abbreviation, and improve the ability of the label to stand alone. Therefore, the % Daily Value, rather than % DV, should be used as the column heading for most formats if space is available. In order to provide flexibility to manufacturers when there are space constraints on packages and to facilitate alignment of the % Daily Value column heading with the nutrient information listed beneath it, particularly on formats in which there are multiple columns of information, we are retaining the provision in our preexisting regulations (§ 101.9(d)(6)) that allows for the substitution of ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' for ''% Daily Value.''

With respect to whether consumers may have difficulty understanding the concept of percent, our public education program will help consumers understand how to use the percent DV information and become more comfortable with the concept of percent. We will continue to use percentages on the Nutrition Facts label for presenting nutrition information because it is useful for assisting consumers in maintaining healthy dietary practices.

(Comment 498) One comment requested clarification with regards to how the percent DV information should be displayed for the nutrients of public health significance when these nutrients are listed either vertically or horizontally in two columns (*i.e.,* the side-by-side arrangement), as permitted in § 101.9(d)(8). The comment said there was a discrepancy in how we described the vertical arrangement of nutrient information for vitamins and minerals in § 101.9(d)(8) and how this information was displayed in the label format shown in proposed § 101.9(d)(12). The comment further suggested that the phrase ''or may be listed in two columns'' should be clarified, particularly with regards to the placement of the nutrient name, the % Daily Value, and the quantitative amounts, and that an example of this label would be helpful.

(Response) The description of the vertical array of vitamins and minerals in § 101.9(d)(8), which the comment said was inconsistent with the associated mockup because the percent Daily Values were listed in parentheses in the regulation, was not meant to be a literal description of what was shown in the label mockup in proposed § 101.9(d)(12). However, we agree with the comment that the phrase ''or may be listed in two columns'' needs to be clarified, particularly with regards to where the percent Daily Values and the absolute amounts are displayed relative to the names of the respective vitamins and minerals. Therefore, we have now stated in § 101.9(d)(8) that the name of the nutrient will be listed first, followed by the absolute amount and then by the percent Daily Value (which will be listed to the right of the absolute amount and without parentheses). Furthermore, as the comment suggested, we have provided a mockup showing the horizontal (*i.e.,* side-by-side) display of the vitamins and minerals in § 101.9(d)(8). However, we also note that mockups are provided as examples of labels, and are meant to serve as illustrations rather than as indications of specific requirements. We have not provided mockups of all possible types of labels and we did not intend to state literally in the regulation what was shown in the various label mockups.

8. Placement of ''Added Sugars''

The proposed rule would require the declaration of added sugars as an indented line item underneath the declaration of total sugars on the Nutrition Facts label. In the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule that would, among other things, establish a DRV of 10 percent of total energy intake from added sugars and require the declaration of the percent DV for added sugars.

We did not receive any comments regarding the indentation of the added sugars declaration. We discuss the requirements for the added sugars declaration in part II.H.3.

9. Declaration of Absolute Amounts of Vitamins and Minerals

The proposed rule would require the declaration of quantitative amounts for all vitamins and minerals listed on the Nutrition Facts label (except on labels of smaller packages with a total surface area available for labeling of 40 square inches or less as described in § 101.9(j)(13)(ii)(A)(*1*) and (*2*)), in addition to maintaining the current

requirement of declaring percent DVs. Because of space limitations, we proposed to require only the percent DV for vitamins and minerals (other than sodium) on labels of foods in small or intermediate-size packages having a total surface area available to bear labeling of 40 or less square inches. As we explained in the preamble to the proposed rule (79 FR 11879 at 11928 through 11929), comments received in response to the 2007 ANPRM, as well as the 2003 IOM report (Ref. 219) supported declaring both the absolute amounts of mandatory and voluntary micronutrients on the Nutrition Facts label in addition to the percent DVs (when they exist). Among other reasons, the IOM report said that listing absolute amounts of all vitamins and minerals would make the Nutrition Facts label internally consistent and more aligned with the current requirements of the Supplement Facts labels (§ 101.36(b)(3)(ii) and (iii)).

We also considered previous research which indicated that both consumers and health professionals have difficulty understanding how percent DVs relate to the absolute amounts of nutrients listed on the Nutrition Facts label (Ref. 239). The previous research indicated that physicians, dietitians, and other health professionals found it easier to refer to absolute amounts of nutrients rather than to the percent DVs when advising patients. The results suggested that declaring both the absolute amount and the percent DV would improve understanding of the label.

(Comment 499) Many comments agreed that we should require the declaration of absolute amounts of all vitamins and minerals on the Nutrition Facts label. Some comments said that people, especially those with low numeracy skills, have difficulty understanding the concept of ''percentage'' (such as percent DV) and would prefer using nutrition information expressed in absolute amounts rather than in percentages to plan diets. The comments also suggested that people who want to follow a health professional's nutrition guidance, such as advice to consume a specific amount of a nutrient (*e.g.,* 500 mg calcium/day), would find quantitative amounts on labels to be more useful than the percent DVs.

Other comments from registered dietitians said they perceived percent DVs to be confusing and cumbersome and preferred to use absolute amounts of nutrients when counseling clients on how to use the Nutrition Facts label to build a healthy diet, compare food products, and establish dietary goals.

In contrast, many comments expressed concerns that declaring absolute amounts of all vitamins and minerals, in addition to the percent DV, would make the label more confusing, cluttered, and difficult to read. The comments said that listing quantitative amounts of all vitamins and minerals would take up valuable label space and add complexity to the label without providing any tangible benefits to consumers. Several comments said that the percent DV listing already provides consumers with the information they need for choosing foods for a healthy diet, so it is not necessary to also list the absolute amounts for all nutrients on the Nutrition Facts label. The comments questioned whether consumers would understand how to use absolute amounts in conjunction with the percent DV and said there was little evidence that declaring absolute amounts on the Nutrition Facts label would help consumers maintain healthful dietary practices. Some comments expressed concerns that, because consumers in general are not familiar with metric system units such as grams, milligrams, and micrograms or the relative magnitude of differences between these units, they may not realize that a quantitative weight listed as a large number, but expressed in micrograms, can actually represent a small amount of the nutrient. Another comment said that, because some high DVs are based on small quantitative amounts and some small DVs are based on high quantitative amounts, the quantitative information could be confusing to consumers.

(Response) In the past, we have stated that we must be selective with regard to the information we require to be listed on the label and that not all vitamins and minerals are of equal public health significance (58 FR 2206 at 2107). We have limited the mandatory declaration of vitamins and minerals to those of particular public health significance. These vitamins and minerals include vitamin D, calcium, iron, and potassium, which are ''shortfall'' nutrients in the general U.S. population that are often consumed in inadequate amounts. In addition, we are requiring the absolute amount for folic acid in mcg to be declared when folic acid is added as a nutrient supplement or claims are made about the vitamin on the label or in labeling of foods (§ 101.9(c)(8)(ii) in the final rule).

As we stated in the preamble to the proposed rule, research suggests that consumers and health professionals have difficulty understanding how percent DVs relate to the absolute amounts of nutrients (79 FR 11879 at 11928 through 11929). We recognize that some consumers, particularly those with low numeracy skills, may be better able to understand and use the listed quantitative amounts of nutrients (*e.g.,* milligrams of calcium) on the label when making dietary choices, rather than relying solely on the percent DV, because they would need to know the calculation for converting percent DV to milligrams. Thus, although some comments would not list absolute amounts because (according to the comments) the percent DV already gives consumers the information they need for choosing foods for a healthy diet, the percent DVs and absolute amounts, particularly for nutrients of public health significance, are useful because consumers receive information on the recommended intake of these vitamins and minerals in quantitative amounts (*i.e.,* the advice is given in milligrams, micrograms, or International Units) through public sources and from health professionals (Refs. 219, 271–272). Furthermore, folic acid intake is related to the risk reduction of neural tube defects, and is generally provided in terms of mcg of folic acid. By requiring the mandatory declaration of folic acid as a quantitative amount by weight in mcg, when folic acid is added or when a claim is made about the vitamin in labeling, women of childbearing age can gain a better understanding of the unique contribution that synthetic folic acid from food provides in reducing the risk of neural tube defects and will have the information they need to improve their ability to adhere to nutrition recommendations with respect to folic acid.

Thus, requiring both the quantitative amount and the percent DV will help to ensure that consumers are fully informed about the content of these products, similar to how these nutrients are declared in dietary supplement product labeling (56 FR 60366; November 27, 1991). Nevertheless, we have decided not to include in the final rule the proposed requirement to include the declaration of absolute amounts for all vitamins and minerals. We clarify, in § 101.9(c)(8)(ii), that the declaration of voluntarily declared vitamins and minerals listed in paragraph (c)(8)(iv) may include the quantitative amount by weight and percent of the RDI. We also revised the preexisting requirement in § 101.9(c)(8) to remove the requirement that the declaration for vitamins and minerals include a statement of the amount per serving as a percent DV. A requirement to compel absolute amounts for all vitamins and minerals could make it

difficult for consumers to use and read the label, particularly on fortified foods such as cereals where many vitamins and minerals may be listed. In addition, the public health need among the general U.S. population is not as great for listing quantitative amounts for voluntary vitamins and minerals, such as thiamin, riboflavin, or niacin, because deficiencies of these vitamins are rare and because enriched bread, rolls, and buns must be fortified with these nutrients. Requiring the declaration of absolute amounts of nutrients of public health significance, and folic acid when added as a nutrient supplement or claims are made about the vitamin, while providing voluntary declaration of absolute amounts for other vitamins and minerals, will provide manufacturers with flexibility in assessing how much voluntary information to provide on the Nutrition Facts label without creating unnecessary clutter. However, if one of these other vitamins or minerals is added as a nutrient supplement or there is a claim made about it, the manufacturer must include a declaration of the nutrient as a percent DV, or alternatively, as a quantitative amount by weight and percent DV (§ 101.9(c)(8)(ii) in the final rule).

With respect to the comment expressing concern that quantitative information could be confusing to consumers, the comment discussed a situation where a product that contains 100 percent DV for vitamin D and lists only 20 mcg (a ''low'' amount) on the label also contains 5 percent DV for potassium, which would correspond to an absolute amount of 235 mg (a ''high'' amount). However, only two of the four nutrients (vitamin D and potassium) are new nutrient declarations under the final rule, and we expect consumers to become familiar with these nutrients as part of the new label. Vitamin D is a shortfall nutrient that many health professionals discuss with their clients or patients as part of a healthy dietary intake. As noted elsewhere in part II.N.4, vitamin D must be listed in micrograms and may be listed voluntarily in International Units. In addition, although only the percent Daily Values for calcium and iron are currently listed on the Nutrition Facts label, consumers who take these nutrients as dietary supplements may be familiar with the corresponding quantitative amounts because these must be declared on Supplement Facts labels. Furthermore, the Nutrition Facts label has included metric units since its inception in 1993, so consumers have had considerable exposure to metric units such as grams and milligrams. To the extent consumers are less likely to be familiar with ''micrograms'' (mcg), we anticipate that consumers will become increasingly familiar and comfortable with this metric unit and others on the Nutrition Facts label. We plan to address the different nutrients of public health concern and their units of measure as part of our education efforts aimed at enhancing consumer understanding of the label.

(Comment 500) Some comments said that for people who have special dietary requirements because of a medical condition, such as chronic kidney disease, the percent DV by itself may be inadequate for making decisions about food selections (*e.g.,* kidney patients who monitor their phosphorus intake would find the phosphorus content expressed in milligrams to be more useful than the % DV of phosphorus).

(Response) While the Nutrition Facts label information has never been, nor is it now, targeted to individuals with acute or chronic disease, consumers may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions (see part II.B.2).

(Comment 501) Several comments questioning the need for declaring absolute amounts of vitamins and minerals on the Nutrition Facts label said that people who meet their nutritional needs through conventional foods are less likely to be interested in quantitative amounts of vitamins and minerals compared to those who use dietary supplements to supplement their diets with specific amounts of such nutrients. The comments said that labels designed for conventional food products and for dietary supplements are not necessarily analogous because the two types of products have different purposes as reflected in their nutrient composition; *e.g.,* nutrient levels in dietary supplements are often much higher than those in foods and beverages. The comments also noted that, because there is a greater potential for toxicity resulting from the use of dietary supplement products due to overconsumption compared to conventional food products, it is important that nutrient levels on Supplement Facts labels be expressed in absolute amounts so that this information is plainly visible to consumers.

(Response) Requiring the absolute amounts of vitamins and minerals for the nutrients of public health significance and folic acid under the circumstances previously described will help ensure that consumers are fully informed about the content of conventional foods and will achieve parity in labeling for nutrients of public health significance in conventional foods and dietary supplements. We do not consider issues related to potential greater toxicity from consumption of nutrients in dietary supplements to negate the benefits of also providing for conventional foods the information on absolute amounts for these particular nutrients of public health significance that are considered shortfall nutrients.

Requiring absolute amounts of vitamins and minerals of public health significance and folic acid under the circumstances previously described to be listed on the Nutrition Facts label will make it easier for both consumers and health professionals to understand and use the Nutrition Facts label and help consumers in maintaining healthy dietary practices. Furthermore, consumers can use the information to obtain these shortfall nutrients primarily through healthy eating patterns containing nutrient-dense conventional foods, as recommended by the DGA (Ref. 28).

(Comment 502) Several comments expressed concerns that requiring the absolute amounts of all vitamins and minerals to be listed on the Nutrition Facts label would be problematic because FDA's established rounding rules only apply to percent DV declarations, and the proposed rounding rules for declaring quantitative amounts of vitamins and minerals are not clear. The comments said that different products having the same absolute amounts of a nutrient listed on the label may have different percent DVs associated with that nutrient due to rounding. Some comments also said that two different products having the same percent DV for a nutrient may declare different absolute amounts for that nutrient, which would lead to consumer confusion. In addition to such discrepancies, several comments said it is not feasible to require absolute amounts of vitamins and minerals to be listed because analytical assays for obtaining this information lack the necessary precision, resulting in considerable variability in results from assay to assay. Other comments said that levels of nutrients in foods and food products are naturally variable and due to this variability, declaring absolute amounts would imply greater precision than is currently required for the declaration of the percent DV. The comments also said it would be particularly difficult and costly to obtain information on vitamin D levels because this information was not

previously required for most conventional food products.

(Response) The quantitative amount of sodium has always been required to be declared on the Nutrition Facts label, and dietary supplement products have required weight amounts to be declared since 1993. Rounding rules for the Nutrition Facts label have been established for potassium (§ 101.9(c)(5)) and for other vitamins and minerals (§ 101.9(c)(8)(iii)) in the Nutrition Facts label and for vitamins and minerals declared on labels of dietary supplements (§ 101.36(b)(2)(ii)(B) and § 101.36(b)(2)(iii)(B)). We discuss this topic further in part II.M.6. To declare the percent DV for vitamins and minerals on the Nutrition Facts label, manufacturers should already have information about the levels of nutrients in their products. Such information also can be obtained through laboratory analysis or by consulting standard nutrient databases, such as the USDA Nutrient Data Lab Standard Reference (*http://www.ars.usda.gov/Services/docs.htm?docid=8964*). Substituting vitamin D and potassium for vitamin A and vitamin C for the nutrient analysis should not result in a significant difference in cost to the manufacturer. Furthermore, we are not aware of problems in obtaining quantitative data related to variability and precision. Manufacturers already must address these issues to comply with the preexisting nutrition labeling regulations.

(Comment 503) One comment included the results of a consumer study to suggest that it is more important for FDA to gain a better understanding of how consumers use percent DV information rather than understand how consumers would use information on absolute amounts. The comment said that, according to its research, declaring absolute amounts on the label would decrease consumer attention to the percent DV information and would present ''significant implementation challenges.''

(Response) The comment refers to the study which we addressed in our response to comment 184. We are not aware of any evidence that including absolute amounts for the public health nutrients would detract from the percent DV information, and we intend to conduct consumer education on increasing the understanding of the percent DVs.

10. Single and Dual Column Labeling

The preamble to the proposed rule (79 FR 11879 at 11952 through 11953) noted that we have preexisting regulations for voluntary dual column labeling and that dual column labeling is mandatory for products that are promoted on the label, or in advertising, for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (*e.g.,* liquid cream substitutes promoted for use with breakfast cereals) (§ 101.9(b)(11)). The proposed rule would require (under certain conditions) dual column labeling where nutrition information would be presented based both on the serving size and on the entire package or unit of food.

We respond to comments on single and dual-column labeling in the final serving size rule.

(Comment 504 and Response) We address comments regarding dual column labeling in the final rule on ''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'' which is published elsewhere in this issue of the **Federal Register**.

11. The Footnote

Our preexisting regulations, at § 101.9(d)(9)(i), require the Nutrition Facts label to bear an asterisk after the ''% Daily Value'' declaration; the asterisk refers to a footnote that reads: ''*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.'' Our preexisting regulations also require, below the footnote, a table that lists DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets (§ 101.9(d)(9)(i)). However, the preamble to the proposed rule (79 FR 11879 at 11953) explained that the percent DV is not described in the footnote or anywhere else on the Nutrition Facts label, and so we wondered if such a description would help improve consumer understanding of the percent DV information. We also noted that consumers did not understand what was being conveyed in the footnote or the DRV table (id.). Consequently, we proposed to remove the requirement for the footnote table and to reserve a subparagraph (proposed § 101.9(d)(9)) for a future footnote. The preamble to the proposed rule (79 FR 11879 at 11953) also stated our tentative view that a new, simple footnote was needed to help consumers understand the meaning of the percent Daily Value. We said that the new footnote should have a larger type size, be more noticeable than the preexisting footnote, and include a statement that 2,000 calories a day is used for general nutrition advice (id.).

We also stated in the preamble of the proposed rule (id. at 11953 through 11954) that we would continue to conduct research during the rulemaking process to evaluate how variations in label format, including percent DV information in the footnote area, may affect consumer understanding and use of the Nutrition Facts label and that we would make the results of our study available for public review and comment.

In the preamble to the supplemental proposed rule (80 FR 44303 at 44306 and 44309), we described an experimental study on consumer responses to Nutrition Facts labels with various footnote formats. (We summarize the footnote study at part II.B.5.) The supplemental proposed rule would add language to the space reserved in proposed § 101.9(d)(9) to explain that the % Daily Value tells how much a nutrient in a serving of food contributes to a daily diet and that 2,000 calories a day is used for general nutrition advice. The supplemental proposed rule also would create an exemption to the proposed footnote requirement in § 101.9(d)(9) for the foods that can use the terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the Nutrition Facts label or in the labeling of foods as defined in § 101.60(b) because such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses. The supplemental proposed rule also would amend § 101.9(j)(13)(ii)(C) to allow the footnote to be omitted on small or intermediate-size packages (§ 101.9(j)(13)(ii)(A)(*1*) and § 101.9(j)(13)(ii)(A)(*2*)) provided that an abbreviated footnote statement (that % DV = % Daily Value) is used. Although the preamble to the supplemental proposed rule discussed allowing the footnote proposed in § 101.9(d)(9) to be omitted from products that qualify for a simplified format (§ 101.9(f)) (80 FR 44303 at 44309) provided that the abbreviated footnote statement is used, this provision was inadvertently omitted from the codified section of the supplemental proposed rule.

With respect to the Supplement Facts label, our preexisting regulations, at § 101.36(b)(2)(iii)(D), require that, if the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary

fiber, or protein on the Supplement Facts label, a footnote state that ''Percent Daily Values are based on a 2,000 calorie diet.'' The proposed rule would require, for a product that is represented or purported to be for children 1 through 3 years of age and contains a percent DV declaration for total fat, total carbohydrate, dietary fiber, or protein, that a symbol be placed next to the percent DV declaration that refers the consumer to a statement at the bottom of the label that says ''Percent Daily Values are based on a 1,000 calorie diet'' (79 FR 11879 at 11947). We illustrated this footnote in a mockup of a Supplement Facts label depicting a multiple vitamin product for children and adults (§ 101.36(e)(11)(ii)). In the preamble to the proposed rule, we invited comments on whether changes to the footnote statement on the Supplement Facts label should be consistent with any changes that are made to the footnote statement in the Nutrition Facts label (79 FR 11879 at 11948). In the preamble to the supplemental proposed rule, we invited comments on whether we should replace the preexisting footnote in the Supplement Facts label with a footnote comparable to what we would require for the Nutrition Facts label; *i.e.,* ''2,000 calories a day is used for general nutrition advice'' (80 FR 44303 at 44307).

(Comment 505) Many comments supported removing the footnote table listing DRVs for certain nutrients based on 2,000 and 2,500 calorie diets. The comments said that the footnote table is confusing and difficult to read; consumers generally do not understand how to use it and probably derive little value from it; and the footnote occupies valuable label space that could be used for other information. However, other comments favored retaining the footnote table, indicating that it is useful for nutrition education purposes, may help consumers gain a perspective on their daily nutrient intake, and is a convenient reference for consumers who want this information.

Other comments suggested that the footnote should contain additional information beyond what is currently included or proposed. For example, some comments said the footnote should continue to explain that percent DVs are based on a 2,000 calorie diet and that an individual's Daily Values may be higher or lower depending on one's particular calorie needs. Some comments expressed concern that, without context, the public will not know whether 2,000 calories represents too many or too few calories. In addition, some comments said we should require language in the footnote explaining that growing children and adolescents may need more or less than 2,000 calories per day, depending on their age, gender, size, and activity level.

Other comments suggested that, because some consumers may view the label serving size as a recommended portion size, or use these terms interchangeably, we should include a footnote clarifying that ''serving size'' is based on the amount typically consumed and is not a recommended amount.

Another comment said that the Nutrition Facts label should go beyond just providing factual information and be a ''tool'' to help consumers make healthier food and beverage choices. For example, the comment said we should use a footnote to provide consumers with information about nutrients on the label that are ''beneficial'' (such as dietary fiber) or ''harmful'' (such as saturated fat) to their health. Several comments also said that we should consider including a link to a Web page where consumers can find more information about nutrition, health and calorie needs.

Several comments suggested that we seek a broader understanding of how consumers use the footnote. The comments emphasized that any revisions to the footnote should be based on research, and that the results of our consumer research should be made available to the public for review and comment. However, other comments would remove the footnote entirely, and some comments suggested that, as part of our consumer studies, we should evaluate whether a footnote is even needed. Several comments noted that the footnote itself is not an effective means for educating consumers and should not be used as an educational tool.

Several comments said that, regardless of which footnote was ultimately decided upon, the footnote should be succinct, occupy little space, and fit on small packages. Many comments emphasized that, because the proposed rule did not specify the exact footnote text and the amount of space the new footnote would require, it would be difficult to submit meaningful comments until further details were provided.

(Response) We agree with removing the footnote table listing DRVs for certain nutrients based on 2,000 and 2,500 calorie diets. As stated in the proposed rule (79 FR 11879 at 11953), we are aware of research suggesting that consumers do not understand what is being conveyed in the footnote table (Ref. 273). We also recognize that label space is limited and agree that eliminating the footnote table would free up space on the label that could be used for other purposes. Therefore, the final rule does not require the footnote table which lists the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets.

We disagree with comments suggesting that a footnote be used to explain that calorie needs vary among population groups (including children and adolescents) or to clarify the meaning of ''serving size.'' The footnote area of the label is not an appropriate place for providing this information because of limited space on the label. Furthermore, we do not agree that it would be appropriate to use a footnote to indicate ''beneficial'' or ''harmful'' nutrients that are declared on the label, as the comment suggested. We considered a similar concept in the alternative visual format that was discussed in the preamble to the proposed rule (79 FR 11879 at 11995), but, after reviewing the comments on the proposed rule, indicated that we did not intend to consider the alternative format for the Nutrition Facts label further (see 80 FR 44302).

With respect to comments suggesting that we base revisions of the footnote (including the option of not having any footnote at all) on research and that our research results should be made available to the public for review and comment, we did conduct research on various footnote options and made those results publicly available (see 80 FR 44302; 80 FR 44303).

Finally, we do not agree with the comments stating that we should consider including a link to a Web page where consumers can find more information about nutrition, health and calorie needs. Information on the Nutrition Facts label should be available to the consumer at the time of product purchase or consumption.

(Comment 506) Many comments to the supplemental proposed rule supported FDA's proposed footnote, ''*The percent DV tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice,'' and generally agreed that the footnote should include both a definition of percent DV as well as a reference calorie level. The comments said that the proposed footnote conveys the information that consumers need to understand the significance of the percent DV declaration in the context of a daily diet and highlights factors (*i.e.,* nutrient values and total calorie intake)

that are important in making dietary decisions. Several comments also pointed out that, because the footnote has been condensed (*i.e.,* by removing the footnote table), it would help counterbalance the increased space requirements of the Nutrition Facts label.

Other comments objected to the proposed footnote and suggested alternative footnote text. For example, one comment said that the first sentence in the footnote is confusing grammatically; the second sentence does not flow naturally from the first sentence; it is unclear how the two concepts expressed in the footnote are related; and the proposed footnote text is longer than that of the current footnote and will take up too much valuable label space. The comment suggested an alternative footnote, ''*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a 2,000 calorie daily diet.'' The comment said its suggested footnote is more concise and easier to follow.

Another comment said that the footnote should specify that a 2,000 calorie daily diet pertains to adults and suggested the following footnote text: ''The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice for adults.'' Another comment that criticized the proposed footnote for being ''too verbose'' and provided six different, but similar, versions of a ''more succinct'' alternative footnote, with one option reading as: ''* %DV = %Daily Value, how much a nutrient in a serving contributes to a daily 2,000 calorie diet.''

Several other comments either suggested modifications to the proposed footnote (*e.g.,* expanding the term ''food'' to ''food or beverage'' to emphasize that beverages also contribute to one's daily nutrient intake) or opposed the footnote because, according to the comments, the footnote was not tested and was not supported by research. Furthermore, several comments said that, because no significant differences were found among the footnotes in our consumer study, we should give further consideration to some footnotes that were tested, but ultimately rejected. In particular, the comments said we should reconsider the footnote which included the statement, ''5% or less is a little, 20% or more is a lot'' after the % Daily Value description (experimental footnote 2). The comments said that this guideline for what constitutes a ''lot'' or a ''little'' of a nutrient may be helpful to consumers in judging the nutrient content of a particular product. One comment also expressed support for the footnote stating, ''These are nutrients to reduce in your diet,'' with the footnote symbol inserted to the left of the listings for saturated fat, *trans* fat, cholesterol, sodium, and sugars in the Nutrition Facts label (experimental footnote 5). The comment said that this footnote scored well in our consumer study and offers ''real value'' for consumers seeking information on nutrients in the diet that should be reduced.

(Response) We appreciate the suggestions for modifying or refining the footnote. However, the alternative footnote statements do not offer a significant improvement over the footnote text that we have proposed. Furthermore, the comments did not provide any evidence or data indicating that any alternative footnote represented an improvement over the proposed footnote.

The second statement of our proposed footnote, ''2,000 calories a day is used for general nutrition advice,'' is the same as the succinct statement that will be required on menus and menu boards under FDA's menu labeling final rule (79 FR 71156 (December 1, 2014)). Moreover, by including this statement as a separate, stand-alone sentence in the footnote text, we provide consistency between labels on packaged foods and those on foods sold in restaurants. Adding the words ''for adults'' at the end of this sentence, as one comment suggested, would undermine this consistency, take up additional space, and is not needed because the Nutrition Facts label is intended to apply to individuals 4 years of age and older (with the exception of labels on products other than infant formula represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age). Furthermore, as we explain in part II.E.3, a 2,000 calorie reference intake level is applicable to the general population and is used as the basis for setting DRVs for total fat, saturated fat, total carbohydrate, dietary fiber, and protein, so there is no need to add the words ''for adults'' in the footnote text.

Regarding the comment suggesting the modified footnote text, ''The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a 2,000 calorie daily diet,'' the statement is brief and grammatically correct, but may not be technically correct because the daily values of some declared nutrients, such as sodium and cholesterol, do not depend on the caloric intake. Therefore, it would not be accurate to link the percent DV in a serving ''to a 2,000 calorie daily diet,'' as stated in the modified footnote, rather than ''to a daily diet'' as stated in our footnote.

Although we agree that including ''5% or less is a little, 20% or more is a lot'' after the % Daily Value description (experimental footnote 2) can be helpful in judging the nutrient content of a particular product, we note that our consumer research study did not demonstrate that this footnote performed any better than the other footnotes that we investigated. As we explained in the preamble to the supplemental proposed rule (80 FR 44303 at 44306), our results indicated that none of the modified footnotes we tested significantly affected consumer perceptions of the products or judgments of nutrient levels; all five footnote options elicited similar perceptions and judgments relative to the current footnote and a no-footnote control. We also are concerned that including this qualifying phrase would increase the amount of space required for the footnote. However, as we stated in the preamble to the proposed rule (79 FR 11879 at 11954), the ''5/20 rule'' can be used as a general frame of reference for evaluating the nutrient content of foods. We anticipate that explaining this approach for using the percent DV information will be a part of our future consumer education efforts, so it would not be necessary to include an explanation of the ''5/20 rule'' in the footnote.

As for the comments that favored consideration of the footnote which indicated ''nutrients to reduce in your diet'' (footnote 5), we previously considered this concept in our ''alternative format'' (79 FR 11879 at 11995), but found it offered no clear advantages over the current and proposed formats in helping consumers to identify specific information on the label or to make healthier food choices.

We do not agree with the comment that said our proposed footnote is ''confusing grammatically.'' We deliberately used language that was informal rather than grammatically rigid or technical. Our intent was to make the footnote consumer friendly. We also consider our footnote to be simple and brief in providing a description of the percent Daily Value, which is lacking in the preexisting footnote.

Finally, we decline to include the word ''beverage'' in the footnote. The term ''food'' is defined in section 201(f)(1) of the FD&C Act as including articles used for both ''food or drink.'' Moreover, the Nutrition Facts label has

appeared on beverages for more than 20 years, so consumers should understand that the entire label, including the footnote, applies to foods that are beverages.

We expect that our footnote, which explains the term ''% Daily Value'' and provides a reference calorie level, will assist consumers in better understanding the information on the Nutrition Facts label and in maintaining healthy dietary practices. Therefore, the final rule, at § 101.9(d)(9), requires a footnote stating that, ''* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice,'' in all Nutrition Facts label formats except for the exemptions previously noted. The final rule also requires, on labels of products represented or purported to be for children 1 through 3 years of age, that the second sentence of the footnote substitute ''1,000 calories'' for ''2,000 calories,'' so the footnote statement will read: ''* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.''

(Comment 507) Many comments supported the exemption for a footnote on products containing a negligible amount of calories and that can use the term ''calorie free'' or one of its synonyms. The comments agreed that a footnote which addresses a 2,000 calorie intake is not relevant for these products, and the exemption would be a practical way of conserving label space for the nutrient declarations that are required.

However, other comments opposed the exemptions because, according to comments, products that have little or no impact on calorie intake still may contain substantial amounts of nutrients such as vitamins and minerals. As an example, one comment said that fortified beverages may contain significant amounts of electrolytes as well as 100 percent of the DV of certain vitamins. The comment suggested that ''calorie free'' products include the first sentence of the footnote, ''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' because it would help consumers understand the vitamin and mineral content of these calorie-free foods.

Other comments supported the use of an abbreviated footnote, such as ''% DV = % Daily Value'' on the simplified format label and on labels of small and intermediate-size packages. Some comments explained that an abbreviated footnote would save label space. However, one comment opposed allowing the abbreviated footnote to be used on small and intermediate-size packages because, according to the comment, such products are often high in added sugars and are routinely marketed to children and adolescents. The comment suggested that consumers would benefit by having the complete footnote appear on these food packages.

(Response) As we explained in the preamble to the supplemental proposed rule (80 FR 44303 at 44309), we are applying the same rationale in this final rule that we used in the 1993 final rule with regards to exempting small and intermediate-size packages from some of the footnote language we required for larger products. The 1993 final rule gave manufacturers flexibility in using the complete footnote on all product labels. We recognized that the benefits of requiring this footnote were not relative to the specific product that carries the information and that the information would be available to consumers if it appeared on a significant percentage of food labels (58 FR 2079 at 2129). Therefore, although the final rule does not require any footnote on these products, we will allow the voluntary use of the first part of the footnote statement, ''* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' on products that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods, as defined in § 101.60(b).

We acknowledge that small and intermediate-size packages may be high in added sugars and marketed to children and adolescents. However, both the absolute amount and % DV of added sugars will be declared on labels of small packages, so this information will be available to consumers. We also recognize the need to conserve space on smaller packages, which is why we allow other adjustments, such as not requiring the declaration of absolute amounts of the public health nutrients and the use of the tabular (§ 101.9(j)(13)(ii)(A)(*1*)) and linear (§ 101.9(j)(13)(ii)(A)(*2*)) display on small packages and intermediate-size packages having a total surface area available to bear labeling of 40 or less square inches. Therefore, the final rule does not require the footnote in § 101.9(d)(9) to be used on products in small packages as specified in § 101.9(j)(13)(ii)(A)(*1*) and § 101.9(j)(13)(ii)(A)(*2*), but manufacturers may voluntarily include the abbreviated footnote ''% DV = % Daily Value'' on these packages and in a type size no smaller than 6 point. Furthermore, the final rule does not require the footnote in § 101.9(d)(9) to be used on products that qualify for using the simplified format, as explained in § 101.9(f)(5), provided that the abbreviated footnote ''% DV = % Daily Value'' in a type size no smaller than 6 point is used on these package labels when Daily Value is not spelled out in the column heading.

Finally, in the preamble to the proposed rule (79 FR 11879 at 11953), we recognized that the footnote, by appearing in a small type size at the bottom of the label, may be less noticeable to consumers and of less use than if it had been larger and otherwise more noticeable. Consequently, our tentative view was that increasing the type size of the footnote would assist consumers in using the information, and we requested comments on this issue. We did not receive any comments that supported increasing the type size of the footnote (although comments supported increasing the font size for certain other declarations, *e.g.,* ''Calories'' and ''Serving size''), but some comments supported using as little space as possible for the footnote information. Therefore, the final rule does not affect the pre-existing requirement in § 101.9(d)(1)(iii) that specifies that the information required in § 101.9(d)(9) be in a type size no smaller than 6 point.

(Comment 508) Many comments discussed whether there should be a footnote on the labels of foods represented for infants 7 to 12 months of age or children 1 through 3 years of age. Most comments supported having a footnote on the label of foods intended for these subpopulation groups. For example, one comment said that a voluntary footnote should be permitted for foods specifically marketed to children 1 through 3 years of age and that the footnote should state, ''Percent Daily Values are based on a 1,000 calorie diet.'' Other comments said that both conventional foods and dietary supplement products marketed for these age groups should have a footnote (denoted by an asterisk) indicating the number of calories that the percent DVs listed on the labels is based on. One comment noted that this had already been proposed for dietary supplements (79 FR 11879 at 11947). The comment further suggested that information about percent DVs of nutrients for different age groups be made available online (arranged by age group) so that parents and others interested in nutrition would have ready access to this information.

Another comment suggested that we allow a voluntary footnote stating ''Total fat and cholesterol should not be limited in the diets of children less than 2 years

unless directed by a physician'' to provide dietary guidance to parents and other caregivers to help assure total fat is not restricted in the diet of young children. The comment said that the American Academy of Pediatrics recommends not restricting fat or cholesterol for infants and children younger than 2 years of age, as rapid growth and development occur during this time, necessitating a high energy intake. Another comment said we should not finalize the rule until we had conducted appropriate research, including consumer testing, to better understand the impacts of declaring saturated fat and cholesterol on the labels of products represented or purported to be specifically for infants and children 1 through 3 years of age and if an explanatory footnote would assist in improving consumer understanding when accompanying any relative declaration.

(Response) We recognize that the percent DVs of certain nutrients (*e.g.,* fats, carbohydrates, protein) for foods specifically intended for children 1 through 3 years of age are based on a reference calorie intake of 1,000 calories/day. However, as explained in part II.O (Subpopulations), the IOM's quantitative intake recommendations (AIs and RDAs), rather than a calorie level, provide a basis on which to determine RDIs (and percent DVs) for vitamins and minerals for this subpopulation. Although the comments suggested including the footnote ''Percent Daily Values are based on a 1,000 calorie diet'' on labels of foods specifically intended for children 1 through 3 years of age, this statement would not be accurate for all nutrients. Therefore, as illustrated in the label mockup in § 101.9(j)(5)(ii), the final rule requires the labels of these food products to have a footnote that includes the statement ''1,000 calories a day is used for general nutrition advice;'' this information would parallel the footnote statement used on food labels for the general population (*i.e.,* 4 years of age and older).

With respect to the comment suggesting we allow a voluntary footnote stating that total fat should not be limited in the diets of children less than 2 years unless directed by a physician (or similar wording), we acknowledge, in general, that total fat should not be limited in the diets of young children less than 2 years of age unless directed by a health professional (as previously explained in part II.O, Subpopulations). Because the final rule requires the mandatory declaration of saturated fat and cholesterol on labeling for infants and children, we are continuing to consider how a voluntary footnote explaining that total fat should not be restricted in the diets of children less than 2 years of age may help caregivers maintain healthy dietary practices for these subgroups, and how the information can be conveyed effectively. Although, for this final rule, we decline to allow this voluntary statement to be located within the Nutrition Facts label, manufacturers may place this or a similar statement in another area of the package, provided the statement is truthful and not misleading. We intend to engage in education efforts to explain changes to the Nutrition Facts label and will include labeling of foods for infants and children 1 through 3 years of age in these efforts.

(Comment 509) One comment said that the Supplement Facts label should be similar to the Nutrition Facts label used for conventional foods because different versions of the labels may decrease consumer use, understanding and trust. However, it was not clear if the comment was referring specifically to the footnotes of these labels. Another comment said there should not be a footnote on the Supplement Facts labels because consumers do not receive nutrition solely from these products, so a footnote referring to total calories would be unnecessary. The comment added that, because nutrition calculations are based on 2,000 calories, this information is already standardized across the industry, making the notation unnecessary.

Another comment expressed concern that the statement ''2,000 calories a day is used for general nutrition advice'' on Supplement Facts labels would not be useful to consumers in the absence of additional information. However, the comment said it would be difficult to include additional, explanatory text because of limited space, especially on small packages. Therefore, the comment would retain the preexisting footnote, ''Percent Daily Values are based on a 2,000 calorie diet,'' on Supplement Facts labels.

(Response) We agree that information about calories is not relevant for many dietary supplement products because the products contain only vitamins and minerals and do not contain nutrients that provide calories, such as total fat, saturated fat, total carbohydrate, and protein. Therefore, the footnote in previously required § 101.9(d)(9) would not be appropriate on Supplement Facts labels for products that do not contain these calorie sources. Furthermore, dietary supplements are intended to supplement the diet, and the information in the footnote for conventional foods that references 2,000 calories as a basis for ''general nutrition advice,'' or explains percent DV in the context of what a serving contributes to a daily diet, is for a different use from that of dietary supplements.

Although the intent of the comment regarding the need for consistency between the Nutrition Facts label and Supplement Facts label is not clear, we recognize the necessity of having different footnotes on labels of conventional foods and dietary supplements, consistent with how these products are used. Therefore, the final rule retains the preexisting footnote on Supplement Facts labels and amends the list of macronutrients, for when the footnote is required, to include added sugars. Therefore, the final rule requires a footnote if the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars), stating that ''Percent Daily Values are based on a 2,000 calorie diet'' (§ 101.36(b)(2)(iii)(D)) because that information is related to the calorie contribution of the calorie-containing ingredients. The footnote statement for Supplement Facts labels does not contain the statement required for conventional foods that states ''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet.'' In addition, if a product declares a percent DV for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars, and is represented or purported to be for use by children 1 through 3 years of age, the final rule, at § 101.36(b)(2)(iii)(D), requires a footnote statement, ''Percent Daily Values are based on a 1,000 calorie diet.''

(Comment 510) One comment asked us to clarify the footnote's width because the width requirements were not specified. The comment said that this issue would be particularly important when either the tabular format (§ 101.9(d)(11)(iii)) or the dual column tabular format (§ 101.9(e)(6)(ii)) was used because, without a specific width requirement, the footnote text could be wrapped in various ways, resulting in the footnote occupying space varying from being mostly horizontal (*i.e.,* wide and short) to mostly vertical (*i.e.,* narrow and tall). The comment suggested the possibility of specifying a minimum width that would require at least the words ''The % Daily Value'' to fit on a single line.

(Response) Manufacturers have the flexibility, within certain parameters, in how they display the footnote to satisfy the configuration and design constraints of their packages. Therefore, we decline to specify a minimum number of words

per line for the footnote, as the comment suggested. However, we intend to monitor how firms comply with the format requirements, including the footnote display. If we determine that manufacturers are having difficulty fitting the footnote text and other required information within the Nutrition Facts label, we will consider whether further action, including rulemaking, is needed with regard to positioning the footnote.

12. Use of Highlighting With a Type Intermediate Between Bold or Extra Bold and Regular Type

Under our preexisting regulations, only nutrients that are not indented (*i.e.,* ''Calories,'' ''Total Fat,'' ''Cholesterol,'' ''Sodium,'' ''Total Carbohydrate,'' and ''Protein'') on the Nutrition Facts label are required to be highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). In the preamble to the proposed rule (79 FR 11879 at 11954), we stated that, based on design considerations of using bold type to help differentiate the name of the nutrient from its absolute amount (Ref. 262), all of the other nutrients listed on the Nutrition Facts label, including those that are indented and the vitamins and minerals, should also be highlighted to help set the names of the nutrients apart from other information that appears on the label. The key nutrients that are not indented would still be highlighted in a font that is bolder than the indented nutrients, so the overall style of the Nutrition Facts label would not change. Thus, we proposed to amend § 101.9(d)(1)(iv) to remove the restriction that prohibits any other information on the label to be highlighted and to require that all voluntary nutrients specified in § 101.9(c), including the vitamins and minerals listed in § 101.9(c)(8)(iv), appear in a type intermediate between bold and regular type (if bold type is used) or between extra bold and regular type (if extra bold type is used) on the Nutrition Facts label.

(Comment 511) One comment suggested that if too much information on the Nutrition Facts label was bolded, nothing would stand out. The comment also said that too much bolding would be especially problematic for small packages because it would be difficult to maintain legibility of the printed information. The comment said that small print that is bolded would be even more difficult to read, because the letters would appear to run together even more.

Another comment suggested that, as an alternative to bolding, we might want to reconsider the restriction of using reverse highlighting (*i.e.,* white text printed in a black box, also known as reverse printing) as a method of increasing prominence. The comment stated that since the Nutrition Facts label was introduced in 1993, vast improvements have been made in printing technologies and capabilities, which should help alleviate previous concerns with regards to whether reverse printing could meet minimum printing tolerances.

(Response) We agree that too much bolding may reduce the contrast between information that is intended to be relatively more or less prominent on the Nutrition Facts label and that maintaining adequate resolution of printed information on labels of small packages might be particularly difficult. We also agree that it is more likely that letters or numbers may run together when information is highlighted, especially on labels of small packages, and we note that our preexisting regulations (§ 101.9(d)(1)(ii)(D)) specify that letters on the Nutrition Facts label should never touch. Therefore, based on the graphic design principle of using contrast to distinguish differences between adjacent items that would otherwise appear similar, and the importance of preserving adequate resolution to ensure the sharpness and clarity of the label information, the final rule does not amend the portion of proposed § 101.9(d)(1)(iv) that would require the indented nutrients and the vitamins and minerals (except sodium) to be highlighted in a type intermediate between bold or extra bold type and regular type.

As for the comment suggesting that we reconsider the use of reverse printing, we had concluded in the 1993 final rule (58 FR 2079 at 2137), based on comments and the professional literature at that time, that the use of reverse printing on the Nutrition Facts label would give rise to technical and legibility problems, especially on small containers, and therefore we declined to permit reverse printing as a form of highlighting (§ 101.9(d)(1)(iv)). While advances in technology may have removed some previous barriers that existed with this printing technique, we need to learn more about the technology before we consider revising the rule to address reverse printing.

13. Addition of a Horizontal Line Beneath the Nutrition Facts Heading

Our preexisting regulations, at § 101.9(d)(2), require that the Nutrition Facts heading be set in a type size larger than all other print size in the nutrition label (§ 101.9(d)(2)) but does not require that this heading be set apart from the rest of the label with a horizontal hairline rule, which is a thin line. Horizontal lines are used throughout the Nutrition Facts label as a key graphic element to divide space, direct the eye, and give the label a unique and identifiable look. The proposed rule would require that a thin horizontal line (*i.e.,* a 0.25 point hairline rule) be inserted directly beneath the Nutrition Facts heading with the exception of the linear display for smaller packages in § 101.9(j)(13)(ii)(A)(*2*).

(Comment 512) One comment said that the hairline rule beneath the Nutrition Facts title improves the overall appearance of the Nutrition Facts label and its ''ease of use.'' Another comment said that the use of horizontal lines and other design elements (*e.g.,* white space, bold fonts, etc.) are visual cues that draw attention to important information on the Nutrition Facts label, helping to improve readability and make the information easier to process and remember. Another comment said that a horizontal line beneath the Nutrition Facts heading would help separate the heading from the ''____ servings per container'' declaration, because all of the information in the first two lines of the label was presented in bold type.

(Response) We agree that a thin horizontal line directly beneath the Nutrition Facts heading would make the heading more visually appealing. Our requirement in § 101.9(d)(1)(v) to insert the horizontal line beneath the Nutrition Facts heading for all formats (except the linear display for smaller packages described in § 101.9(j)(13)(ii)(A)(*2*)) is based on graphic design principles and other design considerations previously discussed in the preamble to the proposed rule.

14. Replacing ''Total Carbohydrate'' With ''Total Carbs''

Nutrition information declared on the Nutrition Facts label must be presented using the nutrient names specified in § 101.9(c) or § 101.9(j)(13)(ii)(B). According to § 101.9(c)(6), the nutrient name used for listing information about the carbohydrate content of a product is ''Total Carbohydrate.'' Certain abbreviations, as specified in § 101.9(j)(13)(ii)(B), may be used on the Nutrition Facts label on packages that have a total surface area available to bear labeling of 40 or less square inches.

In the preamble to the proposed rule (79 FR 11879 at 11954), we explained that replacing ''Total Carbohydrate,'' the nutrient name currently required on most formats, with the shorter term ''Total Carbs'' would maximize white space, maintain simplicity, and because

it is a commonly used term, help the public to readily observe and comprehend the nutrition information presented in the Nutrition Facts label.

(Comment 513) Most comments objected to replacing ''Total Carbohydrate'' with ''Total Carbs'' on the Nutrition Facts label. Several comments referred to the term ''Total Carbs'' as being ''jargon,'' ''slang,'' ''sloppy,'' or ''denigrating.'' Other comments stated that ''Total Carbohydrate'' is a term that is familiar to consumers, is frequently used in the media, and has appeared on the Nutrition Facts label for more than 20 years. The comments also noted that ''carbohydrate'' is the correct, scientifically accurate term specified in the FD&C Act and NLEA and is used in the DGA, IOM reports, and other government or scientific documents.

One comment questioned whether any data exist suggesting that consumers are either confused by the word ''carbohydrate'' or would understand the term ''carbs'' any better. Another comment suggested that research is needed to evaluate whether the proposed change would affect consumer use and understanding of the carbohydrate information presented on the label.

Many comments said that listing the total carbohydrate content in a serving of food as ''Total Carbs'' rather than ''Total Carbohydrate'' could have a negative impact on the ability of people with diabetes to accurately assess their carbohydrate intake and thus their ability to manage their disease. The comments explained that diabetics, who monitor their blood glucose levels and adjust their insulin requirements accordingly, must be able to accurately determine the carbohydrate content of their foods, such as through ''carbohydrate counting.'' Several comments pointed out that many diabetics, especially those who are newly diagnosed, recognize the term ''carb choice'' or ''carb serving'' as referring to a serving of food that contains 15 grams of total carbohydrate. The comments noted that, in this context, the word ''carb'' has a specific meaning, and that declaring ''Total Carbs'' on the Nutrition Facts label could cause confusion and result in diabetics taking the wrong dose of insulin.

Other comments suggested that ''carb'' or ''carbs'' frequently carries a negative connotation when it is linked to a ''low carb'' diet, the ''net carbs'' of a product, or to ''carb loading'' before an athletic competition. The comments expressed concerns that the term may be used in a context that does not support healthy dietary practices. One comment noted that the term ''carbs,'' if perceived negatively, could inadvertently challenge advice to consume 65 percent of calories from carbohydrates, as recommended in the 2010 DGA. Another comment questioned why carbohydrates should be treated differently than other nutrients on the Nutrition Facts label because it would be the only abbreviated nutrient on most label formats.

One comment said that, because previous research suggests that consumers have difficulty understanding acronyms and abbreviations, the term ''carbs'' may not be appropriate on the label, and may present an additional challenge on bilingual labels. Another comment indicated that if the final rule uses ''Total Carbs,'' the ''Added Sugars'' declaration would become more prominent, leading to consumer confusion and distracting from an overall focus of reducing calorie consumption from all macronutrient sources.

Some comments supported replacing the term ''Total Carbohydrate'' with ''Total Carbs'' and said that ''carbs'' is a term that is part of the daily vocabulary of many people and the term would ''draw their attention'' which could be beneficial.

(Response) We acknowledge that ''carbohydrate'' is the correct, scientifically accurate term used in government or scientific documents and that ''carbs'' may be perceived as jargon. We further recognize the possibility that some diabetics may have difficulty distinguishing between the terms ''Total Carbs,'' ''carb choice,'' and ''carb serving,'' but note that the Nutrition Facts label, and any associated changes in format resulting from this rulemaking, applies to the general healthy population rather than to those with a specific disease. We are unaware of any data suggesting that consumers would be confused by the abbreviation ''Carbs'' or that this term would adversely affect the ability of consumers to interpret other parts of the Nutrition Facts label, or adversely impact dietary advice, as suggested by some comments. Furthermore, we already permit the abbreviation ''carb.'' (singular) for ''carbohydrate'' on small packages having space constraints, as specified in § 101.9(j)(13)(ii)(B), and we note that the term ''carbohydrate'' is spelled out on the Nutrition Facts label of most food products and therefore is readily observable for consumers who might be confused by the abbreviated term on small packages. However, because ''carbs'' (plural) may be perceived as an informal term and may have a negative connotation for some individuals and because a ''Total Carbs'' declaration may be problematic on some bilingual labels when this term is used instead of ''Total Carbohydrate'' generally, we will continue to require that ''Total Carbohydrate'' be used as the nutrient name for carbohydrates, as specified in § 101.9(c)(6), and that ''Total carb.'' continue to be the abbreviation for this term (*e.g.,* as applicable on small packages) as specified in § 101.9(j)(13)(ii)(B).

15. Alternative Visual Formats/Fonts

We did not propose any changes to the basic format of the Nutrition Facts label, as specified in § 101.9(d)(12), because we were unaware of any evidence that would support an alternative format. However, the preamble to the proposed rule did contain a mockup of an alternative concept for the Nutrition Facts label format (79 FR 11879 at 11955) that categorized nutrient declarations as ''quick facts'' about certain nutrients, nutrients to ''avoid too much'' of, and nutrients to ''get enough of,'' and we invited comment on whether we should require a specific type style for the Nutrition Facts label.

After reviewing the comments on the proposed rule, we tentatively concluded that we did not intend to further consider the alternative format for the Nutrition Facts label (80 FR 44302). Most comments agreed with our tentative conclusion, and other comments raised questions that we may consider if we decide to conduct further research on this issue in the future. A review of the results of FDA's consumer research, which we made available in reopening of the comment period as to specific documents (80 FR 44302), did not provide information to change our tentative conclusion, so we are not giving further consideration to the alternative format as part of this rulemaking.

16. Miscellaneous Comments

a. *Size and space issues.* The preamble to the proposed rule did not invite comments on whether our proposed format changes would affect the ability of small packages to accommodate the Nutrition Facts label. Our intention was to use graphic design principles to improve the overall visual appearance of the Nutrition Facts label formats without altering the labels' dimensions. However, several comments addressed this issue, particularly with regards to the use of the proposed linear format on small and very small food packages.

(Comment 514) Many comments said the proposed Nutrition Facts label formats appeared to be larger than the preexisting label formats and, therefore, would take up too much space on food packages. The comments said that implementing many proposed changes, such as increasing the prominence of ''servings per container and the ''calorie'' information as well as adding a line for ''Added Sugars,'' would necessarily increase label size. One comment suggested that we did not adequately consider how the proposed Nutrition Facts labels would fit on actual food products and asked us to ''verify'' that the proposed formats would not result in larger labels. Several comments said that companies would need to redesign their packages to accommodate the increased amount of space that would be necessary for labels to comply with the proposed format changes and to fit on packages, resulting in significant costs to the industry.

Other comments indicated that, for all of the required information to fit within the boundaries of certain proposed formats, some labels would be cluttered, difficult to read, and challenging for consumers to use. One comment said that the label's overall visual appearance would be dense, complex, cluttered, and contradict FDA's intent to maintain the NLEA requirements. The comment said that the Nutrition Facts label should have a simple format, minimize clutter, and enable consumers to observe and comprehend the information readily.

Several comments emphasized that a larger nutrition label would occupy ''valuable'' package space that could be used for other purposes. One comment said that a larger Nutrition Facts label might reduce the available package space that could be used for marketing and promotional messages, and this would be of particular concern to small firms unable to afford advertising costs. Another comment said that the proposed format changes might limit the amount of space on packages that could be used for product recipes and cooking instructions (*e.g.,* information about proper cooking times and temperature settings) which may be necessary for ensuring food safety.

(Response) We disagree with the comments suggesting that the proposed formats would be significantly larger than the current formats. Each label was specifically designed to occupy the same amount of package space as the preexisting label. While some nutrient information will be declared in a larger font size and style compared to the preexisting format, and the final rule requires the declaration of ''Added Sugars'' information, we are also removing the requirement for the ''Calories from Fat'' declaration and reducing the amount of space that will be necessary for the footnote. In certain cases (*e.g.,* on labels of foods represented or purported to be specifically for infants through 12 months of age or on labels of foods that can use the terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the Nutrition Facts label or in the labeling of foods as defined in § 101.60(b)), we are removing the footnote requirement altogether. We also note that we are reducing the type size of the numerical value for calories, from 24 point to 22 point, and 14 point for the tabular display and linear display for smaller packages with a total surface area available to bear labeling of 40 square inches or less in § 101.9(j)(13)(ii)(A)(*1*) and (*2*). Taken together, these format modifications will not result in a significant change in the size of the labels. Therefore, we decline to ''verify'' that the revised formats will not be larger than the current ones and disagree that manufacturers will need to redesign packages extensively to accommodate the revised Nutrition Facts labels. Also, because we are not requiring that absolute amounts be listed for voluntary nutrients, we do not anticipate that excessive crowding will be problematic on labels with multiple columns, such as those on breakfast cereal packages which list nutrition information for the product as packaged, as served (*e.g.,* with milk), and for a subpopulation (*e.g.,* children less than 4 years of age). Although providing nutrition information for these categories is voluntary, if a manufacturer chooses to use such multiple columns and adequate space is not available on the side panel, the Nutrition Facts label may be placed on the back panel of the package (as provided for in § 101.2(a)(1)) where more space is likely to be available.

With respect to the comment regarding the need for small businesses to have adequate space on packages for promotional and marketing messages, we acknowledge the importance of communicating information about the product. Similarly, we recognize the importance of providing consumers with information about food preparation, recipes, and safety issues relative to the product. However, as specified in § 101.9(j)(17), non-mandatory label information on the package information panel (as described in § 101.2(a)) is not considered to be a factor in determining the sufficiency of available space for the placement of the Nutrition Facts label. Therefore, all manufacturers, regardless of size, who are required to display the Nutrition Facts label on its products must follow the regulations with regards to general food labeling requirements and provisions as discussed in § 101.1 through 101.5.

(Comment 515) Several comments noted that label space, which is already limited, would be further constrained on bilingual labels. The comments suggested that bilingual labels will become increasingly common and that we should provide examples of bilingual labels for further public comment.

(Response) The use of bilingual Nutrition Facts labels is voluntary. We do not agree that our format changes will prevent manufacturers from using a bilingual label, as many options are available regarding where the label is located on a package (*e.g.,* the back panel). We have provided an example of a bilingual Nutrition Facts label in ''A Food Labeling Guide: Guidance for Industry'' (Ref. 122). Manufacturers who use a bilingual label can review this guidance document. We anticipate that future updates will be made to ''A Food Labeling Guide: Guidance for Industry'' to correspond to format changes in the final rule.

(Comment 516) One comment said that, because the standard format requires both percent DV and absolute amounts of mandatory vitamins and minerals to be declared, there would not be enough space on some packages to allow the nutrients of public health concern to be listed side by side in two columns (as specified in § 101.9(d)(8)), which the comment called a ''space saving feature.'' The comment provided an example of a label demonstrating that it is not possible to list micronutrients in two columns because of layout constraints caused by the package's configuration. The comment said that although the proposed Nutrition Facts label changes were intended to have a minimum impact on product packages, layout constraints in some cases would necessitate significant package redesign to comply with the revised format. The comment suggested that we had not adequately considered certain package shapes where changes in format would have ''consequential'' effects on package design.

(Response) We acknowledge there are layout constraints with certain packages, but we have given manufacturers flexibility in how they apply the Nutrition Facts label on

products having significant size and space challenges. The comment's example used certain text sizes and bolding that were initially proposed, but are not included in the final rule, so the comment's example, under the final rule's requirements, would take up less space. In response to concerns of products that have significant size and space constraints we are removing the requirement for the footnote statements in § 101.9(j)(13)(ii)(C) for the tabular format for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear format as shown in § 101.9(j)(13)(ii)(A)(*2*), however, the abbreviated footnote ''% DV = % Daily Value'' may be used on these packages. Because we are removing the requirement in § 101.9(j)(13)(ii)(C), we are redesignating § 101.9(j)(13)(ii)(D) as § 101.9(j)(13)(ii)(C). We also are allowing ''vitamin'' to be abbreviated as ''vit.'' and potassium to be abbreviated as ''Potas.'' in § 101.9(j)(13)(ii)(B) which will further conserve space. Although we cannot predict all the different sizes and shapes of packages that may enter the marketplace, we permit various formats of the Nutrition Facts label and allow flexibility in order to accommodate packages having various design features.

(Comment 517) Many comments said that the proposed linear display for small packages (illustrated in § 101.9(j)(13)(ii)(A)(*2*) (79 FR 11879 at 11979)) would not fit on many small packages, such as those for candy, chewing gum, and other confectionery products, because it occupies substantially more space than the current linear display format. Some comments included detailed mockups of complete small product packages demonstrating that, due to their shape or size, some packages would not be able to accommodate the proposed Nutrition Facts labels without obscuring some information on the package or label, even if a minimum legible font size of 6 point was used on the label. Other comments pointed out that the preexisting linear format was specifically designed to be flexible because it allows nutrition information to be presented as a wrapped string of text that can be adapted to fit the specific dimensions of a small package. The comments suggested that the proposed ''linear'' display is not accurate because it has a ''table'' format rather than an arrangement that is linear, and it cannot be displayed as a string of wrapped text. According to the comments, the proposed linear display would not fit on many small packages for which it was intended (*i.e.,* packages that could not otherwise accommodate the tabular display for small packages, as provided in § 101.9(j)(13)(ii)(A)(*1*) (79 FR 11879 at 11979)). Other comments said that the proposed linear format would be especially problematic for products having small labels (*e.g.,* packages with 13 square inches of available labeling space) but that are not small enough to qualify for the complete exemption under § 101.9(j)(13)(i), which exempts nutrition labeling when the total surface area available to bear labeling is less than 12 square inches and no claims are made in labeling or advertising. The comments asked us to propose a revised linear format that would fit on small packages (*i.e.,* <12 square inches) or retain the preexisting linear format as an option when neither of the proposed small label formats would fit on a package. Other comments suggested that we broaden the criteria that would allow more labels to qualify for the linear and tabular formats (as provided in § 101.9(j)(13)(ii)(A)); for example, by increasing the intermediate package size from ≤40 square inches to ≤50 square inches.

(Response) We agree that the proposed linear format for small packages may not be able to fit on many small packages, such as those of confectionery products. We also acknowledge the advantage of the text wrapping feature of the preexisting linear format in providing flexibility for labels on small packages having various shapes and sizes. Consequently, we are not finalizing the requirements for the proposed linear format. Instead, we are retaining the text wrapping feature of the preexisting linear format, but adapting it to maintain consistency with the other format changes we are finalizing, *i.e.,* increasing the prominence of ''Calories'' information, removing the ''Calories from Fat'' declaration, changing ''Sugars'' to ''Total Sugars,'' including an ''Added Sugars'' declaration, modifying the mandatory vitamins and minerals, and making the abbreviated footnote ''% DV = % Daily Value'' optional for small packages. We also are providing that the actual number of servings may be listed after the ''____ servings per container'' declaration and note that ''Servings'' is an acceptable abbreviation for ''____ Servings per container'' (as provided in § 101.9(j)(13)(ii)(B)). Additionally, on our own initiative, we have revised the rule so that ''Incl. Xg added sugars'' is an acceptable abbreviation for ''includes X g of added sugars.''

However, we are concerned that some companies may be using the linear format inappropriately because we have seen the linear format used on packages that could accommodate the tabular display for small packages or on larger-size packages that could accommodate the standard format. Manufacturers should understand that the linear format is only to be used for certain size packages (as described in § 101.9(j)(13)(ii)(A)), and only if the label will not accommodate a tabular display. The linear format is more difficult to read than other formats and is not permitted for larger packages. We consider the use of a linear display as a last resort when the tabular display for small packages cannot be accommodated in the available label space (*e.g.,* when small packages with a total surface area available to bear labeling of less than 12 square inches, or 40 square inches or less and the package shape or size cannot accommodate a standard vertical column or tabular display would otherwise have to take advantage of the exemption allowing use of an address or telephone number in lieu of nutrition information). Consumers would be expected to be more likely to take a few extra moments to read a linear nutrition label than to write a letter or call the manufacturer. We do not want the linear format to be misused, so we intend to monitor the marketplace to ensure that the proper Nutrition Facts label format is used on the correct size package.

We have addressed the size and space concerns expressed in the comments for smaller packages by decreasing the prominence of the calorie declaration from our original proposal, by removing the requirement for a footnote, and permitting the abbreviated footnote ''% DV = % Daily Value'' to be optional, providing acceptable abbreviations for terms, and also permitting the text wrapping feature. Based on these spacing accommodations, we decline to increase the intermediate package size from ≤40 square inches to ≤50 square inches, as the comment suggested, because retaining the preexisting linear format and other space saving requirements would preclude the necessity of doing so.

(Comment 518) One comment stated that because foods in small packages (*i.e.,* less than 12 square inches) must bear the Nutrition Facts label if the food's label makes nutrition claims (*e.g.,* ''sugar-free'' gums), manufacturers need a Nutrition Facts label format that would fit on such packages. Otherwise, manufacturers would be prohibited from making a claim, which the comment suggested might be an unintended consequence of the final rule and adversely affect consumers (because the claim would not be available to them). Alternatively, the

comment suggested that we exempt foods in very small packages from bearing a Nutrition Facts label, even if a nutrient content claim is made or if the nutritional contribution of the food is minimal. The comment urged us to carefully consider the impact that the increase in certain type sizes and the additional ''Added Sugars'' information would have on the ability of the Nutrition Facts label to fit on very small packages.

Several comments also asked us to consider additional label formats that would be appropriate for products in small and very small packages making nutrient content claims or health claims. Some comments offered suggestions that would enable the Nutrition Facts label to fit on small and intermediate-size packages, remain legible when printed with a 6 point font size, and still ''embrace the spirit'' of our proposed rule. Specifically, the comments suggested allowing a proportional reduction of the tabular and linear formats to accommodate certain package shapes or sizes; an abbreviated format that lists fewer nutrients but would still allow a claim to be made (such as ''sugar free'' or ''calorie free''); the declaration of certain information to be voluntary; and either a telephone number, Web site, or mailing address that consumers could use to obtain more complete nutrition information (similar to the provision in § 101.9(j)(13)(i)(A)) for very small packages (*i.e.,* having less than 6 square inches of available space to bear labeling).

(Response) While we appreciate the extensive amount of time and effort that manufacturers devoted to designing alternative labels for small product packages, we disagree that such products, in general, should not be required to display a Nutrition Facts label if claims are made for the product. Depending on the particular claim and product, a variety of information may be required on the label (*e.g.,* a disclosure statement, as described in § 101.13(h)(1)) to prevent the claim from being misleading. The packages described in the comment appear to be hypothetical, as we are not aware that such packages currently exist in the marketplace.

We also decline to exempt foods in small packages that have a total surface area available to bear labeling of less than 12 square inches from bearing a Nutrition Facts label if a nutrition claim is made or if the nutritional contribution of the food is minimal. We also are continuing to allow the preexisting linear format for small packages, as described in § 101.9(j)(13)(ii)(A), which we anticipate will fit on most small confectionery packages. Furthermore, we will retain the preexisting requirement in § 101.9(j)(13)(ii)(A) that stipulates that the linear format may only be used if the label will not accommodate a tabular display.

(Comment 519) Several comments pointed out that the proposed leading requirements (*i.e.,* the vertical space between lines) differ from the preexisting leading requirements so that the proposed labels will take up more space. One comment said we could increase the amount of white space by enlarging the leading requirements. Another comment said that there was a lack of detail about the leading requirements for the information displayed in the Nutrition Facts label format shown in § 101.9(d)(12).

(Response) We agree with the comment and acknowledge an error in § 101.9(d)(1)(ii)(C) in which the leading requirements were increased. This has now been corrected in the final rule so that the original leading requirements are retained, *i.e.,* all information within the nutrition label shall utilize at least one point leading except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12). We allow manufacturers some degree of discretion and flexibility with respect to the leading requirements, and the label mockups that we have provided in this final regulation are for the purpose of illustration rather than to provide exact specifications. An underlying purpose of the Nutrition Facts label is to help consumers make healthful food choices, and we expect manufacturers to provide legible labels to help consumers do this.

b. Calorie conversion factors. In the preamble to the proposed rule (79 FR 11879 at 11954), we requested comments and supporting data on the extent that consumers use the caloric conversion information (*i.e.,* ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') that may voluntarily be declared at the bottom of the footnote area of the Nutrition Facts label under § 101.9(d)(10). We stated that we may consider deleting this optional requirement in the final rule if we determine the information is not useful (id.).

(Comment 520) Some comments would prohibit the voluntary listing of caloric conversion information. These comments stated that it is too much information for consumers; its purpose in relation to the rest of the Nutrition Facts label is not readily apparent; it would require ''hands-on consumer education'' to be useful or understood; and the information is underused. One comment said that allowing the optional use of this information on the label may lead to consumer confusion because we have proposed new caloric conversion factors for certain carbohydrate subtypes.

Another comment suggested that, if we retain the optional caloric conversion information, there should also be a ''disclaimer'' or ''education statement'' indicating that the calorie values listed for fat, carbohydrate, and protein are not exact. The comment said that a disclaimer or education statement would help consumers understand that, if the grams of fat, carbohydrate, and protein that are listed on the Nutrition Facts label are multiplied by their respective caloric values (*i.e.,* 9, 4 and 4), the total may not necessarily be the same as the number of calories listed near the top of the label in the ''Calories'' declaration. The comment further suggested that such a discrepancy might cause consumer confusion. Another comment suggested the caloric information for fat, carbohydrate, and protein should be provided on a ''per ounce'' basis rather than on a ''per gram'' basis. Finally, one comment said that retaining the caloric conversion information could help consumers adjust their caloric intake if their individual calorie needs were above or below 2,000 calories per day.

(Response) We previously recognized that 9, 4, and 4 calories per gram for fat, carbohydrates, and protein, respectively, are general factors that are applicable to the majority of foods, and displaying them on the label can help consumers better understand and use the nutrition information on the label and to apply the DGA recommendations (58 FR 2079 at 2131). For example, the calorie conversion information might be useful to consumers who want to keep track of the number (or percentage) of calories they consume derived from fat and carbohydrate, or who are following certain dietary recommendations, such as for weight loss or other health reasons. Furthermore, because we are no longer requiring the number of calories from fat to be declared on the label, consumers who want this information can do their own calculations using the caloric conversion factors. We are unaware whether the caloric conversion information is underused by consumers, as suggested by one comment, and disagree that it comprises too much information, as it is displayed succinctly and is listed voluntarily. However, given the comments' concerns related to the need to conserve space on the Nutrition Facts label, we will continue to allow the caloric conversion factors to be listed voluntarily.

We disagree with the comment stating that the proposed caloric conversion factors for carbohydrate sub-types might lead to consumer confusion if the current caloric conversion information is retained. The comment did not explain this assertion. Although we proposed new caloric conversion factors for certain carbohydrate sub-types, including soluble fiber (2 calories per gram) and specific sugar alcohols (ranging from 1.6–3.0 calories per gram), consumers would not be expected to be aware of this information and would have no reason to use it because it is intended for manufacturers to use in developing product labels. Therefore, we disagree that retaining the caloric conversion information on the Nutrition Facts label would lead to consumer confusion. Furthermore, although the general conversion factors may not apply to all foods (but relatively few products would be expected to include caloric values for soluble fiber and sugar alcohols as part of the total calorie calculations), we do not consider that to be a reason to prohibit their use.

We also decline to provide a ''disclaimer'' or ''education statement'' on the label to indicate that the caloric conversion factors are approximations. The reason that multiplying the grams of fat, carbohydrate, and protein listed on the label by 9, 4, and 4 calories per gram, respectively, does not exactly add up to the number of calories listed on the label is due mainly to rounding rules that apply to the Nutrition Facts label. Rather than explain this in a footnote, however, we intend to include information about rounding as part of our planned nutrition education efforts and clarify why the caloric values of individual macronutrients may not add up to the total number of calories listed on the label.

We also do not agree that the caloric conversion factors on the label should be listed on a ''per ounce'' basis, rather than on a ''per gram'' basis, as one comment suggested. The information, if present, must be provided on a per gram basis (§ 101.9(d)(10)), which is consistent with the units that are used for declaring amounts of fat, carbohydrate, and protein on the Nutrition Facts label and therefore most likely to be useful for consumers. Furthermore, the comment did not provide data to show that ounces would be better understood or would be more useful to consumers than grams, and we have no evidence to support listing the conversion factors on a ''per ounce'' basis. We also note that the final rule no longer amends § 101.9(d)(10); we had proposed revising § 101.9(d)(10) as part of the proposed rule when we also proposed removing and reserving § 101.9(d)(9). Our proposed amendment to § 101.9(d)(10) would have removed a cross-reference to § 101.9(d)(9) and referred, instead, to a part of the Nutrition Facts label. In the supplemental proposed rule, however, we suggested text that would become a new § 101.9(d)(9) (thereby eliminating the need to reserve that paragraph). Thus, the proposed amendment to § 101.9(d)(10) is no longer necessary, and the final rule does not amend § 101.9(d)(10). (We have made a similar revision to § 101.9(d)(11) to restore a cross-reference to § 101.9(d)(9).)

With respect to the comment that said retaining the caloric conversion information could help consumers adjust their caloric intake if their individual calorie needs were above or below 2,000 calories per day, we acknowledge this is a reasonable assumption because understanding the relative amount of calories contributed by fat, carbohydrate, and protein may help consumers better comprehend and use the Nutrition Facts label, which may assist them in maintaining healthy dietary practices.

R. Compliance

Section 101.9(g) provides information about how we determine compliance with our nutrition labeling requirements, including the methods of analysis used to determine compliance, reasonable excesses and deficiencies of nutrients, and acceptable levels of variance from declared values.

1. Level of Variance Allowed for the Label Declaration of Specific Nutrients

Under our preexisting regulations, at § 101.9(g)(5), a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The provision provides that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

The proposed rule would not change the level of variance allowed in § 101.9(g)(5).

(Comment 521) One comment suggested that we tighten the allowable variance to no more than 10 percent. The comment was concerned that the 20 percent allowable variance could result in inaccurate and misleading information going to consumers. The comment said that modern manufacturing and testing methods should allow food manufacturers to provide a more accurate representation of the nutrient content of foods.

(Response) As we stated in the preamble to the proposed rule (79 FR 11879 at 11955), we received a similar comment to the 2007 ANPRM asking us to reevaluate the level of variance permitted for nutrient content declarations. When initially determining the allowances for variability, we considered the variability in the nutrient content of foods, analytical variability inherent to test methods used to determine compliance, and statistical probability (38 FR 2125 at 2128, January 19, 1973). We also evaluated compliance procedures and found them to be statistically sound and adequate.

The comment provided no information for us to consider, such as information to show that the variability in the nutrient content of foods or analytical variability inherent in test methods used to determine compliance have decreased. Therefore, because we do not have a basis to change the level of variance permitted for the label declaration of nutrients, we decline to revise the rule as suggested by the comment.

2. Methods Used To Determine Compliance

Under our preexisting regulations, at § 101.9(g)(2), a composite of 12 subsamples, each taken from 12 different randomly chosen shipping cases are analyzed by appropriate methods as given in the ''Official Methods of Analysis of the AOAC International,'' 15th Ed. (1990) to determine compliance with the requirements in § 101.9, unless a particular method of analysis is specified in § 101.9(c). If no AOAC method is available or appropriate, we use other reliable and appropriate analytical procedures (see § 101.9(g)(2)).

The proposed rule would amend § 101.9(g)(2) to update the reference to the 19th Edition of the ''Official Methods of Analysis of the AOAC International.'' The preamble to the proposed rule (79 FR 11879 at 11913) explained that the 19th edition published in 2012 and that if a newer edition were published before we issued a final rule, we intended to finalize the rule to refer to the newer edition provided there are no substantive changes in the newer edition requiring additional comment. The Official Methods of Analysis of AOAC International, 20th Edition was

published in 2016. The 20th Edition includes a number of new methods of analysis as well as changes to current methods. We need additional time to consider the additions and changes, and to determine if additional public comment is necessary on the 20th Edition of the AOAC Methods of Analysis. Therefore, the final rule, at § 101.9(g)(2), incorporates by reference the 19th Edition of the Official Methods of Analysis of the AOAC International.

(Comment 522) Some comments supported incorporating the 19th Edition of the AOAC Methods by reference in the final rule. Other comments suggested other alternatives. Some comments suggested that a specific edition of the AOAC Methods should not be incorporated by reference to allow companies to use future editions of the reference to meet compliance requirements. One comment stated that, given the potential limitations of the two AOAC methods for fiber identified in the proposed rule (AOAC 2009.01 and AOAC 2011.25) and the inevitable delays between adoption by AOAC of the most relevant, updated, and appropriate methods, we should incorporate all appropriate, equivalent, and validated methods into the final rule.

(Response) We decline to revise the rule to adopt the alternative approaches suggested by the comments. We note that, under the incorporation by reference regulations issued by the Office of the **Federal Register**, incorporation by reference of publication is limited to a specific edition and ''future amendments or revisions of the publication are not included'' (1 CFR 51.1(f)). Thus, under Federal regulations, we cannot incorporate by reference a specific AOAC method and all future editions of that method.

(Comment 523) Some comments questioned what we mean by ''equivalent AOAC method,'' and whether the terms mean that any other AOAC method is acceptable for determining fiber content.

(Response) We used the terminology ''equivalent AOAC method'' to mean a reliable and appropriate method which can be used for measuring dietary fiber, soluble fiber, and insoluble fiber. For example, the definition of dietary fiber requires that the fiber must contain 3 or more monomeric units. We would consider a reliable and appropriate method for dietary fiber to be one that can measure fibers with 3 or more monomeric units.

(Comment 524) Several comments suggested that AOAC 2009.01 and AOAC 2011.25 do not capture all dietary fibers. Many comments recommended that we allow for the use of all validated AOAC methods for the determination of dietary fiber. (We discuss issues related to AOAC methods in greater detail in our response to comment 299.)

(Response) In proposed § 101.9(c)(6)(i), we stated that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent method of analysis given in the 19th edition of the AOAC methods. We stated, in proposed § 101.9(c)(6)(i)(A), that soluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis as given in the 19th edition of the AOAC Methods and stated, in proposed § 101.9(c)(6)(i)(B), that insoluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis given in the 19th edition of the AOAC Methods. Although we intended that the terms ''other equivalent methods'' refer to other AOAC methods and their AACCI counterparts, to provide clarification, the final rule omits the incorporation by reference of the specific AOAC methods in § 101.9(c)(6)(i), (c)(6)(i)(A), and (c)(6)(i)(B). Any dietary fiber declared on the label would have to meet the new definition of dietary fiber and manufacturers can measure the amount of dietary fibers in their product accurately by using a method that can measure lower molecular weight nondigestible oligosaccharides with DP 3–9. We would determine compliance by using appropriate methods, as given in the ''Official Methods of Analysis of the AOAC International,'' 19th Ed. (2012). We consider AOAC 2009.01 and AOAC 2011.25 to be reliable and appropriate methods to measure the amount of dietary fiber in a serving of a product. We consider AOAC 2011.25, as given in the ''Official Methods of Analysis of the AOAC International,'' 19th Ed. (2012), to be a reliable and appropriate method to measure the amount of soluble and insoluble fiber in a serving of a product, if separately declared. There may be other methods which manufacturers may use to measure certain fibers which can provide an accurate and consistent result. We will consider the method to use for purposes of determining compliance consistent with § 101.9(g).

3. Records Requirements

Our preexisting regulations, at § 101.9(g)(2), set forth requirements for composite sampling and analysis to determine compliance with labeling declarations. Specifically, unless a specific analytical method is identified by regulation, composites are analyzed by the appropriate AOAC method or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

In the preamble to the proposed rule (79 FR 11879 at 11956), we noted that, for certain nutrients subject to the proposed rule, there is no AOAC official method of analysis or other reliable or appropriate analytical procedure that is available for us to verify the amount of the declared nutrient on the Nutrition Facts label and ensure that the declared nutrient amount is truthful, accurate and complies with all applicable labeling requirements. The preamble to the proposed rule (79 FR 11879 at 11956) stated that there is no suitable analytical procedure available to measure the quantity of: (1) Added sugars (when a food product contains both naturally occurring sugars and added sugars and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and/or fermentation); (2) dietary fiber (when a food product contains both non-digestible carbohydrate(s) that meets the proposed definition of dietary fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber); (3) soluble fiber (when a mixture of soluble fiber and added nondigestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (4) insoluble fiber (when a mixture of insoluble fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (5) vitamin E (when a food product contains both RRR- α-tocopherol and *all rac*-α-tocopherol acetate); and (6) folate (when a food product contains both folate and folic acid).

Under our preexisting regulations, at § 101.9(g)(9), we may permit the use of an alternative means of compliance or additional exemptions when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of § 101.9. Under § 101.9(g)(9), firms must submit a written request to us for the use of an alternative means of compliance or for a labeling exemption.

The proposed rule would establish an alternative approach for assessing compliance of the declared amount of certain nutrients when there is no suitable analytical method available to measure the nutrient's quantity as

declared on the label or in labeling. Specifically, the proposed rule, at proposed § 101.9(g)(10) and (g)(11), would require the manufacturer to make and keep records that are necessary to verify the declaration of: (1) The amount of added sugars when both naturally occurring and added sugars are present in a food (in § 101.9(c)(6)(iii)); (2) the amount of added non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the dietary fiber present in a food is a mixture of non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)); (3) the amount of added soluble non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the soluble dietary fiber present in a food is a mixture of soluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(A)); (4) the amount of added insoluble non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the insoluble dietary fiber present in a food is a mixture of insoluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(B)); (5) the amount of *all rac*-α-tocopherol acetate added to the food and RRR-α-tocopherol in the finished food when a mixture of both forms of vitamin E are present in a food (in § 101.9(g)(10)(i)); and (6) and the amount of folic acid added to the food and the amount of folate in the finished food when a mixture of both forms are present in a food (in § 101.9(g)(10)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11956), we explained that the manufacturer is in the best position to know which of its records provide the documentation required under the circumstances described for us to determine compliance. These records could include one or more of the following: Analyses of databases, recipes or formulations, or batch records. We stated that most manufacturers should already have the type of records needed to validate the declared amount of these nutrients and that the proposed records requirements provide flexibility in what records the manufacturer makes available to us to verify the declared amount of these nutrients for a particular marketed product (id.).

The proposed rule, at proposed § 101.9(g)(11), also would require that records be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce and that such records be provided to us upon request during an inspection for official review and copying or other means of reproduction. The proposed rule also stated that records could be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records in accordance with 21 CFR part 11.

(Comment 525) Many comments agreed with the proposed recordkeeping requirements. However, other comments objected to the proposed recordkeeping requirements. Some comments said that our compliance program for nutrition labeling should be based on the validation of nutrient declarations through analytical methods and not through recordkeeping. Other comments said that compliance should be based on objective, analytical measures to yield consistent labeling practices across the food industry. Others comments said that the proposed recordkeeping requirements could invite unethical manufacturers to provide inaccurate information about the quantity of nutrients in a serving of their product.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11956), for certain nutrients, there are no official methods of analysis or other reliable or appropriate analytical procedures that are available to verify the amount of the declared nutrient on the Nutrition Facts label. In the absence of such methods, there needs to be some means for determining compliance, and so we proposed recordkeeping as an alternative approach for assessing compliance of the declared amount of certain nutrients. While the amount of most other nutrients in Nutrition Facts can be verified analytically, for those nutrients whose amounts cannot be determined analytically, recordkeeping enables FDA to determine compliance with § 101.9(g). Regarding the potential for encouraging manufacturers to provide inaccurate information to FDA, we note that all nutrient declarations must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, whether determined analytically or through calculations documented in appropriate records, manufacturers are obligated to provide nutrient information that is not false or misleading.

(Comment 526) Several comments said that it would be very difficult to obtain and retain the information required by FDA. Some comments noted that the number of product formulations can be greater than 20,000 for certain manufacturers and that they would need to create systems and dedicate additional resources to create and maintain appropriate records on a large scale. Other comments said that manufacturers typically get ingredients from suppliers in an extensive supply chain and that many ingredients also contain multiple ingredients themselves. Suppliers may not have the information themselves, or the information for the formulations could be proprietary. Additionally, nutrient information could be provided in ranges, and manufacturers would be unable to determine or verify the specific amounts of certain nutrients analytically.

(Response) Although some manufacturers could have a large number of foods that contain nutrients that would necessitate recordkeeping to verify amounts, we do not agree that determining the nutrient composition of a food and recording that information would present undue difficulty for manufacturers. On the contrary, knowledge of what ingredients and nutrients are in a food and providing that information truthfully to consumers is a basic requirement for food producers. Manufacturers, even those who produce large amounts of food products, have experience with determining nutrient content of the food they produce, and the maintenance of records of nutrient content, either written or electronic. Regarding obtaining information from ingredient suppliers, manufacturers are well suited to work with suppliers to ensure that proper information is communicated throughout the supply chain. Ingredient suppliers are obliged to have knowledge of the contents of ingredients they provide to food manufacturers and this information will need to be properly communicated. Manufacturers may be able to choose suppliers that provide appropriate information as to the contents of their ingredients or be able to ask their ingredient suppliers for nutrient information.

(Comment 527) Some comments suggested that the required approach should be flexible and not mandate a specific type of record. The comments indicated that manufacturers should be able to substantiate using the records they believe best accomplish the validity of nutrient information. The comments stated that we did not need access to manufacturing records and that other methods, such as database information or an explanation from a manufacturer, would suffice.

(Response) Manufacturers will be responsible for the type of records they maintain and are not required to

produce any specific form or document for verification purposes. Records used to verify nutrient content could include various types of batch records providing data on the weight of certain nutrient contributions to the total batch, records of test results conducted by the manufacturer or an ingredient supplier, certificates of analysis from suppliers subject to initial and periodic qualification of the supplier by the manufacturer, or other appropriate verification documentation that provide the needed assurance that a manufacturer has adequately ensured the food or ingredients comply with labeling requirements. The records submitted for inspection by FDA would only need to provide information on the nutrient(s) in question. Information about other nutrients can be redacted if necessary to ensure confidentiality of a food product formulation.

(Comment 528) Several comments addressed our legal authority to require recordkeeping as described in the proposed rule.

(Response) We address these comments in part II.C.4.

(Comment 529) Some comments expressed concern that proprietary information in recipes and formulations could be divulged and said that the ability to retain and claim the proprietary nature of product formulations is essential to staying competitive in the marketplace. Other comments suggested that we clarify that the recordkeeping requirements will not require access to proprietary information, such as recipes and formulations. In addition, the comments recommended that we specify what level of information and types of documents are required to meet the recordkeeping requirements. Several comments requested that manufacturers be permitted to develop a stand-alone document that articulates the basis for the declaration of added sugars in a product. Other comments recommended that, if we finalize the recordkeeping requirements and require the copying of records, we address the security of the information coming from inspections and the protection of confidential information.

(Response) The final rule does not require a specific document to be retained nor does it require information on proprietary recipes or overall formulations. Instead, the recordkeeping requirements seek specific content information for certain nutrients, and this information can be provided in various forms. For example, information in some batch records could include data on the total batch weight of the production of a particular food and also provide data on the weight of certain nutrient contributions to the total batch. With these types of data, calculations can be made to determine nutrient content for individual foods or servings of a food. Documentation of this type would not reveal any proprietary recipes or formulations and would be limited to specific nutrient information. Information about the nutrient content of the ingredients of a food product could be acquired from ingredient suppliers subject to initial qualification and periodic requalification by the manufacturer, and this type of information on quantitative source amounts can be included in the batch records.

Furthermore, even if a manufacturer's records contained confidential commercial information or trade secret information or a manufacturer believes that certain information should be protected from public disclosure, we note that there are safeguards to protect against public disclosure of that information and mechanisms that a manufacturer can use to assert that certain information should be protected from disclosure. As we stated in the preamble to the proposed rule (79 FR 11879 at 11957), we would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and part 20 (21 CFR part 20). For example, our regulations pertaining to disclosure of public information, at part 20, include provisions that protect trade secrets and commercial or financial information which is privileged or confidential. If a manufacturer keeps proprietary recipe information in its records, it should mark the information as such before providing the records to us upon request.

(Comment 530) One comment expressed concerns that allowing for recordkeeping as a way to verify the amount of nutrients such as added sugar in some products would encourage those manufacturers to provide false reporting of the added sugar content of their products.

(Response) We note that having a false declaration on the label is a violation of section 403(a)(1) of the FD&C Act. Providing false information in records to the Agency may also be a potential criminal violation under 18 U.S.C. 1001. Under 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully: (1) Falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry may be subject to a fine or imprisonment.

(Comment 531) Some comments disagreed with the proposed requirement to keep records for at least 2 years after a food's introduction into interstate commerce. The comments said manufacturers would have to keep track of an additional data point (the date on which the food is actually shipped) as opposed to the date on which it is manufactured. The comments said that shipping dates can vary, even for foods from the same batches, and could occur months after manufacture, and this could result in extremely divergent record maintenance timeframes for foods.

Furthermore, some comments said that is unclear whether the term ''food'' is intended to refer to a particular batch of food or to an individual food.

Other comments suggested that 2 years is a long time for foods with very short shelf lives. Some comments noted that the Seafood Hazard Analysis and Critical Control Points (HACCP) regulations allow for a 1-year record retention period for refrigerated products and a 2 year period for frozen, preserved, or shelf-stable products. The comments suggested that, similarly, the 2 year requirement for recordkeeping related to nutrition labeling should be limited to frozen, preserved, or shelf-stable products and that a shorter period of 1 year should be allowed for maintenance of records for refrigerated and perishable foods.

(Response) We recognize that there can be a wide variation of manufacturing practices, shipping practices, and shelf lives among packaged foods. We believe, however, that it is more practical to establish a single recordkeeping period rather than establish different recordkeeping periods for different products or for different manufacturing or shipping practices. It would be more difficult for FDA to establish a compliance program for one segment of the regulated industry that starts the recordkeeping process when the food is made and a different compliance program for another segment of the industry that starts the recordkeeping process when the food is shipped. Likewise, for manufacturers who make several food products, it may be easier for them to use the same recordkeeping period for all products rather than use different recordkeeping periods for different products. Therefore, we have designed a

compliance program or strategy that involves a single recordkeeping period.

As for the comment asking whether ''food'' referred to a particular batch or to an individual food, the term food refers to an individual food item, but there are not specific requirements on what type of documentation is required. If the same documentation addresses the declarations on an entire batch of food or an even greater quantity of food, those records may be sufficient.

(Comment 532) Some comments suggested that manufacturers should be allowed to keep records at locations separate from factories (*e.g.,* corporate headquarters) and that we allow a reasonable timeframe (*e.g.,* 72 hours or 15 days) to obtain the records and make them available.

(Response) Records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610). The records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food has been manufactured and labeled in compliance with labeling requirements. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

(Comment 533) Some comments said that the recordkeeping requirements could present a barrier to trade. They stated that access to records of manufacturers of imported foods may not be possible unless reciprocal agreements are in place and that such agreements could pose a challenge to trade with certain countries.

(Response) We disagree with the comments. As in the case of domestic manufacturers, foreign manufacturers of food produced for sale in the United States must follow all applicable laws and regulations related to nutrition labeling. The final rule establishes the same recordkeeping requirements for foreign and domestic firms. To the extent records are not available during a foreign facility inspection for imported products, that would certainly inform a determination about the admissibility of the food.

(Comment 534) Several comments addressed recordkeeping as it pertained to added sugars. The comments said the proposed recordkeeping requirements were overreaching, especially when, according to the comments, we acknowledged that added sugars do not pose a safety issue and are not uniquely or directly related to a risk of chronic disease, a health-related condition, or a physiological endpoint. Some comments noted that previous FDA recordkeeping requirements involved pharmaceutical safety or potentially adulterated foods that pose safety hazards. Some comments stated that we have never required recordkeeping to support a mandatory disclosure on the Nutrition Facts label that does not involve risk of disease. A few comments explained that obtaining added sugar information, in particular, from ingredient suppliers is difficult because ingredients do not distinguish between naturally occurring and added sugars and manufacturers are unable to distinguish them analytically.

(Response) We recognize that it may be difficult to determine the quantity of added sugars and intrinsically occurring sugars in a particular ingredient or food, and we stated this several times in the preamble to the proposed rule (see 79 FR 11879 at 11905, 11906, and 11956). The recordkeeping requirement, in the absence of an analytical method that would distinguish between added and intrinsically occurring sugars in a food, is an alternative means of verifying compliance; contrary to the comments' statements regarding added sugars and safety hazards or chronic disease, the recordkeeping requirement was not based on or otherwise dependent on an independent relationship between added sugars and chronic disease. Instead, as we stated in the preamble to the proposed rule (79 FR 11879 at 11956), the information contained in manufacturers' records is an accurate and practical method for assuring that the nutrient declarations comply with section 403(q) of the FD&C Act.

(Comment 535) Some comments suggested that we extend the requirement in proposed § 101.9(g)(10)(v) to all foods declaring added sugar to allow food manufacturers to keep records to demonstrate the amount of added sugars remaining in the finished food when that amount is less than the initial amount of added sugars.

(Response) We decline to revise the rule as suggested by the comment. Section 101.9(g)(10)(v) states that when the amount of added sugars is reduced through non-enzymatic browning and/or fermentation, the manufacturer must make and keep certain data, information, and records to document the differences in added sugar content between the unfinished and finished products. Not all foods undergo non-enzymatic browning and/or fermentation, so extending § 101.9(g)(10)(v) to all foods is unnecessary.

(Comment 536) One comment noted that we have described the new recordkeeping requirement for certain nutrients as analogous. The comment said that the recordkeeping for added sugars is different than those for other nutrients, such as fiber, folate, or vitamin E in that the recordkeeping requirement for added sugars is unavoidable due to the mandatory nature of the added sugars declaration.

(Response) The new recordkeeping requirements are analogous based on the fact that inspection of records is the only method to evaluate compliance with the nutrition labeling regulations for a certain number of nutrients. For certain nutrients there are no AOAC official methods of analysis or other reliable or appropriate analytical procedures that are available for us to verify the amount of the declared nutrient on the Nutrition Facts label and ensure that the declared nutrient amounts are truthful, accurate and complies with all applicable labeling requirements. However, we agree that there are difference as to which manufacturers will need to keep records for nutrient content and which products will necessitate recordkeeping. Some manufacturers who voluntarily declare vitamin E content, for example, will have to keep records for vitamin E content but manufacturers who do not declare vitamin E will not need to maintain any records for vitamin E content. Conversely, most manufacturers will need to maintain records on added sugar content. As discussed in part II.H.3, however, we have concluded that the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. Thus, the added sugars declaration is required and, as is the case for any nutrient that does not have any analytical method available to assess compliance, the records described here will have to be maintained and made available for inspection.

(Comment 537) One comment stated that we have said that requiring recordkeeping could spur reformulation, but also stated that we have not provided any evidence of this.

(Response) We do not cite potential reformulation of food products as a reason for or a benefit resulting from recordkeeping requirements. The recordkeeping requirements are only being created to establish an alternative approach for assessing compliance of the declared amount of certain nutrients when there is no suitable analytical method available to measure the

nutrient's quantity as declared on the label or in labeling.

4. Inclusion of Potassium as a Mineral

Potassium is specified as a Class I and Class II nutrient in our preexisting regulations at § 101.9(g)(4)(i) and (g)(4)(ii), respectively and is the only vitamin or mineral that is specifically listed under the description of both Class I and Class II nutrients. Because the proposed rule (at § 101.9(c)(8)(iv)) would establish an RDI for potassium and require declaration of the absolute amount along with a percent DV on the Nutrition Facts label, we also proposed to not list potassium separately under the description of Class I and Class II nutrients and to remove the term ''potassium'' from § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6). Instead, potassium would be covered under the term ''mineral'' that appears in each section, and any listing of potassium on the Nutrition Facts label would have to meet the specific compliance requirements for minerals under § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6).

We did not receive any comments regarding potassium and § 101.9(g)(4) or (g)(6). Therefore, we have finalized those provisions without change.

5. Requirements for Other Carbohydrate, Soluble and Insoluble Fiber, Added Sugars, and Sugar Alcohols

Our preexisting labeling requirements for Class I and Class II nutrients are at § 101.9(g)(4). Because the proposed rule would revise § 101.9(c)(6)(iv) to remove the provision for voluntary declaration of ''Other carbohydrate,'' we proposed to remove the compliance requirements related to ''Other carbohydrate'' in § 101.9(g)(4) and (g)(6).

We also proposed, when all of dietary fiber in a food product meets the proposed definition of dietary fiber, to include soluble and insoluble fiber as both Class I and Class II nutrients under § 101.9(g)(4); include added sugars within § 101.9(g)(5) such that the label declaration of added sugars will be deemed misbranded under section 403(a) of the FD&C Act if the nutrient composite is greater than 20 percent in excess of the added sugars value declared on the label, and within § 101.9(g)(6) such that reasonable deficiencies of added sugars would be permitted; and include soluble and insoluble fiber and sugar alcohols within § 101.9(g)(6) such that reasonable excesses of these nutrients would be permitted.

We did not receive comments with respect to the removal of other carbohydrate from § 101.9(g)(4) and (6) or on the addition of soluble and insoluble fiber to § 101.(g)(4) and (6), and so we have finalized those provisions without change. We address comments on the compliance requirements for added sugars in part II.H.3; however, we are finalizing the addition of added sugars to the compliance requirements of § 101.9(g)(5) and (g)(6) as proposed.

6. Miscellaneous Comments

Although we did not receive any comments on our proposed revisions to the compliance requirements in § 101.9(g)(4), (g)(5), and (g)(6), we did receive a number of comments related to Class I and Class II nutrients.

(Comment 538) We proposed to amend § 101.9(g)(4)(i) to say that, when a vitamin, mineral, protein, or non-digestible carbohydrate(s) (when the food contains only non-digestible carbohydrates (soluble or insoluble) that meet the definition of dietary fiber) meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label. Currently, our preexisting regulations, at § 101.36(f)(1), state that compliance for dietary supplements will be determined in accordance with § 101.9(g)(1) through (g)(8) and that the criteria on Class I and Class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients.

Two comments would revise the requirements for Class I nutrients in § 101.9(g)(4)(i) and § 101.36(f)(1) such that added nutrients in fortified or fabricated foods must contain at least 90 percent of the declared amount rather than the current requirement of 100 percent of the declared amount. The comments recommended that we allow for fortified and fabricated foods to contain less than the declared amount of a Class I nutrients because degradation of dietary ingredients is anticipated and can occur during the shelf life of the product. The comments said that degradation can occur faster in some nutrients than others with certain matrices. The comments expressed concern that firms may include large excesses (greater than 120 percent of the declared amount) to remain in compliance with requirements for Class I nutrients and other dietary ingredients over the shelf life of the product. One comment stated that a lower limit of 90 percent potency as in the U.S. Pharmacopeia (USP) should be permitted because DSHEA made it clear that Congress' intent was that the compendial standards should be the guiding influence where compendial standards exist and products are represented as complying with those standards (21 U.S.C. 343(s)(2)(D)).

One comment also would revise § 101.36(f)(1) to state that the food is also in compliance if it conforms to the specifications of an official compendium. The comment suggested that reasonable excesses of dietary ingredients over labeled amounts would still be acceptable within current good manufacturing practices.

Another comment noted that jurisdictions outside of the United States, such as Denmark, Korea, and the United Kingdom, recognize a minimum value of 80 to 90 percent of the declared amount for added vitamins and minerals at the end of shelf life. The comment suggested that allowing for a minimum of 90 percent of the declared amount of an added vitamin or mineral in the Class I requirements would promote harmonization with other jurisdictions.

One comment suggested that allowing for a minor loss of strength during the product shelf life for Class I nutrients and other dietary ingredients would be similar to what is allowed in drug monographs.

(Response) We acknowledge the comments' arguments for revising our compliance requirements for Class I nutrients, but decline to revise the rule to allow for less than 100 percent of the amount declared on the label. We note that the USP compendial standards for label claims deviations vary from nutrient to nutrient and even vary with different dietary supplement formulations (*e.g.,* high potency products). This is a complex issue that warrants further consideration. We need to further consider and review the available information and to make a determination whether to propose changes with respect the requirements for Class I nutrients and/or other requirements that may be affected.

(Comment 539) One comment referred to a statement made in the preamble to the proposed rule (79 FR 11879 at 11958) that we expect that, when a food product contains added sugars, added dietary fiber, vitamin E as *all rac*-α-tocopherol acetate, and added folic acid, the declared amount must be at least equal to the amount of the nutrient added to the food. The comment noted that there are instances when the declared amount of vitamin E, fiber, or folic acid could be less than the amount added to the recipe as a result of process losses or losses over shelf life. The comment said it is incorrect to assume that the declared amount would be equal to at least the amount added to the recipe.

(Response) We agree that there could be process losses or losses over shelf life for some nutrients added to a product. Product loss over the shelf-life of a product is a complex issue that warrants further review. We need additional time to review the available information and to make a determination whether to propose changes with respect the requirements for Class I nutrients and/or other requirements that may be affected.

(Comment 540) The proposed rule, at § 101.9(g)(3)(ii), would state that when a nutrient or nutrients are not naturally occurring in an ingredient added to a food, the total amount of such nutrient in the final food product is subject to Class I requirements. One comment supported the rule, but two comments asked us to clarify that this provision is referring to ingredients, such as vitamin premixes, that contribute to, but do not account for, the total declared amount of the nutrient. The comments expressed concern that the rule could be construed to apply to the use of ingredients such as enriched flour or vitamin A fortified milk which may not contribute substantially to the nutrient composition of foods. An example might be a mixed dish containing carrots and a small amount of milk with added vitamin A. Because the naturally occurring vitamin A in the carrots would be the primary source of vitamin A in the product rather than the added vitamin A in the milk, the comment would have us consider vitamin A to be a Class II nutrient.

(Response) We decline to revise the rule to refer to ingredients that contribute to, but do not account for, the total declared amount of the nutrient. There are cases when fortified ingredients contribute significantly to the amount of a nutrient when the same nutrient also occurs naturally in the food. For example, enriched flour containing thiamin could be added to bread containing oats where oats are also a source of thiamin. Our intent in proposing to amend § 101.9(g)(3)(ii) was to clarify, rather than alter, the requirement for manufacturers so that, even if a small amount of a nutrient is added to a food, where the final food product also contains an ingredient with the same nutrient in a naturally occurring form, the final food product is subject to the Class I requirements. Thus, contrary to the comments' interpretation, we would not consider the vitamin A to be a Class II nutrient in the example provided by the comment.

We note that manufacturers can choose to use ingredients that are not fortified when formulating their products. In the example provided in the comment, the manufacturer could use milk that is not fortified with vitamin A in formulating the product. In such case, the vitamin A in the finished food would be from a naturally occurring source, and the food would have to meet the requirements for Class II nutrients rather than Class I nutrients.

S. Technical Amendments

The proposed rule also would make certain technical amendments, such as changing the name of the program office to reflect its current name and making non-substantive edits for purposes of plain language.

1. Changing the Name of the Program Office

The proposed rule would update the name of the program office that is responsible for developing regulations and answering questions related to nutrition labeling as well as for maintaining some references discussed throughout § 101.9. The program office's former name was the Office of Nutritional Products, Labeling and Dietary Supplements; at the time we issued the proposed rule, the program office's name was the Office of Nutrition, Labeling and Dietary Supplements. We proposed to update the name throughout § 101.9.

We did not receive any comments regarding the change in the program office's name. However, since we issued the proposed rule, the program office's name changed again, to be the Office of Nutrition and Food Labeling, and so we have revised § 101.9 accordingly.

2. Changing the Publication Date of Report Incorporated by Reference

Our preexisting regulations, at § 101.9(c)(7)(ii), provide that the protein digestibility-corrected amino acid score must be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1990, except that when official AOAC procedures described in § 101.9(c)(7) require a specific food factor other than 6.25 to be used. We incorporated the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation'' by reference in § 101.9(c)(7)(ii), but § 101.9(c)(7)(ii) incorrectly uses 1990 as the publication date when the report actually was published in 1991. Thus, the proposed rule would change the publication date of the report that is incorporated by reference from 1990 to 1991.

We received no comments regarding this change and have revised § 101.9(c)(7)(ii) by replacing ''1990'' with ''1991.'' However, with respect to this and other references that we incorporated by reference in the final rule, we have revised the incorporation-by-reference language in the final rule to meet the current requirements at 5 CFR part 51. Consequently, much of the incorporation by reference language can be found at a new § 101.9(l).

3. Plain Language Edits

On October 13, 2010, the President signed the Plain Writing Act of 2010 requiring that Federal Agencies use ''clear Government communication that the public can understand and use.'' On January 18, 2011, the President issued Executive Order (E.O.) 13563, ''Improving Regulation and Regulatory Review'' (75 FR 3821 (January 21, 2011)); section 1 of E.O. 13563 sets forth ''General principles of regulation,'' and these principles include ensuring that regulations are ''accessible, consistent, written in plain language, and easy to understand.'' To make the requirements of § 101.9 easier to understand, we proposed editorial changes that would not change the meaning or intent of the language in § 101.9(g)(3)(ii); (g)(4)(i); (g)(4)(ii); (g)(5); and (g)(8). Specifically, the proposed rule would:

- Revise § 101.9(g)(3)(ii) to clarify that when a nutrient or nutrients are not naturally occurring (exogenous) in an ingredient that is added to a food, the total amount of such nutrient(s) in the final food product is subject to Class I requirements rather than Class II requirements. We proposed this change because the existing rule did not explicitly state that such a nutrient would be subject to Class I requirements.
- Remove ''Class I'' and ''Class II'' from § 101.9(g)(4)(i) and (g)(4)(ii), and to state instead that when the list of nutrients provided in those sections meets the definition of a Class I or Class II nutrient provided for in § 101.9(g)(3)(i) and (g)(3)(ii), the declaration of those nutrients must meet certain requirements. We explained that this change was intended to prevent confusion by having two different definitions of a ''Class I'' and ''Class II'' nutrient for compliance with nutrition labeling requirements.
- Remove the words ''Provided, That'' from §§ 101.9(g)(4)(ii) and (g)(5) because the words do not provide further clarification and are unnecessary.
- Add the word ''Alternatively'' at the beginning of § 101.9(g)(8) to indicate that use of an FDA approved database

is an alternative to the type of nutrient analysis described in § 101.9(g)(1) and (g)(2).

(Comment 541) One comment stated that the proposed rule does not meet the requirements of the Plain Writing Act of 2010 (Pub. L. 111–274) and said it should be rewritten at a much lower literacy level.

(Response) Although we strive to use plain language and to draft our regulations in a manner such that they are easy to understand, we disagree with the comment. The comment did not provide any specific examples or suggestions on how we should rewrite the rule, so we do not have an adequate basis to determine which parts of the rule, in the comment's view, should be rewritten or how they should be revised.

We also note that, while we have made every effort to write the rule in plain language and in easily understood terms, the rule imposes requirements on firms who have Nutrition Facts or Supplement Facts labels on their products rather than on laymen. The intended ''audience'' for the rule is an important consideration when it comes to plain language. As the Federal Plain Language Guidelines state:

> One of the most popular plain language myths is that you have to ''dumb down'' your content so that everyone everywhere can read it. That's not true. The first rule of plain language is: Write for your audience. Use language your audience knows and feels comfortable with. Take your audience's current level of knowledge into account. Don't write for an 8th grade class if your audience is composed of Ph.D. candidates, small business owners, working parents, or immigrants. Only write for 8th graders if your audience is, in fact, an 8th grade class.

Federal Plain Language Guidelines, ''Think About Your Audience,'' p. 1 (March 2011).

Consequently, the final rule makes the plain language edits to § 101.9(g)(4)(i), (g)(4)(ii), and (g)(8). However, we have made additional revisions to § 101.9(g)(3)(ii) for clarification. In addition, upon further consideration, we decided to retain the words ''Provided, That'' in §§ 101.9(g)(4)(ii) and (g)(5). Removing the clause would no longer signal to the reader that no regulatory action will be taken based on a determination of a nutrient value that falls above a certain level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

4. Correcting § 101.9(c)(8)(iii) To Provide Instructions for Rounding Percent DVs

(Comment 542) One comment noted that the first sentence in proposed § 101.9(c)(8)(iii) did not provide clear instructions for how to declare the percent DVs for vitamins and minerals when the percent daily is between 2 to 10 percent, between 10 to 50 percent, or above 50-percent.

(Response) The text in first sentence in proposed § 101.9(c)(8)(iii) was inadvertently changed, and we did not mean to propose to amend this requirement. The text in the first sentence of § 101.9(c)(8)(iii) should read ''The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level.''

5. Miscellaneous Changes

The final rule also makes several non-substantive changes.

The proposed rule would amend § 101.9(c) to state that the requirements of § 101.9(c) apply to the labeling of food ''for adults and children over the age of 4 years, and on foods (other than infant formula) purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women.'' After further consideration, we have decided not to amend § 101.9(c) as we had proposed because the additional language is not necessary. As discussed part II.O, we have the same requirements for mandatory and voluntary labeling for products represented or purported to be for pregnant women and lactating women because women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy. Therefore, the requirements for mandatory and voluntary labeling for children and adults 4 years of age and older also apply to products represented or purported to be for pregnant women and lactating women, and there is no reason to mention requirements for pregnant women and lactating women in § 101.9(c). In addition, the requirements for mandatory and voluntary labeling for products purported to be for infants through 12 months of age and children 1 through 3 years of age are provided in § 101.9(j)(5). Therefore, there is no reason to mention requirements for mandatory and voluntary labeling of nutrients on products represented or purported to be for infants through 12 months or children 1 through 3 years in § 101.9(c).

The proposed rule also would make minor conforming changes to § 101.9(c)(1)(i)(D) and (E) by deleting the word ''or'' from the former and adding the word ''or'' to the latter. This change reflected the addition of a new subparagraph (F), such that we needed to move the conjunction to its correct place between the last two subparagraphs in § 101.9(c)(1)(i). The final rule adopts these changes.

T. Miscellaneous Comments

We also received comments on a variety of topics that were unrelated to the proposed rule. In brief, we received comments asking about:

- Declaring the presence of genetically modified organisms (GMOs) or GMO-related issues;
- Ingredient listing, particularly with respect to specific ingredients such as high-fructose corn syrup;
- Front-of-package labeling;
- Labeling of alcoholic beverages by another Federal Agency;
- Declaring whether a product contains caffeine, gluten, allergens, ''toxins'' (particularly from pesticides and food containers);
- Listing the glycemic index of foods and listing whole grains in a food;
- Health claim or nutrient content claim regulations;
- Expiration dates on food labels;
- Whether we should define the term ''natural'' on food labels;
- Issues related to our final rules on menu labeling and vending machine labeling; and
- Listing artificial sweeteners in the Nutrition Facts label.

Generally speaking, these topics are distinct from the Nutrition Facts and Supplement Facts label requirements, and so they are beyond the scope of this rulemaking. We note, however, that we have issued regulations regarding ''gluten-free'' labeling (see 78 FR 47154 (August 5, 2013) (now codified at 21 CFR 101.91), labeling of standard menu items in restaurants and similar retail food establishments (known informally as ''menu labeling'') (see 78 FR 71155 (December 1, 2014)) (now codified at 21 CFR 101.9), calorie labeling of articles of food in vending machines (78 FR 71259 (December 1, 2014) (also codified at 21 CFR 101.9), and Small Entity Compliance Guides for the gluten-free labeling rule and the menu labeling rules (see 79 FR 36322 (June 26, 2014) and 80 FR 13225 (March 13, 2015) respectively).

We also have a longstanding policy for the use of the term ''natural'' on labels of human food (see 56 FR 60421 at 60466 (November 27, 1991) (proposed rule on food labeling, nutrient content claims, and general principles)), and, in the **Federal Register** of November 12,

2015 (80 FR 69905), issued a notice to receive information and comments on the use of the term ''natural'' in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering and on specific questions we posed in the notice.

III. Effective and Compliance Dates

In the preamble to the proposed rule (79 FR 11879 at 11959), we indicated that a final rule, as well as any final rule resulting from the proposed rule entitled ''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,'' would become effective 60 days after the date of the final rule's publication in the **Federal Register** (79 FR 11879 at 11959). We also suggested that a final rule have a compliance date that would be 2 years after the effective date (*id.*). We explained that industry might need some time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update records of product labels, and print new labels.

(Comment 543) Several comments asked that we provide for a longer compliance date. Some comments specifically requested more time for small businesses. Some comments said that there are a limited number of label printing facilities and that they anticipated that small firms would have to wait longer to have new labels printed. The comments indicated that printing facilities would work with larger companies before working with small businesses or that the large companies would be able to negotiate more quickly with printing facilities to fill their labeling orders first. Other comments stated that small businesses often order a 2-year supply of labels or packaging, so a 2-year compliance date would force small businesses to discard inventory. One comment said that some manufacturers would need to work with design firms to revise or develop label designs.

Another comment requested a longer compliance date because of other label changes that we or other nations are requiring or anticipated new labeling requirements. The comment mentioned our declaratory order regarding partially hydrogenated oils (80 FR 34650 (June 17, 2015)), a Vermont state law requiring labeling of genetically engineered foods and similar legislation in other States, and a possible change to the Nutrition Facts Table and ingredient statements in Canada. Some comments said that synchronizing compliance dates would reduce the economic impact of food manufacturers or that providing a longer compliance date would reduce the economic impact on manufacturers.

Several comments also said that manufacturers may decide to reformulate products. One comment said that a longer compliance date would make it possible for more manufacturers to reformulate products to reduce added sugars, to qualify for nutrient content claims, or ''otherwise meet FDA's public health objectives.'' Another comment said that a longer compliance period would give companies time to reformulate ''where appropriate.''

Some comments said there would be environmental consequences or impacts if companies had to dispose of labels or could not use existing label stock.

In general, the comments suggested different compliance dates, ranging from 3 to 5 years, and stressed the impact on small businesses.

(Response) After considering the comments, we have maintained the compliance date of 2 years after the effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the effective date. Because the comments emphasized the rule's potential impact on small businesses, we agree that the impacts to smaller businesses may be more substantial than those on larger businesses, and so we have decided to provide a 3-year compliance date for manufacturers with less than $10 million in annual food sales. Thus, for manufacturers with less than $10 million in annual food sales, the compliance date will be July 26, 2019.

We take no position with respect to the comment's statements on label printing facilities and their interaction with large companies, but agree, generally, that small businesses may have fewer resources (both in terms of personnel and financial resources) to deal with regulatory changes and that an extended compliance date may mitigate the rule's impact on small businesses and reduce the need to dispose of potentially non-compliant labeling stock. Although the comments did not suggest any criteria to decide what constitutes a ''small business,'' for purposes of this rulemaking, we consider a small business to be a manufacturer with less than $10 million in annual sales, which we estimate using Nielsen data that covers approximately 95 percent of all food manufacturers and 48 percent of food UPCs.

We also decline to extend the compliance date for small businesses to 4 or 5 years. We note that the Nutrition Facts label's principal purpose is to assist consumers in maintaining healthy dietary practices. In establishing the compliance date for the rule, we have tried to balance the label's principal purpose against the need for industry to analyze products and to review, update, change, and print labels (see 79 FR 11879 at 11959). If we were to extend the compliance date for small businesses to 4 or 5 years, we may inadvertently create consumer confusion because different versions of the Nutrition Facts label would exist in the market for a longer period of time. The more years that differences exist between label formats on different products due to extended compliance periods, the more concern we would have about these differences frustrating, rather than enhancing, the consumer's ability to maintain healthy dietary practices and potentially undermining public confidence in the Nutrition Facts label.

IV. Economic Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct 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) (Ref. 274) that assesses the impacts of the two final rules taken together; the RIA is available at *http://www.regulations.gov* (Docket No. FDA–2012–N–1210) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/*. 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 Agencies 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. The analysis that we have performed to examine the impacts of the final rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 274) and is available at *http://www.regulations.gov* (Docket No. FDA–2012–N–1210).

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the OMB under the PRA. The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping 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.

A. 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 also are 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 asking us to 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 in the preceding sentence 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 any other 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	Number of recordkeepers	Number 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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Type of declaration/CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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 product 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 approximately 28 isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen petition 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. 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 and 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.

B. 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; or (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	Number of respondents	Number 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/§ 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
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, which 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.

C. 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]

21 CFR section	Number of respondents	Number 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.

D. 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 the 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 $2.47 billion (2014$).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this 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 this final rule.

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.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required (Refs. 275–276). Our finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535, 104 Stat. 2353, 2364 (1990)). If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

(Comment 544) One comment argued that our federalism analysis in the proposed rule should have included a discussion of the limits which the First Amendment places on Federal law. The comment also said that section 403A of the FD&C Act is limited to food in interstate commerce.

(Response) It is correct that, as quoted in the proposed rule's Federalism section, section 403A of the FD&C Act applies to food in interstate commerce. We decline to change our Federalism section to include a First Amendment analysis. The Federalism section discusses the limitations on states or political subdivisions of a State with regard to requirements for food labeling.

We address First Amendment arguments in part II.C.1.

VIII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Sinclair S., Hammon D., Goodman S. ''Sociodemographic Differences in the Comprehension of Nutrition Labels on Food Products''. *Journal of Nutrition Education and Behavior.* 2013;45:767–772.
2. Institute of Medicine (IOM) of the National Academies. ''Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices'', Washington, DC: National Academies Press; 2012.
3. U.S. Food and Drug Administration. ''Resources for You'', 2016. Retrieved from: *http://www.fda.gov/Food/ResourcesForYou*.
4. U.S. Department of Agriculture. Agricultural Research Service—Nutrient Data Laboratory. ''USDA National Nutrient Database for Standard Reference, Release 27'', 2014. Retrieved from: *http://www.ars.usda.gov/ba/bhnrc/ndl*.
5. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)'', Washington, DC: National Academies Press; 2002.
6. Graham J.D. ''Memorandum for the President's Management Council—Guidance on Agency Survey and Statistical Information Collections'', 2006.
7. American Association for Public Opinion Research. ''Why Sampling Works''. 2006.
8. U.S. Food and Drug Administration. ''What We Do'', 2016. Retrieved from: *http://www.fda.gov/AboutFDA/WhatWeDo/default.htm*.
9. Cowburn G., L.S., ''Consumer Understanding and Use of Nutrition Labeling: A Systematic Review''. *Public Health Nutrition*. 2005;8:21–28.
10. Kim S.Y., Nayga R.M., Capps Jr O. ''Food Label Use, Self-Selectivity, and Diet Quality''. *The Journal of Consumer Affairs*. 2001;35:346–363.
11. Lin C.T.J., Lee J.Y. ''Who Uses Food Label Information—a Case Study of Dietary Fat''. *Journal of Food Products Marketing*. 2004;10:17–37.
12. U.S. Food and Drug Administration. ''Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats (OMB No. 0910–0774)—Table 7'', 2015.
13. U.S. Food and Drug Administration. ''Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats—Additional Analyses (OMB No. 0910–0774)'', 2016.
14. U.S. Food and Drug Administration. ''Memorandum to File: Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB Control Number 0910–0764)'', 2015.
15. U.S. Food and Drug Administration. ''Memorandum to the File: Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking (Docket FDA–2012–N–1210)'', 2015.
16. U.S. Food and Drug Administration. ''Regulatory Impact Analysis for Final

Rules On: ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (Docket 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'', 2016.

17. National Heart Lung and Blood Institute. ''Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group'', Bethesda, MD; 2013.
18. Eckel R.H., Jakicic J.M., Ard J.D., et al. ''2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines''. *Journal of the American College of Cardiology.* 2014;63:2960–2984.
19. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
20. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Figure D1.36 Food Sources of Added Sugars'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC: U.S. Government Printing Office, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
21. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). ''National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–750''. Hyattsville, MD, 2016. Retrieved from: *https://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#DBQ750.*
22. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). ''National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–685''. Hyattsville, MD, 2016. Retrieved from: *https://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#CBQ685.*
23. U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. ''2014 FDA Health and Diet Survey''. 2016.
24. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 5: Energy'', Washington, DC: National Academies Press; 2002.
25. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification'', Washington, DC: National Academies Press; 2003.
26. U.S. Food and Drug Administration. ''Memorandum to the File: Comments Considered in the Development of the Revision of the Nutrition and Supplements Facts Proposed Rule'', 2014.
27. IUPAC. *Compendium of Chemical Terminology (the ''Goldbook'').* 2nd ed. Oxford: Blackwell Scientific Publications, 1997.
28. U.S. Department of Health and Human Services and U.S. Department of Agriculture. ''Dietary Guidelines for Americans 2015–2020'', 8th ed. Washington, DC: U.S. Government Printing Office, 2015–2020. Retrieved from: *http://health.gov/dietaryguidelines/2015/guidelines/.*
29. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 8: Dietary Fats: Total Fat and Fatty Acids'', Washington, DC: National Academies Press; 2002.
30. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Dietary Guidelines for Americans, 2010'', 7th ed. Washington, DC: U.S. Government Printing Office, 2010. Retrieved from: *http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.*
31. Eckel R.H., Jakicic J.M., Ard J.D., et al. ''2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines''. *Circulation.* 2014;129:S76–99.
32. Stone N.J., Robinson J.G., Lichtenstein A.H., et al. ''2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines''. *Circulation.* 2014;129:S1–45.
33. AOAC. ''AOAC Official Method 996.06, Fat (Total, Saturated, and Unsaturated) in Foods''. Official Methods of Analysis (AOAC). Gaithersburg, MD: AOAC International, 2008.
34. Tyburczy C., Mossoba M.M., Rader J.I. ''Determination of Trans Fat in Edible Oils: Current Official Methods and Overview of Recent Developments''. *Analytical and Bioanalytical Chemistry.* 2013;405:5759–5772.
35. U.S. Food and Drug Administration. ''Health Claim Notification for Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease'', 2007. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073631.htm.*
36. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 7: Dietary, Functional, and Total Fiber'', Washington, DC: National Academies Press; 2002.
37. U.S. Food and Drug Administration. ''Letter Responding to Health Claim Petition Dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003q–0401)'', 2004. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm072932.htm.*
38. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium and Vitamin D, Chapter 5: Dietary Reference Intakes for Adequacy: Calcium and Vitamin D'', Washington, DC: National Academies Press; 2011.
39. Akabas S.R., Deckelbaum R.J. ''Summary of a Workshop on N–3 Fatty Acids: Current Status of Recommendations and Future Directions''. *American Journal of Clinical Nutrition.* 2006;83:1536S–1538S.
40. Papanikolaou Y., Brooks J., Reider C., et al. ''U.S. Adults Are Not Meeting Recommended Levels for Fish and Omega-3 Fatty Acid Intake: Results of an Analysis Using Observational Data from NHANES 2003–2008''. *Nutrition Journal.* 2014;13:31.
41. Madden S.M., Garrioch C.F., Holub B.J. ''Direct Diet Quantification Indicates Low Intakes of (N–3) Fatty Acids in Children 4 to 8 Years Old''. *Journal of Nutrition.* 2009;139:528–532.
42. Casula M., Soranna D., Catapano A.L., et al. ''Long-Term Effect of High Dose Omega-3 Fatty Acid Supplementation for Secondary Prevention of Cardiovascular Outcomes: A Meta-Analysis of Randomized, Double Blind, Placebo Controlled Trials''. *Atherosclerosis Supplements.* 2013;14:243–251.
43. Danaei G., Ding E.L., Mozaffarian D., et al. ''The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors''. *PLoS Medicine.* 2009;6:e1000058.
44. Kotwal S., Jun M., Sullivan D., et al. ''Omega 3 Fatty Acids and Cardiovascular Outcomes: Systematic Review and Meta-Analysis''. *Circulation Cardiovascular Quality and Outcomes.* 2012;5:808–818.
45. Kwak S.M., Myung S.K., Lee Y.J., et al. ''Efficacy of Omega-3 Fatty Acid Supplements (Eicosapentaenoic Acid and Docosahexaenoic Acid) in the Secondary Prevention of Cardiovascular Disease: A Meta-Analysis of Randomized, Double-Blind, Placebo-Controlled Trials''. *Archives of Internal Medicine.* 2012;172:686–694.
46. Lim S.S., Vos T., Flaxman A.D., et al. ''A Comparative Risk Assessment of Burden

of Disease and Injury Attributable to 67 Risk Factors and Risk Factor Clusters in 21 Regions, 1990–2010: A Systematic Analysis for the Global Burden of Disease Study 2010''. *The Lancet.* 2012;380:2224–2260.
47. Rizos E.C., Ntzani E.E., Bika E., et al. ''Association between Omega-3 Fatty Acid Supplementation and Risk of Major Cardiovascular Disease Events: A Systematic Review and Meta-Analysis''. *JAMA: The Journal of the American Medical Association.* 2012;308:1024–1033.
48. Engell R.E., Sanman E., Lim S.S., et al. ''Seafood Omega-3 Intake and Risk of Coronary Heart Disease Death: An Updated Meta-Analysis with Implications for Attributable Burden''. *The Lancet.* 2013;381:S45.
49. Mozaffarian D., Lemaitre R.N., King I.B., et al. ''Plasma Phospholipid Long-Chain Omega-3 Fatty Acids and Total and Cause-Specific Mortality in Older Adults: A Cohort Study''. *Annals of Internal Medicine.* 2013;158:515–525.
50. Nehra D., Pan A.H., Le H.D., et al. ''Docosahexaenoic Acid, G Protein-Coupled Receptors, and Melanoma: Is G Protein-Coupled Receptor 40 a Potential Therapeutic Target?''. *Journal of Surgical Research.* 2014;188:451–458.
51. Miller P.E., Van Elswyk M., Alexander D.D. ''Long-Chain Omega-3 Fatty Acids Eicosapentaenoic Acid and Docosahexaenoic Acid and Blood Pressure: A Meta-Analysis of Randomized Controlled Trials''. *American Journal of Hypertension.* 2014;27:885–896.
52. EFSA. ''Scientific Opinion: Labelling Reference Intake Values for N-3 and N-6 Polyunsaturated Fatty Acids. Global Recommendation for EPA and DHA Intake''. *EFSA Journal.* 2009;1176:1–11.
53. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 9: Cholesterol'', Washington, DC: National Academies Press; 2002.
54. Weggemans R.M., Zock P.L., Katan M.B. ''Dietary Cholesterol from Eggs Increases the Ratio of Total Cholesterol to High-Density Lipoprotein Cholesterol in Humans: A Meta-Analysis''. *American Journal of Clinical Nutrition.* 2001;73:885–891.
55. Grande F., Anderson J.T., Chlouverakis C., et al. ''Effect of Dietary Cholesterol on Man's Serum Lipids''. *Journal of Nutrition.* 1965;87:52–62.
56. Hopkins P.N. ''Effects of Dietary Cholesterol on Serum Cholesterol: A Meta-Analysis and Review''. *American Journal of Clinical Nutrition.* 1992;55:1060–1070.
57. Howell W.H., McNamara D.J., Tosca M.A., et al. ''Plasma Lipid and Lipoprotein Responses to Dietary Fat and Cholesterol: A Meta-Analysis''. *American Journal of Clinical Nutrition.* 1997;65:1747–1764.
58. Ballesteros M.N., Cabrera R.M., Saucedo Mdel S., et al. ''Dietary Cholesterol Does Not Increase Biomarkers for Chronic Disease in a Pediatric Population from Northern Mexico''. *American Journal of Clinical Nutrition.* 2004;80:855–861.
59. Fernandez M.L., Webb D. ''The LDL to HDL Cholesterol Ratio as a Valuable Tool to Evaluate Coronary Heart Disease Risk''. *Journal of the American College of Nutrition.* 2008;27:1–5.
60. Greene C.M., Zern T.L., Wood R.J., et al. ''Maintenance of the LDL Cholesterol:HDL Cholesterol Ratio in an Elderly Population Given a Dietary Cholesterol Challenge''. *Journal of Nutrition.* 2005;135:2793–2798.
61. Herron K.L., Vega-Lopez S., Conde K., et al. ''Pre-Menopausal Women, Classified as Hypo- or Hyperresponders, Do Not Alter Their LDL/HDL Ratio Following a High Dietary Cholesterol Challenge''. *Journal of the American College of Nutrition.* 2002;21:250–258.
62. Li Y., Zhou C., Zhou X., et al. ''Egg Consumption and Risk of Cardiovascular Diseases and Diabetes: A Meta-Analysis''. *Atherosclerosis.* 2013;229:524–530.
63. Rong Y., Chen L., Zhu T., et al. ''Egg Consumption and Risk of Coronary Heart Disease and Stroke: Dose-Response Meta-Analysis of Prospective Cohort Studies''. *British Medical Journal.* 2013;346:e8539.
64. Scrafford C.G., Tran N.L., Barraj L.M., et al. ''Egg Consumption and Chd and Stroke Mortality: A Prospective Study of US Adults''. *Public Health Nutrition.* 2011;14:261–270.
65. Shin J.Y., Xun P., Nakamura Y., et al. ''Egg Consumption in Relation to Risk of Cardiovascular Disease and Diabetes: A Systematic Review and Meta-Analysis''. *American Journal of Clinical Nutrition.* 2013;98:146–159.
66. Voutilainen S., Nurmi A., Mursu J., et al. ''Regular Consumption of Eggs Does Not Affect Carotid Plaque Area or Risk of Acute Myocardial Infarction in Finnish Men''. *Atherosclerosis.* 2013;227:186–188.
67. Fernandez M.L. ''Rethinking Dietary Cholesterol''. *Current Opinion in Clinical Nutrition and Metabolic Care.* 2012;15:117–121.
68. McNamara D.J. ''Dietary Cholesterol, Heart Disease Risk and Cognitive Dissonance''. *Proceedings of the Nutrition Society.* 2014;73:161–166.
69. Merrill A.L., Watt B.K. ''Energy Value of Foods. Basis and Derivation''. Human Nutrition Research Branch, Agricultural Research Service, US Department of Agriculture, Agriculture Handbook No 74, 1973.
70. Iida T., Hayashi N., Yamada T., et al. ''Failure of D-Psicose Absorbed in the Small Intestine to Metabolize into Energy and Its Low Large Intestinal Fermentability in Humans''. *Metabolism: Clinical and Experimental.* 2010;59:206–214.
71. Matsuo T., Suzuki H., Hashiguchi M., et al. ''D-Psicose Is a Rare Sugar That Provides No Energy to Growing Rats''. *Journal of Nutritional Science and Vitaminology.* 2002;48:77–80.
72. Opinion Research Corporation International. ''Online Caravan Nutrition Facts Label''. Princeton, NJ, 2014.
73. World Health Organization. ''Guideline: Sugars Intake for Adults and Children''. Geneva: World Health Organization, 2015. Retrieved from: *http://who.int/mediacentre/news/notes/2014/consultation-sugar-guideline/en/.*
74. Johnson R.K., Appel L.J., Brands M., et al. ''Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement from the American Heart Association''. *Circulation.* 2009;120:1011–1020.
75. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 6: Dietary Carbohydrates: Sugars and Starches'', Washington, DC: National Academies Press; 2002.
76. National Cancer Institute. ''Usual Dietary Intakes: Food Intakes, US Population, 2007-10: Applied Research Program.'', 2015. Retrieved from: *http://epi.grants.cancer.gov/diet/usualintakes/pop/2007-10/table_a41.html.*
77. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans''. Washington, DC: U.S. Government Printing Office, 2010. Retrieved from: *http://www.cnpp.usda.gov/DGAs2010–DGACReport.htm.*
78. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Dietary Guidelines for Americans'', Home and Gardening Bulleting No 232, 2nd ed. Washington DC: U.S. Government Printing Office, 1985.
79. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Dietary Guidelines for Americans'', Home and Gardening Bulletin No 232, 1st ed. Washington DC: U.S. Government Printing Office, 1980. Retrieved from: *http://health.gov/dietaryguidelines/1985thin.pdf.*
80. U.S. Department of Health and Human Services and U.S. Department of Agriculture. ''Dietary Guidelines for Americans, 2005'', 6th ed. Washington, DC: U.S. Government Printing Office, 2005. Retrieved from: *http://health.gov/dietaryguidelines/dga2005/doc.*
81. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Nutrition and Your Health, Dietary Guidelines for Americans'', Home and Gardening Bulletin No 232, 3rd ed. Washington, DC: U.S. Government Printing Office, 1990. Retrieved from: *http://www.health.gov/DietaryGuidelines/1990thin.pdf.*
82. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Nutrition and Your Health, Dietary Guidelines for Americans'', Home and Gardening Bulletin No 232, 4th ed. Washington, DC: U.S. Government Printing Office, 1995.

Retrieved from: *http://www.cnpp.usda.gov/Publications/DietaryGuidelines/1995/1995DGConsumerBrochure.pdf*.
83. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Nutrition and Your Health, Dietary Guidelines for Americans'', Home and Gardening Bulletin No 232, 5th ed. Washington, DC: U.S. Government Printing Office, 2000. Retrieved from: *http://www.health.gov/dietaryguidelines/dga2000/dietgd.pdf*.
84. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Chapter 6'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf*.
85. U.S. Food and Drug Administration. ''Guidance for Industry: Evidence-Based Review System for Scientific Evaluation of Health Claims- Final'', 2009. Retrieved from: *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm073332.htm*.
86. Liese A.D., Krebs-Smith S.M., Subar A.F., et al. ''The Dietary Patterns Methods Project: Synthesis of Findings across Cohorts and Relevance to Dietary Guidance''. *Journal of Nutrition.* 2015;145:393–402.
87. George S.M., Ballard-Barbash R., Manson J.E., et al. ''Comparing Indices of Diet Quality with Chronic Disease Mortality Risk in Postmenopausal Women in the Women's Health Initiative Observational Study: Evidence to Inform National Dietary Guidance''. *American Journal of Epidemiology.* 2014;180:616–625.
88. Harmon B.E., Boushey C.J., Shvetsov Y.B., et al. ''Associations of Key Diet-Quality Indexes with Mortality in the Multiethnic Cohort: The Dietary Patterns Methods Project''. *American Journal of Clinical Nutrition.* 2015;101:587–597.
89. Reedy J., Krebs-Smith S.M., Miller P.E., et al. ''Higher Diet Quality Is Associated with Decreased Risk of All-Cause, Cardiovascular Disease, and Cancer Mortality among Older Adults''. *Journal of Nutrition.* 2014;144:881–889.
90. Fung T.T., Chiuve SE., McCullough M.L., et al. ''Adherence to a Dash-Style Diet and Risk of Coronary Heart Disease and Stroke in Women''. *Archives of Internal Medicine.* 2008;168:713–720.
91. Folsom A.R., Parker E.D., Harnack L.J. ''Degree of Concordance with Dash Diet Guidelines and Incidence of Hypertension and Fatal Cardiovascular Disease''. *American Journal of Hypertension.* 2007;20:225–232.
92. Yang Q., Zhang Z., Gregg E.W., et al. ''Added Sugar Intake and Cardiovascular Diseases Mortality among US Adults''. *JAMA Intern Med.* 2014;174:516–524.
93. Lee R., Nieman D. *Nutritional Assessment.* Dubuque, IA: Wm. C. Brown, 1993; pp. 57–58.
94. Schatzkin A., Kipnis V., Carroll R.J., et al. ''A Comparison of a Food Frequency Questionnaire with a 24-Hour Recall for Use in an Epidemiological Cohort Study: Results from the Biomarker-Based Observing Protein and Energy Nutrition (Open) Study''. *International Journal of Epidemiology.* 2003;32:1054–1062.
95. Thompson F.E., Subar A.F. ''Chapter 1: Dietary Assessment Methodology''. In: Coulston AM, Boushey, C.J., Ferruzzi, M.G., ed. Nutrition in the Prevention and Treatment of Disease; 2013.
96. Kit B.K., Fakhouri T.H., Park S., et al. ''Trends in Sugar-Sweetened Beverage Consumption among Youth and Adults in the United States: 1999–2010''. *American Journal of Clinical Nutrition.* 2013;98:180–188.
97. National Cancer Institute Division of Cancer Control and Population Sciences—Epidemiology and Genomics Research Program. ''Usual Intake of Added Sugars, Table A40.'', Added Sugars: Means, Percentiles and Standard Errors of Usual Intake, 2007-2010. Retrieved from: *http://epi.grants.cancer.gov/diet/usualintakes/pop/2007-10/table_a40.html*.
98. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Table D6.1, Chapter 6, P. 19'', Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Washington DC: U.S. Government Printing Office, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf*.
99. Abaluck J. ''What Would We Eat If We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling''; 2011.
100. Murphy S.P., Johnson R.K. ''The Scientific Basis of Recent US Guidance on Sugars Intake''. *American Journal of Clinical Nutrition.* 2003;78:827S–833S.
101. Schroeder N., Park Y.H., Kang M.S., et al. ''A Randomized Trial on the Effects of 2010 Dietary Guidelines for Americans and Korean Diet Patterns on Cardiovascular Risk Factors in Overweight and Obese Adults''. *Journal of the Academy of Nutrition and Dietetics.* 2015;115:1083–1092.
102. Marriott B.P., Olsho L., Hadden L., et al. ''Intake of Added Sugars and Selected Nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006''. *Critical Reviews in Food Science and Nutrition.* 2010;50:228–258.
103. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 11, P. 788''; 2002.
104. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Figure D1.31, P.146'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf*.
105. International Food Information Council (IFIC) Foundation and the U.S. Food and Drug Administration. ''Food Ingredients and Colors'', 2010. Retrieved from: *http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/ucm094249.pdf*.
106. Weaver D., Finke M. ''The Relationship between the Use of Sugar Content Information on Nutrition Labels and the Consumption of Added Sugars''. *Food Policy.* 2003.
107. Laquatra I., Sollid K., Smith Edge M., et al. ''Including ''Added Sugars'' on the Nutrition Facts Panel: How Consumers Perceive the Proposed Change''. *Journal of the Academy of Nutrition and Dietetics.* 2015;115:1758–1763.
108. Graham D.J., Jeffery R.W. ''Predictors of Nutrition Label Viewing During Food Purchase Decision Making: An Eye Tracking Investigation''. *Public Health Nutrition.* 2012;15:189–197.
109. U.S. Food and Drug Administration. ''Comment to Docket FDA–2012–N–1210 from American Heart Association & American Stroke Association''. 2015.
110. U.S. Food and Drug Administration. ''Memorandum to the File: Comments on Proposed Format Changes to the Nutrition Facts Label Added Sugars Declaration''; 2016A.
111. U.S. Food and Drug Administration. ''Memorandum to the File: Comments on Proposed Format Changes to the Nutrition Facts Label Added Sugars Declaration''; 2016B.
112. Kools M. *Making Reading Materials Easier to Understand.* Los Angeles: Sage, 2012.
113. Spyridakis J.H. ''Signaling Effects: Increased Content Retention and New Answers—Part II''. *Journal of technical writing and communication.* 1989;19:395–415.
114. Spyridakis J.H., Standal T.C. ''Signals in Expository Prose: Effects on Reading Comprehension''. *Reading Research Quartely.* 1987:285–298.
115. Chung J.S. ''Signals and Reading Comprehension—Theory and Practice''. *System.* 2000;28:247–259.
116. Wright P. ''The Comprehension of Tabulated Information: Some Similarities between Reading Prose and Reading Tables''. *NSPI Journal.* 1980;19:25–29.
117. Rhee S.J., Lee J.E., Lee C.H. ''Importance of Lactic Acid Bacteria in Asian Fermented Foods''. *Microb Cell Fact.* 2011;10 Suppl 1:S5.
118. Yun J.W., Kang S.C., Song S.K. ''Mannitol Accumulation During Fermentation of Kimchi''. *Journal of Fermentation and Bioengineering.* 1996;81:279–280.
119. Golon A., Kuhnert N. ''Unraveling the Chemical Composition of Caramel''.

Journal of Agricultural and Food Chemistry. 2012;60:3266–3274.
120. U.S. Food and Drug Administration. ''Memorandum to the File: Effects of Maillard Reaction, Caramelization, and Fermentation on Added Sugar Content of Foods'', 2014.
121. Codex Alimentarius. ''Guidelines on Nutrition Labeling CAC/GL 2–1985'', 2010. Retrieved from: *www.codexalimentarius.net/download/standards/34/CXG_002e.pdf*.
122. U.S. Food and Drug Administration. Office of Nutrition and Food Labeling. ''Guidance for Industry: A Food Labeling Guide'', 2013. Retrieved from: *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm2006828.htm*.
123. Hess J., Latulippe M.E., Ayoob K., et al. ''The Confusing World of Dietary Sugars: Definitions, Intakes, Food Sources and International Dietary Recommendations''. *Food & Function.* 2012;3:477–486.
124. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Appendix E–3.1'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf*.
125. Te Morenga L., Mallard S., Mann J. ''Dietary Sugars and Body Weight: Systematic Review and Meta-Analyses of Randomised Controlled Trials and Cohort Studies''. *British Medical Journal.* 2013;346:e7492.
126. Moynihan P.J., Kelly S.A. ''Effect on Caries of Restricting Sugars Intake: Systematic Review to Inform WHO Guidelines''. *Journal of Dental Research.* 2014;93:8–18.
127. U.S. Food and Drug Administration. ''Calories Count:Report of the Working Group on Obesity'', 2004. Retrieved from: *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm081696.htm*.
128. EU. ''Regulation No. 1169/2011 of the European Parliment and of the Council, October 2011''. 2011.
129. Life Sciences Research Office (LSRO). ''The Evaluation of the Energy of Certain Sugar Alcohols Used as Food Ingredients'', Bethesda, MD: Life Sciences Research Office; 1994.
130. Life Sciences Research Office (LSRO). ''Evaluation of the Net Energy Value of Maltitol'', Bethesda, MD: Life Sciences Research Office; 1999.
131. Livesey G. ''The Energy Values of Dietary Fibre and Sugar Alcohols for Man''. *Nutrition Research Reviews.* 1992;5:61–84.
132. Hiele M., Ghoos Y., Rutgeerts P., et al. ''Metabolism of Erythritol in Humans: Comparison with Glucose and Lactitol''. *British Journal of Nutrition.* 1993;69:169–176.
133. Wilson E.B. *An Introduction to Scientific Research.* Toronto: General Publishing Company, 1990.
134. Institute of Medicine (IOM) of the National Academies. ''Dietary Supplements: A Framework for Evaluating Safety. Chapter 7, Categories of Scientific Evidence—in Vitro Data'', Washington DC; National Academies Press; 2005, pp. 217–234.
135. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Page 346''. 2002.
136. Howlett J.F., Betteridge V.A., Champ M., et al. ''The Definition of Dietary Fiber—Discussions at the Ninth Vahouny Fiber Symposium: Building Scientific Agreement''. *Food & Nutrition Research.* 2010;54.
137. U.S. Food and Drug Administration. ''Memorandum to the File: Scientific Review of the Beneficial Physiological Effects of Non-Digestible Carbohydrates for Meeting the FDA Definition of Dietary Fiber'', 2016.
138. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes: Proposed Definition of Dietary Fiber'', Washington DC: National Academies Press; 2001.
139. National Research Council (NRC). ''Diet and Health: Implications for Reducing Chronic Disease Risk'', Washington, DC; National Academies Press; 1989.
140. EFSA. ''Scientific Opinion on the Substantiation of Health Claims Related to Acacia Gum (Gum Arabic) and Reduction of Post-Prandial Glycaemic Responses (Id 842, 1977) and Maintenance of Normal Blood Glucose Concentrations (Id 842, 1977) Pursuant to Article 13(1) of Regulation (EC) No 1924/2006''. *EFSA Journal.* 2010.
141. Torres D.P.M., Gonsalves M.P.F., Teixeira J.A. ''Galacto-Oligosaccharides: Production, Properties, Applications, and Significance as Prebiotics''. *Comprehensive Reviews in Food Science and Food Safety.* 2010;9:438–454.
142. International Food Information Council. ''Food and Health Survey. Consumer Attitudes Towards Food Safety, Nutrition and Health'', 2013. Retrieved from: *http://www.foodinsight.org/articles/2013-food-and-health-survey#sthash.T9Xfw7Mh.dpbs*.
143. Maningat C.C., Seib P., Bassi S.D. ''Dietary Fiber Content of Cross-Linked Phosphorylated Resistant Starch (Rs4) Determined by the Prosky and Mccleary Methods. Part II. Comparison of Assay Data''. *Cereal Foods World.* 2013;58:252–263.
144. World Health Organization & Food and Agriculture Organization (WHO/FAO). ''Diet, Nutrition and Prevention of Chronic Diseases'', Geneva: World Health Organization; 2003.
145. EFSA. ''Scientific Opinion on Dietary Reference Values for Cabohydrates and Dietary Fibre''. *EFSA Journal.* 2010;8:1–77.
146. Auerbach M.H., Craig S.A., Howlett J.F., et al. ''Caloric Availability of Polydextrose''. *Nutrition Reviews.* 2007;65:544–549.
147. Mariotti F., Tome D., Mirand P.P. ''Converting Nitrogen into Protein—Beyond 6.25 and Jones' Factors''. *Critical Review in Food Science and Nutrition.* 2008;48:177–184.
148. Morr C.V. ''Recalculated Nitrogen Conversion Factors for Several Soybean Protein Products''. *Journal of Food Science.* 1982;47:1751–1752.
149. Mosse J. ''Nitrogen to Protein Conversion Factors for Ten Cereals and Six Legumes or Oilseeds: A Reappraisal of Its Definition and Determination''. *Journal of Agricultural and Food Chemistry.* 1990;38:18–24.
150. Sarwar G., Christensen D.A., Finlayson A.J., et al. ''Inter-and-Intra-Laboratory Variation in Amino Acid Analysis of Food Proteins''. *Journal of Food Science.* 1983;526–531.
151. Sosulski F.W., Imafidon G.I. ''Amino Acid Composition and Nitrogen-to-Protein Conversion Factors for Animal and Plant Foods''. *Journal of Agricultural and Food Chemistry.* 1990;38:1351–1356.
152. Tkachuk R. ''Nitrogen-to-Protein Conversion Factors for Cereals and Oilseed Meals''. *Cereal Chemistry.* 1969;46:419–423.
153. Tome D. ''Digestibility Issues of Vegetable Versus Animal Proteins: Protein and Amino Acid Requirements—Functional Aspects''. *Food and Nutrition Bulletin.* 2013;34:272–274.
154. Food and Agriculture Organization of the United Nations. ''Dietary Protein Quality Evaluation in Human Nutrition'', Rome; 2013.
155. Hendriks W.H., van Baal J., Bosch G. ''Ileal and Faecal Protein Digestibility Measurement in Humans and Other Non-Ruminants—a Comparative Species View''. *British Journal of Nutrition.* 2012;108 Suppl 2:S247–257.
156. Rutherfurd S.M., Fanning A.C., Miller B.J., et al. ''Protein Digestibility-Corrected Amino Acid Scores and Digestible Indispensable Amino Acid Scores Differentially Describe Protein Quality in Growing Male Rats''. *Journal of Nutrition.* 2015;145:372–379.
157. Uauy R. ''Report of a Sub-Committee of the 2011 FAO Consultation on ''Protein Quality Evaluation in Human Nutrition'' ''; 2012.
158. World Health Organization. Food and Agriculture Organization. United Nations University. ''Protein and Amino Acid Requirements in Human Nutrition: Report of a Joint FAO/WHO/UNU Expert Consultation''; 2007.
159. World Health Organization. Food and Agriculture Organization. United Nations University. ''Energy and Protein Requirements: Report of a Joint FAO/WHO/UNU Expert Consultation''; 1985.
160. Food and Agriculture Organization & World Health Organization (FAO/WHO). ''Protein Quality Evaluation: Report of Jopint FAO/WHO Expert Consultation''; 1991.
161. Centers for Disease Control and Prevention. ''Nutrition for Everyone:

Basics: Protein'', 2012. Retrieved from: *http://www.cdc.gov/nutrition/everyone/basics/protein.html*.
162. Fryar C.D., Gu Q., Ogden C.L. ''Anthropometric Reference Data for Children and Adults: United States, 2007–2010''. *Vital and Health Statistics Series 11: Data from the National Health Survey.* 2012:1–48.
163. U.S. Department of Agriculture. ''What We Eat in America, NHANES 2011–2012, Individuals 2 Years and over (Excluding Breast-Fed Children), Day 1'', 2013. Retrieved from: *www.ars.usda.gov/nea/bhnrc/fsrg*.
164. International Food Information Council. ''2014 Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health''. Washington DC, 2014.
165. Institute of Medicine (IOM) of the National Academies. ''Strategies to Reduce Sodium Intake in the United States'', Washington, DC: National Academies Press; 2010.
166. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, Chapter 6: Sodium and Chloride'', Washington, DC: National Academies Press; 2005, pp. 269–423.
167. Institute of Medicine (IOM) of the National Academies. ''Sodium Intake in Populations: Assessment of Evidence'', Washington, DC: National Academies Press; 2013, pp. 235–284.
168. Graudal N., Jurgens G., Baslund B., et al. ''Compared with Usual Sodium Intake, Low- and Excessive-Sodium Diets Are Associated with Increased Mortality: A Meta-Analysis''. *American Journal of Hypertension.* 2014;27:1129–1137.
169. U.S. Food and Drug Administration. ''2002 Health and Diet Survey: Topline Frequency Report'', 2007. Retrieved from: *http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm202786.htm*.
170. U.S. Food and Drug Administration. ''Health and Diet Survey: Dietary Guidelines Supplement—Report Findings (2004 & 2005)'', 2008. Retrieved from: *http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/ConsumerResearch/UCM080413.pdf*.
171. U.S. Food and Drug Administration. ''2008 Health and Diet Survey: Topline Frequencies'', 2010. Retrieved from: *http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm193895.htm*.
172. Cook N.R., Cutler J.A., Obarzanek E., et al. ''Long Term Effects of Dietary Sodium Reduction on Cardiovascular Disease Outcomes: Observational Follow-up of the Trials of Hypertension Prevention (Tohp)''. *British Medical Journal.* 2007;334:885–888.
173. Whelton P.K. ''Sodium, Blood Pressure, and Cardiovascular Disease: A Compelling Scientific Case for Improving the Health of the Public''. *Circulation.* 2014;129:1085–1087.
174. Cook N.R., Appel L.J., Whelton P.K. ''Lower Levels of Sodium Intake and Reduced Cardiovascular Risk''. *Circulation.* 2014;129:981–989.
175. U.S. Food and Drug Administration. ''Proposed Changes to the Nutrition Facts Label'', 2014. Retrieved from: *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm*.
176. Maillot M., Monsivais P., Drewnowski A. ''Food Pattern Modeling Shows That the 2010 Dietary Guidelines for Sodium and Potassium Cannot Be Met Simultaneously''. *Nutrition Research.* 2013;33:188–194.
177. ''Intersalt: An International Study of Electrolyte Excretion and Blood Pressure. Results for 24 Hour Urinary Sodium and Potassium Excretion. Intersalt Cooperative Research Group''. *British Medical Journal.* 1988;297:319–328.
178. Powles J., Fahimi S., Micha R., et al. ''Global, Regional and National Sodium Intakes in 1990 and 2010: A Systematic Analysis of 24 H Urinary Sodium Excretion and Dietary Surveys Worldwide''. *British Medical Journal Open.* 2013;3:e003733.
179. Graudal N.A., Hubeck-Graudal T., Jurgens G. ''Effects of Low-Sodium Diet Vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride (Cochrane Review)''. *American Journal of Hypertension.* 2012;25:1–15.
180. Alderman M.H., Madhavan S., Ooi W.L., et al. ''Association of the Renin-Sodium Profile with the Risk of Myocardial Infarction in Patients with Hypertension''. *New England Journal of Medicine.* 1991;324:1098–1104.
181. Ekinci E.I., Clarke S., Thomas M.C., et al. ''Dietary Salt Intake and Mortality in Patients with Type 2 Diabetes''. *Diabetes Care.* 2011;34:703–709.
182. Thomas W., Harvey B.J. ''Mechanisms Underlying Rapid Aldosterone Effects in the Kidney''. *Annual Review of Physiology.* 2011;73:335–357.
183. U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. ''Nutrition Assessment for DRI Review'', 2014. Retrieved from: *http://health.gov/dietaryguidelines/dri/nutrient-assessment.asp*.
184. U.S. Public Health Service. ''U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries'', 2015. Retrieved from: *http://www.publichealthreports.org/fluorideguidelines.cfm*.
185. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 8: Fluoride'', Washington, DC: National Academies Press; 1997, pp. 288–313.
186. U.S. Environmental Protection Agency (EPA) Health and Ecological Criteria Division Office of Water. ''Fluoride: Exposure and Relative Source Contribution Analysis'', 2010. Retrieved from: *http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm*.
187. Food Marketing Institute. ''Shopping for Health Survey, Tables 22, 24, and 26 and Chart 12''; 2004, pp. 42, 43, 45, and 48.
188. Food Marketing Institute. ''Shopping for Health Survey''; 2011, p. 8.
189. Schleicher R.L., Carroll M.D., Ford E.S., et al. ''Serum Vitamin C and the Prevalence of Vitamin C Deficiency in the United States: 2003–2004 National Health and Nutrition Examination Survey (NHANES)''. *American Journal of Clinical Nutrition.* 2009;90:1252–1263.
190. Centers for Disease Control and Prevention. National Center for Environmental Health Division of Laboratory Sciences. ''Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population,'' 2012. Retrieved from: *http://www.cdc.gov/nutritionreport/pdf/Nutrition_Book_complete508_final.pdf#zoom=100*.
191. Gibson R.S. *Principles of Nutrition Assessment, Page 534.* New York, 2005.
192. U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Part D, Chapter 1'', Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf*.
193. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 4: Vitamin A'', Washington, DC: National Academies Press; 2001, pp. 82–161.
194. Fulgoni V.L., 3rd, Keast D.R., Bailey R.L., et al. ''Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?''. *Journal of Nutrition.* 2011;141:1847–1854.
195. Berner L.A., Keast D.R., Bailey R.L., et al. ''Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents''. *Journal of the Academy of Nutrition and Dietetics.* 2014;114:1009–1022 e1008.
196. U.S. Food and Drug Administration. ''Memorandum to the File: Evaluation Process of the Public Health Significance of Essential Vitamins and Minerals'', 2014.
197. U.S. Department of Agriculture. ''Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Final Rule. **Federal Register**, Vol. 79, No. 42. March 4 (Part II).'', 2014. Retrieved from: *http://www.fns.usda.gov/sites/default/files/03-04-14_WIC-Food-Packages-Final-Rule.pdf*.
198. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium and Vitamin D, Chapter 3: Overview of Vitamin D'', Washington DC; National Academies Press; 2011.

199. U.S. Food and Drug Administration. ''Memorandum to the File: Documentation for the Methodology Used to Determine Total Usual Intakes of Vitamins and Minerals Compared to Tolerable Upper Levels (UL) and Results of Analysis'', 2014.
200. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium and Vitamin D'', Washington DC; National Academies Press; 2011.
201. Looker A.C., Melton L.J., 3rd, Harris T.B., et al. ''Prevalence and Trends in Low Femur Bone Density among Older US Adults: NHANES 2005–2006 Compared with NHANES III''. *Journal of Bone and Mineral Research.* 2010;25:64–71.
202. U.S. Department of Health and Human Services. ''Bone Health and Osteoporosis: A Report of the Surgeon General''. Rockville, MD: Public Health Service Office of the Surgeon General, 2004. Retrieved from: *http://www.surgeongeneral.gov/library/reports/bonehealth/*.
203. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium and Vitamin D, Chapter 4'', Washington DC; 2011.
204. U.S. Food and Drug Administration. ''Memorandum to the File: Declaration of Current Voluntarily Declared Essential Vitamins and Minerals and Choline'', 2014.
205. Chiemchaisri Y., Phillips P.H. ''Effect of Dietary Fluoride Upon the Magnesium Calcinosis Syndrome''. *Journal of Nutrition.* 1963;81:307–311.
206. Chiemchaisri Y., Phillips P.H. ''Certain Factors Including Fluoride Which Affect Magnesium Calcinosis in the Dog and Rat''. *Journal of Nutrition.* 1965;86:23–28.
207. Kruse H.D., Orent R.E., McCollum E.V. ''Studies on Magnesium Deficiency in Animals, Part 1: Symptomatology Resulting from Magnesium Deprivation''. *Journal of Biological Chemistry.* 1932;100:603–643.
208. Seelig M.S. ''The Requirement of Magnesium by the Normal Adult. Summary and Analysis of Published Data''. *American Journal of Clinical Nutrition.* 1964;14:342–390.
209. Tufts E.V., Greenberg D.M. ''The Biochemistry of Magnesium Deficiency I. Chemical Changes Resulting from Magnesium Deprivation''. *Journal of Biological Chemistry.* 1938;122:693–714.
210. Iseri L.T., Chung P., Tobis J. ''Magnesium Therapy for Intractable Ventricular Tachyarrhythmias in Normomagnesemic Patients''. *West Journal of Medicine.* 1983;138:823–828.
211. Iseri L.T., Freed J., Bures A.R. ''Magnesium Deficiency and Cardiac Disorders''. *American Journal of Medicine.* 1975;58:837–846.
212. Iseri L.T., French J.H. ''Magnesium: Nature's Physiologic Calcium Blocker''. *American Heart Journal.* 1984;108:188–193.
213. Dritsa V., Pissaridi K., Koutoulakis E., et al. ''An Infrared Spectroscopic Study of Aortic Valve. A Possible Mechanism of Calcification and the Role of Magnesium Salts''. *In Vivo.* 2014;28:91–98.
214. Dorup I., Clausen T. ''Correlation between Magnesium and Potassium Contents in Muscle: Role of Na(+)-K+ Pump''. *American Journal of Physiology.* 1993;264:C457–463.
215. Matsuda H. ''Magnesium Gating of the Inwardly Rectifying K+ Channel''. *Annual Review of Physiology.* 1991;53:289–298.
216. Guasch-Ferre M., Bullo M., Estruch R., et al. ''Dietary Magnesium Intake Is Inversely Associated with Mortality in Adults at High Cardiovascular Disease Risk''. *Journal of Nutrition.* 2014;144:55–60.
217. Hruby A., Ngwa J.S., Renstrom F., et al. ''Higher Magnesium Intake Is Associated with Lower Fasting Glucose and Insulin, with No Evidence of Interaction with Select Genetic Loci, in a Meta-Analysis of 15 Charge Consortium Studies''. *Journal of Nutrition.* 2013;143:345–353.
218. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 6: Magnesium'', Washington DC; National Academies Press; 1997.
219. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification'', Washington DC; National Academies Press; 2003, pp. 111–113.
220. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes: Applications in Dietary Planning'', Washington, DC: National Academies Press; 2003.
221. U.S. Food and Drug Administration. ''Nutrition Information for Raw Fruits, Vegetables, and Fish'', 2015. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm063367.htm.*
222. U.S. Department of Agriculture. ''Nutrition Labeling Information'', 2015. Retrieved from: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/nutrition-labeling-policies/nutrition-labeling.*
223. Aburto N.J., Hanson S., Gutierrez H., et al. ''Effect of Increased Potassium Intake on Cardiovascular Risk Factors and Disease: Systematic Review and Meta-Analyses''. *British Medical Journal.* 2013;346:f1378.
224. Weaver C.M. ''Potassium and Health''. *Advances in Nutrition.* 2013;4:368S–377S.
225. Murphy M.M., Spungen J.H., Barraj L.M., et al. ''Revising the Daily Values May Affect Food Fortification and in Turn Nutrient Intake Adequacy''. *Journal of Nutrition.* 2013;143:1999–2006.
226. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Vitamin a, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 12: Zinc'', Washington, DC: National Academies Press; 2001, pp. 442–501.
227. Bertinato J., Simpson J.R., Sherrard L., et al. ''Zinc Supplementation Does Not Alter Sensitive Biomarkers of Copper Status in Healthy Boys''. *Journal of Nutrition.* 2013;143:284–289.
228. McCann J.C., Ames B.N. ''Adaptative Dysfunction of Selenoproteins from Perspective of Triage Theory: Why Modest Selenium Deficiency May Increase Risk of Diseases of Aging''. *FASEB Journal.* 2011;25:1793–1814.
229. EFSA. ''Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a Request from the European Commisiion on the Safety of Vitamin K2''. *EFSA Journal.* 2008;822:1–32.
230. Geleijnse J.M., Vermeer C., Grobbee D.E., et al. ''Dietary Intake of Menaquinone Is Associated with a Reduced Risk of Coronary Heart Disease: The Rotterdam Study''. *Journal of Nutrition.* 2004;134:3100–3105.
231. Gast G.C., de Roos N.M., Sluijs I., et al. ''A High Menaquinone Intake Reduces the Incidence of Coronary Heart Disease''. *Nutrition Metabolism and Cardiovascular Disease.* 2009;19:504–510.
232. Iwamoto J. ''Vitamin K(2) Therapy for Postmenopausal Osteoporosis''. *Nutrients.* 2014;6:1971–1980.
233. Health Canada. ''Health Canada's Proposed Changes to the Daily Values (Dvs) for Use in Nutrition Labelling'', 2014. Retrieved from: *http://www.hc-sc.gc.ca/fn-an/consult/2014-daily-value-valeurs-quotidiennes/document-consultation-eng.php.*
234. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Vitamin a, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 5: Vitamin K'', Washington, DC: National Academies Press; 2001, pp. 162–196.
235. Shearer M.J., Fu X., Booth S.L. ''Vitamin K Nutrition, Metabolism, and Requirements: Current Concepts and Future Research''. *Advances in Nutrition.* 2012;3:182–195.
236. Shearer M.J., Newman P. ''Recent Trends in the Metabolism and Cell Biology of Vitamin K with Special Reference to Vitamin K Cycling and Mk-4 Biosynthesis''. *Journal of Lipid Research.* 2014;55:345–362.
237. U.S. Pharmacopeial Convention. ''Safety Data Sheet. Phytonadione'', 2013. Retrieved from: *http://www.usp.org/pdf/EN/referenceStandards/msds/1538006.pdf.*
238. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Chapter 8: Folate'', Washington, DC: National Academies Press; 1998, pp. 196–305.
239. Block L.G., Peracchio L.A. ''The Calcium Quandary: How Consumers Use Nutrition Labels''. *Journal of Public Policy & Marketing.* 2006;25:188–196.
240. Christen S., Woodall A.A., Shigenaga M.K., et al. ''Gamma-Tocopherol Traps Mutagenic Electrophiles Such as No(X) and Complements Alpha-Tocopherol: Physiological Implications''. *Proceedings of the National Academy of Sciences of the United States of America.* 1997;94:3217–3222.
241. Jiang Q., Ames B.N. ''Gamma-Tocopherol, but Not Alpha-Tocopherol, Decreases Proinflammatory Eicosanoids

and Inflammation Damage in Rats''. *FASEB Journal.* 2003;17:816–822.
242. Jiang Q., Yin X., Lill M.A., et al. ''Long-Chain Carboxychromanols, Metabolites of Vitamin E, Are Potent Inhibitors of Cyclooxygenases''. *Proceedings of the National Academy of Sciences of the United States of America.* 2008;105:20464–20469.
243. Mahabir S., Schendel K., Dong Y.Q., et al. ''Dietary Alpha-, Beta-, Gamma- and Delta-Tocopherols in Lung Cancer Risk''. *International Journal of Cancer.* 2008;123:1173–1180.
244. Sen C.K., Khanna S., Rink C., et al. ''Tocotrienols: The Emerging Face of Natural Vitamin E''. *Vitamins and Hormones.* 2007;76:203–261.
245. Wolf G. ''How an Increased Intake of Alpha-Tocopherol Can Suppress the Bioavailability of Gamma-Tocopherol''. *Nutrition Reviews.* 2006;64:295–299.
246. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Chapter 6: Vitamin E'', Washington, DC: National Academies Press; 2000, pp. 186–283.
247. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Chapter 6: Vitamin E, Table 6–1.'', Washington DC; 2000.
248. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline'', Washington, DC: National Academies Press; 1998.
249. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Chapter 6: Niacin'', Washington, DC: National Academies Press; 1998.
250. U.S. Department of Health and Human Services. National Institutes of Health. National Heart Lung and Blood Institute. ''Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents:'' The Report of the Expert Panel; NIH Publication No 12–7486A, 2012. Retrieved from: *http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm.*
251. Joint Food and Agriculture Organization of the United States and World Health Organization. ''Protein Quality Evaluation. Report of Joint FAO/WHO Expert Consultation'', Rome Food and Agriculture Organization of the United Nations; 1991.
252. Butte N.F., Fox M.K., Briefel R.R., et al. ''Nutrient Intakes of US Infants, Toddlers, and Preschoolers Meet or Exceed Dietary Reference Intakes''. *Journal of the American Dietetic Association.* 2010;110:S27–37.
253. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 7: Vitamin D'', Washington DC; National Academies Press; 1997.
254. Walravens P.A., Hambidge K.M., Koepfer D.M. ''Zinc Supplementation in Infants with a Nutritional Pattern of Failure to Thrive: A Double-Blind, Controlled Study''. *Pediatrics.* 1989;83:532–538.
255. Gidding S.S., Dennison B.A., Birch L.L., et al. ''Dietary Recommendations for Children and Adolescents: A Guide for Practitioners: Consensus Statement from the American Heart Association''. *Circulation.* 2005;112:2061–2075.
256. Institute of Medicine (IOM) of the National Academies. ''Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, Chapter 5: Potassium'', Washington, DC: National Academies Press; 2005, pp. 186–268.
257. Kessler D.A., Mande J.R., Scarbrough F.E., et al. ''Developing the 'Nutrition Facts' Food Label''. *Harvard Health Policy Review.* 2003;4:13–24.
258. U.S. Food and Drug Administration. ''Memorandum to the File: Letter to Division of Dockets Management from General Mills''. 2015.
259. Lupton E. *Thinking with Type: A Critical Guide for Designers, Writers, Editors, & Students.* 2nd ed. New York, NY: Princeton Archetectural Press, 2010; pp. 132–133.
260. American Academy of Pediatrics. ''American Academy of Pediatrics Committee on Nutrition''. In: Kleinman RE, ed. Pediatric Nutrition Handbook. United States: American Academy of Pediatrics; 2014; pp. 249–273.
261. Institute of Medicine (IOM) of the National Academies. ''Early Childhood Obesity Prevention Policies'', Washington DC; National Academies Press; 2011, pp. 93–94.
262. Lidwell W., Holden K., Buttler J. *Universal Principles of Design.* 1st ed. Beverly, MA: Rockport Publishers, 2003; pp. 40–41.
263. The Free Dictionary. Retrieved from: *www.thefreedictionary.com/contrast.*
264. Juan W.Y., Zhang Y., Kantor M.A., et al. ''Perceptions and Use of Nutrition Labeling Information''. *Abstract Presented at the Experimental Biology Annual Meeting-Boston.* 2013.
265. Zhang Y., Kantor M.A., Juan W. ''Usage and Understanding of Serving Size Information on Food Labels in the United States''. *American Journal of Health Promotion.* 2016;30:181–187.
266. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). ''National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–770'', US Department of Health and Human Services, Centers for Disease Control and Prevention. Hyattsville, MD, 2016. Retrieved from: *http://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#DBQ770.*
267. U.S. Food and Drug Administration. ''Comment to the Docket No. FDA–2012–N–1210 from Kellog Company'', 2014.
268. Gomez-Palacio B., Vit A. *Graphic Design Referenced: A Visual Guide to the Language, Applications, and History of Graphic Design.* 1st ed. Beverly, MA: Rockport Publishers, 2012; pp. 50–54.
269. Center for Science in the Public Interest. ''Comment to Docket No. FDA–2012–1210 from the Center for Science in the Public Interest (CSPI), Page 38 and Appendix 1.'', 2014.
270. U.S. Food and Drug Administration. ''Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats (OMB No. 0910–0774)'', 2015.
271. National Osteoporosis Foundation. 2016. Retrieved from: *www.nof.org.*
272. U.S. Preventive Services Task Force. 2016. Retrieved from: *www.uspreventiveservicestaskforce.org.*
273. International Food Information Council Foundation. ''Food Label Consumer Research Project: Final Qualitative Report'', 2010. Retrieved from: *http://www.foodinsight.org/Content/3145/FINAL%20IFIC%20Foundation%20Food%20Label%20Consumer%20Research%20-%20Phase%20III%20Summary%20Report.pdf.*
274. U.S. Food and Drug Administration. ''Preliminary Regulatory Impact Analysis (PRIA) for the Food Labeling: Revision of the Nutrition and Supplement Facts Labels Notice of Proposed Rulemaking (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 Notice of Proposed Rulemaking (Docket No. FDA–2004–N–0258)'', 2014.
275. U.S. Food and Drug Administration. ''Supplemental Environmental Assessment for the Revisions of the Nutrition and Supplement Facts Label'', 2016.
276. U.S. Food and Drug Administration. ''Supplemental Finding of No Significant Impact for the Revisions to the Nutrition and Supplement Facts Label'', 2016.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.9:
■ a. Revise paragraphs (c)(1)(i)(A) through (E).
■ b. Add paragraph (c)(1)(i)(F).
■ c. Remove paragraph (c)(1)(ii), redesignate paragraph (c)(1)(iii) as (c)(1)(ii), and revise newly designated paragraph (c)(1)(ii).

■ d. Revise paragraphs (c)(2), (c)(5), (c)(6)(i) through (iv), (c)(7), (c)(8) introductory text, (c)(8)(i), (c)(8)(ii) introductory text, and (c)(8)(iii) through (v).
■ e. Add paragraph (c)(8)(vii).
■ f. Revise paragraphs (c)(9), (d)(1) introductory text, (d)(1)(iii) through (v), (d)(2) through (d)(5), (d)(7) introductory text, (d)(7)(i), (d)(8) through (d)(9), (d)(11)(ii), (d)(11)(iii), (d)(12), (d)(13)(ii), (e), (f) introductory text, (f)(2)(ii), (f)(4) and (5), (g) introductory text, (g)(2), (g)(3)(ii), (g)(4) through (6), and (g)(8).
■ g. Add paragraphs (g)(10) and (11).
■ h. Revise paragraphs (h)(3)(iv), (h)(4) introductory text, (j)(5)(i), (j)(5)(ii) introductory text, and (j)(5)(ii)(A) and (B).
■ i. Remove and reserve paragraphs (j)(5)(ii)(C) through (j)(5)(ii)(E); and
■ j. Add paragraph (j)(5)(iii).
■ k. Revise paragraphs (j)(13)(i), (j)(13)(ii)(A)(*1*) and (*2*), and (j)(13)(ii)(B).
■ l. Remove paragraph (j)(13)(ii)(C) and redesignate paragraph (j)(13)(ii)(D) as (j)(13)(ii)(C).
■ m. Revise paragraph (j)(18)(iv) introductory text.
■ n. Add paragraph (l).

The revisions and additions read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) Using specific Atwater factors (*i.e.,* the Atwater method) given in table 13, USDA Handbook No. 74 (slightly revised, 1973),

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11;

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate;

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised, 1973) p. 10; or

(F) Using the following general factors for caloric value of sugar alcohols: Isomalt—2.0 calories per gram, lactitol—2.0 calories per gram, xylitol—2.4 calories per gram, maltitol—2.1 calories per gram, sorbitol—2.6 calories per gram, hydrogenated starch hydrolysates—3.0 calories per gram, mannitol—1.6 calories per gram, and erythritol—0 calories per gram.

(ii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (½) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

* * * * *

(5) ''Fluoride'' (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride. Bottled water that bears a statement about added fluoride, as permitted by § 101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in paragraph (f) of this section.

(6) * * *

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement ''Not a significant source of dietary fiber'' shall be placed at the bottom of the table of nutrient values in the same type size. The following isolated or synthetic non-digestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in § 101.81(c)(2)(ii)(A)), psyllium husk (as described in § 101.81(c)(2)(ii)(A)(6)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram''

may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.''

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of insoluble fiber in the label and labeling of food when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Total Sugars'': A statement of the number of grams of sugars in a serving, except that the label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the total sugars content is not required and, as a result, not declared, the statement ''Not a significant source of total sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Total sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Total sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Added Sugars'': A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement ''Not a significant source of added sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type, except that fruit or vegetable juice concentrated from 100 percent juices sold to consumers, fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2) of this chapter, fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160 of this chapter, or the fruit component of fruit spreads shall not be labeled as added sugars. Added sugars content shall be indented under Total Sugars and shall be prefaced with the word ''Includes'' followed by the amount (in grams) ''Added Sugars'' (''Includes 'X' g Added Sugars''). It shall be expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or total sugars, or added sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (*e.g.,* mannitol or xylitol) or is generally recognized as safe (*e.g.,* sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (*e.g.,* ''xylitol'') present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as a Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be specifically for infants through 12 months, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the ''Official Methods of Analysis of the AOAC International,'' except when official AOAC procedures described in this paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the

RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants through 12 months or children 1 through 3 years of age. When such a declaration is provided, it should be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be specifically for infants through 12 months and the protein quality value is less than 40 percent of the reference standard.

(ii) The ''corrected amount of protein (gram) per serving'' for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' except that when official AOAC procedures described in paragraph (c)(7) of this section require a specific factor other than 6.25, that specific factor shall be used. For foods represented or purported to be specifically for infants through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant women and lactating women.

(8) ''Vitamins and minerals'': The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years, pregnant women, and lactating women shall use the RDIs that are specified for the intended group. For foods represented or purported to be specifically for both infants through 12 months of age and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants through 12 months of age and children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age. The declaration of folic acid shall be included as a quantitative amount by weight when added as a nutrient supplement or a claim is made about the nutrient. The declaration of vitamins and minerals in a food, as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added as a nutrient supplement, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or the labeling or advertising and the vitamins and minerals are:

* * * * *

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Quantitative amounts and percentages of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)'' or ''Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, except as provided for in paragraph (f) of this section, if vitamin D, calcium, iron, or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of—(listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measure	RDI			
		Adults and children ≥4 years	Infants [1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin A	Micrograms RAE [2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg) [3]	20	10	15	15
Vitamin E	Milligrams (mg) [4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE [5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate [6]	Micrograms DFE [7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8] 71

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.

[2] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.

[3] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol .

[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.

[6] ''Folate'' and ''Folic Acid'' must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

[7] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid.

[8] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Calories—Energy
Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2

* * * * *

(vii) When the amount of folate is declared in the labeling of a conventional food or a dietary supplement, the nutrient name ''folate'' shall be listed for products containing folate (natural folate, and/or synthetic folate as a component of dietary supplement, such as calcium salt of L–5-MTHF), folic acid, or a mixture of folate and folic acid. The name of the synthetic form of the nutrient ''folic acid'', when added or a claim is made about the nutrient, shall be included in parentheses after this declaration with the amount of folic acid. The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement) and the percent DV based on folate in mcg DFE, or for conventional food, may be expressed as folate and the percent DV based on folate in mcg DFE. When declared, folic acid must be in parentheses, mcg of folic acid as shown in paragraph (d)(12) of this section in the display that illustrates voluntary declaration of nutrition information.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Fat	Grams (g)	[1] 78	30	[2] 39	[1] 78
Saturated fat	Grams (g)	[1] 20	N/A	[2] 10	[1] 20
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	[1] 275	95	[2] 150	[1] 275

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary Fiber	Grams (g)	[1] 28	N/A	[2] 14	[1] 28
Protein	Grams (g)	[1] 50	N/A	[2] 13	N/A
Added Sugars	Grams (g)	[1] 50	N/A	[2] 25	[1] 50

[1] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women

[2] Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods where the tabular display is permitted as provided for in paragraph (d)(11) of this section, on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants through 12 months of age and children 1 through 3 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA strongly recommends that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101.

* * * * *

(iii) Information required in paragraphs (d)(7) and (8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the ''Calories'' declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11), (e)(6)(ii), and (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and for the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section no smaller than 14 point. The information required in paragraph (d)(9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(ii), (d)(4), and (d)(6) of this section (*i.e.,* ''Nutrition Facts,'' ''Serving size,'' ''Amount per serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (*i.e.,* ''Calories,'' ''Total Fat,'' ''Cholesterol,'' ''Sodium,'' ''Total Carbohydrate'' and ''Protein''), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Nutrition Facts'' from the servings per container statement required in paragraph (d)(3)(i) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section and in Appendix B to Part 101.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size no smaller than all other print size in the nutrition label except for the numerical information for ''Calories'' required in paragraph (d)(5) of this section, and except for labels presented according to the format provided for in paragraphs (d)(11), (d)(13)(ii), (e)(6)(ii), (j)(13)(ii)(A)(*1*), and (j)(13)(ii)(A)(*2*) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on servings per container and serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:

(i) ''____ servings per container'': The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section or on other food containers when this information is stated in the net quantity of contents declaration. The information required in this paragraph shall be located immediately after the ''Nutrition Facts'' heading and shall be in a type size no smaller than 10 point, except the type size for this information shall be no smaller than 9 point in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. For the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section, the actual number of servings may be listed after the servings per container declaration.

(ii) ''Serving size'': A statement of the serving size as specified in paragraph (b)(7) of this section which shall immediately follow the ''____servings per container'' declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 10 point, except the type size shall be no smaller than 9 point for this information in the tabular displays as shown in paragraphs (d)(11) and (e)(6)(ii) of this section, the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. The serving size amount must be right justified if adequate space is available. If the ''Serving size'' declaration does not fit in the allocated space a type size of no smaller than 8 point may be used on packages of any size.

(4) A subheading ''Amount per serving'' shall be separated from the serving size information by a bar as shown in paragraph (d)(12) of this section, except this information is not required for the dual column formats

shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

(5) Information on calories shall immediately follow the subheading ''Amount per serving'' and shall be declared in one line. If ''Calories from saturated fat'' is declared, it shall be indented under ''Calories'' and shall be in a type size no smaller than 8 point.

* * * * *

(7) Except as provided for in paragraph (j)(13)(ii)(A)(*2*) of this section, nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except for folic acid in conventional food and voluntarily declared vitamins and minerals expressed as a statement of the amount per serving calculated as a percent of the RDI and expressed as a percent Daily Value, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams, ''mg'' for milligrams, or ''mcg'' for micrograms as shown in paragraph (d)(12) of this section. The symbol ''<'' may be used in place of ''less than.''

* * * * *

(8) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and may be arrayed vertically as shown in paragraph (d)(12) of this section (*e.g.,* Vitamin D 2 mcg 10%, Calcium 260 mg 20%, Iron 8 mg 45%, Potassium 235 mg 6%) or may be listed horizontally. When listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line, as shown in paragraph (d)(12) of this section in the side-by-side display. When more than four vitamins and minerals are declared voluntarily as shown in paragraph (d)(12) of this section in the label which illustrates the mandatory plus voluntary provisions of paragraph (d) of this section, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from the list by a bar, except that the footnote may be omitted from foods that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods as defined in § 101.60(b). The first sentence of the footnote: ''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' may be used on foods that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods as defined in § 101.60(b). The footnote shall state: ''*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.'' If the food product is represented or purported to be for children 1 through 3 years of age, the second sentence of the footnote shall substitute ''1,000 calories'' for ''2,000 calories.''

* * * * *

(11) * * *

(ii) If the space beneath the mandatory declaration of potassium is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the nutrients and the percent DV information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (*i.e.,* approximately 3 in) to accommodate the required components of the nutrition label up to and including the mandatory declaration of potassium, the nutrition label may be presented in a tabular display as shown in the following sample label.

Tabular Format

Nutrition Facts

10 servings per container
Serving size
2 slices (56g)

Calories per serving **170**

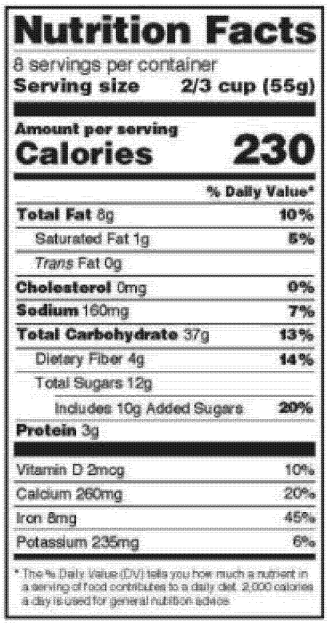
Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 36g	**13%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**7%**
Trans Fat 0.5g		Total Sugars 1g	
Cholesterol 0mg	**0%**	Includes 1g of Added Sugars	**2%**
Sodium 280mg	**12%**	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of paragraph (d) of this section and the side-by-side display.

Standard Vertical



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

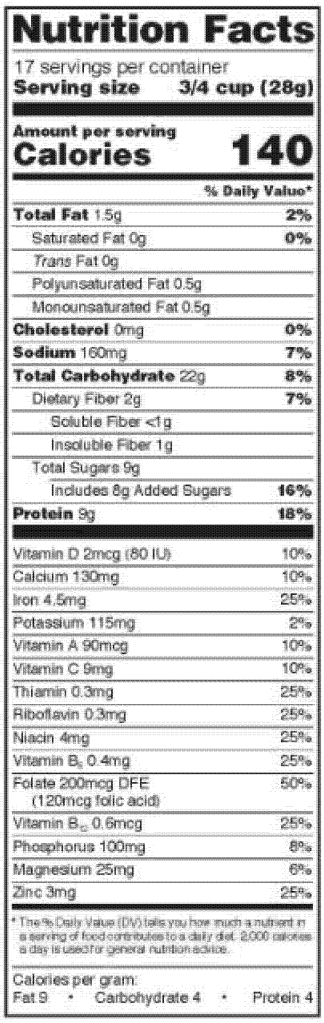
Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Standard Vertical
(w/ Voluntary)



Nutrition Facts

17 servings per container
Serving size **3/4 cup (28g)**

Amount per serving
Calories **140**

	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0.5g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 22g	**8%**
Dietary Fiber 2g	**7%**
Soluble Fiber <1g	
Insoluble Fiber 1g	
Total Sugars 9g	
Includes 8g Added Sugars	**16%**
Protein 9g	**18%**
Vitamin D 2mcg (80 IU)	10%
Calcium 130mg	10%
Iron 4.5mg	25%
Potassium 115mg	2%
Vitamin A 90mcg	10%
Vitamin C 9mg	10%
Thiamin 0.3mg	25%
Riboflavin 0.3mg	25%
Niacin 4mg	25%
Vitamin B_6 0.4mg	25%
Folate 200mcg DFE (120mcg folic acid)	50%
Vitamin B_{12} 0.6mcg	25%
Phosphorus 100mg	8%
Magnesium 25mg	6%
Zinc 3mg	25%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Standard Vertical (Side-by-Side Display)

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	

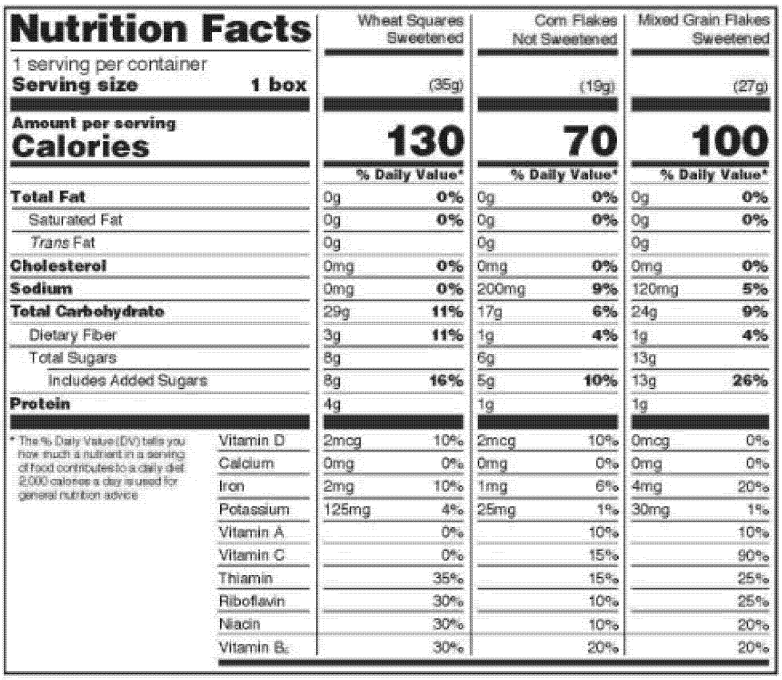
Vit. D 2mcg 10% • Calcium 260mg 20%
Iron 8mg 45% • Potas. 235mg 6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(13) * * *

(ii) Aggregate displays shall comply with the format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified immediately to the right of the ''Nutrition Facts'' heading, and both the quantitative amount by weight (*i.e.,* g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food. The following sample label illustrates an aggregate display.

Aggregate Display



Nutrition Facts

1 serving per container
Serving size **1 box**

Amount per serving
Calories

	Wheat Squares Sweetened (35g)		Corn Flakes Not Sweetened (19g)		Mixed Grain Flakes Sweetened (27g)	
	130		**70**		**100**	
	% Daily Value*		% Daily Value*		% Daily Value*	
Total Fat	0g	**0%**	0g	**0%**	0g	**0%**
Saturated Fat	0g	**0%**	0g	**0%**	0g	**0%**
Trans Fat	0g		0g		0g	
Cholesterol	0mg	**0%**	0mg	**0%**	0mg	**0%**
Sodium	0mg	**0%**	200mg	**9%**	120mg	**5%**
Total Carbohydrate	29g	**11%**	17g	**6%**	24g	**9%**
Dietary Fiber	3g	**11%**	1g	**4%**	1g	**4%**
Total Sugars	8g		6g		13g	
Includes Added Sugars	8g	**16%**	5g	**10%**	13g	**26%**
Protein	4g		1g		1g	
Vitamin D	2mcg	10%	2mcg	10%	0mcg	0%
Calcium	0mg	0%	0mg	0%	0mg	0%
Iron	2mg	10%	1mg	6%	4mg	20%
Potassium	125mg	4%	25mg	1%	30mg	1%
Vitamin A		0%		10%		10%
Vitamin C		0%		15%		90%
Thiamin		35%		15%		25%
Riboflavin		30%		10%		25%
Niacin		30%		10%		20%
Vitamin B_6		30%		20%		20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

* * * * *

(e) Nutrition information may be presented for two or more forms of the same food (*e.g.,* both ''as purchased'' and ''as prepared'') or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (*e.g.,* slices of bread or per 100 grams) as provided for in

paragraph (b) of this section, or for two or more groups for which RDIs are established (*e.g.,* both infants through 12 months of age and children 1 through 3 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same food (*e.g.,* ''Per ¼ cup mix'' and ''Per prepared portion''), the combinations of food, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

(2) The quantitative information by weight as required in paragraph (d)(7)(i) and the information required in paragraph (d)(7)(ii) of this section shall be presented for the form of the product as packaged and for any other form of the product (*e.g.,* ''as prepared'' or combined with another ingredient as shown in paragraph (e)(5) of this section).

(3) When the dual labeling is presented for two or more forms of the same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, the quantitative information by weight and the percent Daily Value shall be presented in two columns and the columns shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Dual Columns, Two Forms of the Same Food

Nutrition Facts

12 servings per container

Serving size **1/4 cup dry mix (44g)**

	Per 1/4 cup dry mix		Per baked portion	
Calories	**170**		**300**	
		% DV*		% DV*
Total Fat	1.5g	**2%**	16g	**21%**
Saturated Fat	1g	**5%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	0mg	**0%**	60mg	**20%**
Sodium	300mg	**13%**	375mg	**16%**
Total Carb.	36g	**13%**	36g	**13%**
Dietary Fiber	<1g	**2%**	<1g	**2%**
Total Sugars	18g		18g	
Incl. Added Sugars	18g	**36%**	18g	**36%**
Protein	2g		3g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	100mg	8%	100mg	8%
Iron	1mg	6%	1mg	6%
Potassium	45mg	0%	45mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(12)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(2)(i)(D) of this section, the quantitative information by weight as required in paragraph (d)(7)(i) and the percent Daily Value as required in paragraph (d)(7)(ii) shall be presented in two columns, and the columns shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

Dual Column Display

Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Dual Columns, Per Serving and Per Unit

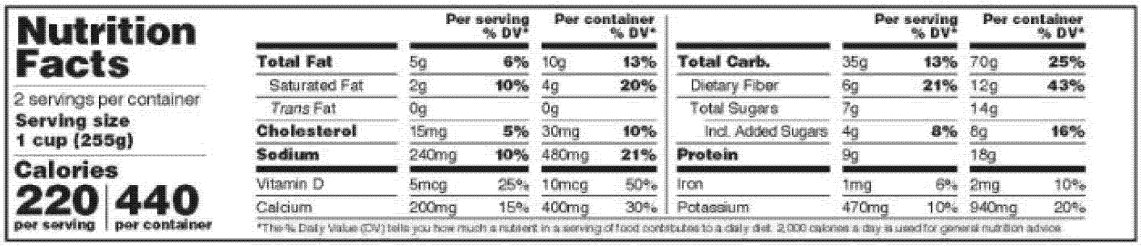
Nutrition Facts

	Per 1/2 muffin		Per 1 muffin	
Calories	**380**		**760**	
		% DV*		**% DV***
Total Fat	16g	**21%**	32g	**41%**
Saturated Fat	3g	**15%**	6g	**30%**
Trans Fat	0g		0g	
Cholesterol	50mg	**17%**	100mg	**33%**
Sodium	480mg	**21%**	960mg	**42%**
Total Carb.	56g	**20%**	112g	**41%**
Dietary Fiber	2g	**7%**	4g	**14%**
Total Sugars	32g		64g	
Incl. Added Sugars	30g	**60%**	60g	**120%**
Protein	3g		6g	
Vitamin D	0.1mcg	0%	0.2mcg	2%
Calcium	40mg	4%	80mg	6%
Iron	2mg	10%	4mg	20%
Potassium	190mg	4%	380mg	8%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(ii) The following sample label illustrates the provisions of paragraphs (b)(2)(i)(D) and (b)(12)(i) of this section for labels that use the tabular display.

Tabular Dual Column Display



Nutrition Facts

2 servings per container
Serving size
1 cup (255g)

Calories
220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%

	Per serving	% DV*	Per container	% DV*
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium; except that for foods intended for infants through 12 months of age and children 1 through 3 years of age to which paragraph (j)(5)(i) of this section applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium.

* * * * *

(2) * * *

(ii) Any other nutrients identified in paragraph (f) of this section that are present in the food in more than insignificant amounts; and

* * * * *

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format or if any nutrition claims are made on the label or in labeling, the statement ''Not a significant source of _____'' (with the blank filled in with the name(s) of any nutrient(s) identified in paragraph (f) of this section that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

Simplified Display

Nutrition Facts

64 servings per container
Serving size **1 tbsp (14g)**

Amount per serving
Calories **130**

	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

*%DV = %Daily Value

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required, and an asterisk shall be placed at the bottom of the label followed by the statement ''% DV = % Daily Value'' when ''Daily Value'' is not spelled out in the heading, as shown in paragraph (f)(4).

(g) Compliance with this section shall be determined as follows:

* * * * *

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the ''Official Methods of Analysis of the AOAC International,'' or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

(3) * * *

(ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and

exogenous) is subject to class I requirements.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) When a vitamin, mineral, protein, or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, or dietary fiber meets the definition of a Class II nutrient, the nutrient content of the composite must be at least equal to 80 percent of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, total sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, total sugars, added sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

* * * * *

(8) Alternatively, compliance with the provisions set forth in paragraphs (g)(1) through (6) of this section may be provided by use of an FDA approved database that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a database shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the database in writing. The approval will be granted where a clear need is presented (*e.g.,* raw produce and seafood). Approvals will be in effect for a limited time, *e.g.,* 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of databases may be found in the ''FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases,'' available from the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 or by going to *http://www.fda.gov*.

* * * * *

(10) The manufacturer must make and keep written records (*e.g.,* analyses of databases, recipes, formulations, information from recipes or formulations, or batch records) to verify the declared amount of that nutrient on the Nutrition Facts label as follows:

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must make and keep written records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of sugars added to food products is reduced through non-enzymatic browning and/or fermentation, manufacturers must:

(A) Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation; or

(B) Make and keep records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or

(C) Submit a petition, under 21 CFR 10.30, to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under paragraph (g)(6) of this section. In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(vi) When a mixture of *all rac*-α-tocopherol and RRR-α-tocopherol is present in a food, manufacturers must make and keep written records of the amount of *all rac*-α-tocopherol added to the food and RRR-α-tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must make and keep written records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food.

(11) Records necessary to verify certain nutrient declarations that are specified in paragraph (g)(10) of this section must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records required to verify information on the label may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Failure to make and keep the records or provide the records to appropriate regulatory authorities, as required by this paragraph (g)(11), would result in the food being misbranded under section 403(a)(1) of the act.

(h) * * *

(3) * * *

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

* * * * *

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section; *e.g.,* a dry ready-to-eat cereal may be described with the percent Daily Value and the quantitative amounts for the cereal as sold (*e.g.,* per ounce), and the percent Daily Value and the quantitative amounts for the cereal and milk as suggested in the label (*e.g.,* per ounce of cereal and ½cup of vitamin D fortified skim milk); and a cake mix may be labeled with the percent Daily Value and the quantitative amounts for the dry mix (per serving) and the percent Daily Value and the quantitative amounts for the serving of the final cake when prepared, as shown in paragraph (e)(5) of this section: Provided, that, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

* * * * *

(j) * * *

(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

(ii) Foods, other than infant formula, represented or purported to be specifically for infants through 12 months of age shall bear nutrition labeling, except that:

(A) Such labeling shall not declare a percent Daily Value for saturated fat, *trans* fat, cholesterol, sodium, dietary fiber, total sugars, or added sugars and shall not include a footnote.

(B) The following sample label illustrates the provisions of paragraph (j)(5)(ii) of this section.

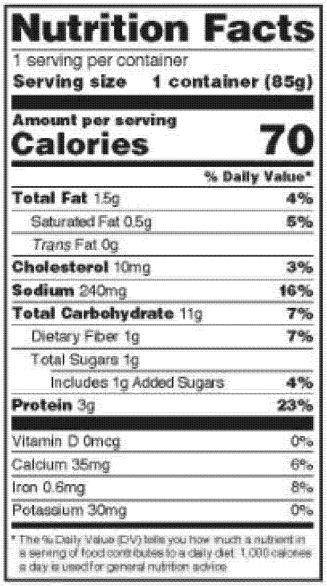
Infants through 12 Months of Age

(iii) Foods, other than infant formula, represented or purported to be specifically for children 1 through 3 years of age shall include a footnote that states: ''*The % Daily Value tells you how much a nutrient in a serving of

food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.''

(A) The following sample label illustrates the provisions of paragraph (j)(5)(iii) of this section.

Children 1-3 Years



Nutrition Facts

1 serving per container

Serving size **1 container (85g)**

Amount per serving

Calories **70**

	% Daily Value*
Total Fat 1.5g	**4%**
Saturated Fat 0.5g	**5%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 240mg	**16%**
Total Carbohydrate 11g	**7%**
Dietary Fiber 1g	**7%**
Total Sugars 1g	
Includes 1g Added Sugars	**4%**
Protein 3g	**23%**
Vitamin D 0mcg	0%
Calcium 35mg	6%
Iron 0.6mg	8%
Potassium 30mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.

(B) [Reserved]

* * * * *

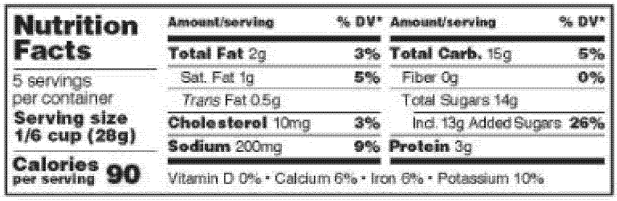
(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided,* That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section. Foods in packages subject to requirements of paragraphs (j)(13)(ii)(A)(*1*) and (*2*) of this section do not require the information in paragraphs (d)(9) and (f)(5) related to the footnote, however the abbreviated footnote statement ''% DV = % Daily Value'' may be used.

(ii) * * *

(A) * * *

(*1*) The following sample label illustrates the tabular display for small packages.

Tabular Display for Small Packages



Nutrition Facts

5 servings per container

Serving size 1/6 cup (28g)

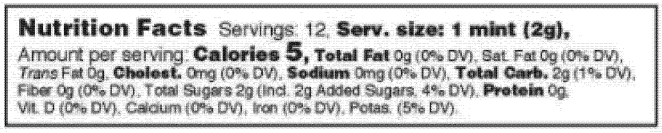
Calories per serving 90

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%

(*2*) The following sample label illustrates the linear display.

Linear Display for Small Packages



Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**

Amount per serving: **Calories 5,** **Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g. Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (5% DV).

(B) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii).
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Vitamin—Vit
Potassium—Potas
Includes—Incl. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

* * * * *

(18) * * *

(iv) A notice shall be filed with the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 and contain the following information, except that if the person is not an importer and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units:

* * * * *

(l) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2404 and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) AOAC Reseller. Techstreet, 6300 Interfirst Dr., Ann Arbor, MI 48108, Toll free in United States: 1–800–699–9277, Outside United States: 1–734–780–8000, Fax: 1–734–780–2046, *www.techstreet.com,techstreet.service@thomsonreuters.com*. FDA does not endorse any particular reseller and notes that other resellers also may have the reference for sale. Consult FDA at 240–402–2404 for more information on additional resellers.

(i) ''Official Methods of Analysis of the AOAC INTERNATIONAL,'' 19th Edition, Volumes 1 and 2, 2012.

(ii) [Reserved]

(2) Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), Publications Division, Viale delle Terme di Caracalla, 00100 Rome, Italy

(i) FAO Food and Nutrition Paper 51,''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1991. *http://apps.who.int/iris/bitstream/10665/38133/1/9251030979_eng.pdf*.

(ii) [Reserved]

(3) United States Department of Agriculture (USDA), Agricultural Research Service, Washington, DC, Nutrient Data Laboratory, Bldg. 005 Room 105 BARC-West, Beltsville, MD 20705, 301–504–0630. *http://www.ars.usda.gov/News/docs.htm?docid=9447*.

(i) USDA Handbook No. 74, Energy Value of Foods—basis and derivation, by A. L. Merrill and B. K. Watt, (slightly revised, 1973) *http://www.ars.usda.gov/SP2UserFiles/Place/80400525/Data/Classics/ah74.pdf*.

(ii) [Reserved]

* * * * *

■ 3. In § 101.30, revise paragraph (e)(2) to read as follows:

§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

* * * * *

(e) * * *

(2) In easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, the title phrase ''Nutrition Facts,'' the declaration of ''Serving size,'' ''Calories'' and the numerical value for ''Calories appearing in the nutrition information as required by § 101.9.

* * * * *

■ 4. In § 101.36:

■ a. Revise paragraphs (b)(2)(i) introductory text, (b)(2)(i)(B), (b)(2)(ii)(A) and (B), (b)(2)(iii) introductory text, (b)(2)(iii)(D) through (G), (b)(3)(ii)(A), (c)(4), (e) introductory text, (e)(8), (e)(11)(i) through (viii), (e)(12), and (f).

■ b. Remove paragraph (i) introductory text.

■ c. Revise paragraph (i)(1).

The revisions read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(2) * * * (i) The (b)(2)-dietary ingredients to be declared, that is, total calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohol may be declared, but they shall be declared when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (*e.g.,* amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

* * * * *

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutritional label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow choline, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_6, folate and folic acid, vitamin B_{12}, biotin, pantothenic acid, choline, calcium, iron, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and fluoride. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)(*2*) of this section.

(*1*) When ''Calories'' are declared, they shall be listed first in the column of names, beneath a light bar separating the heading ''Amount Per Serving'' from the list of names. When ''Calories from saturated fat'' are declared, they shall be indented under ''Calories.''

(*2*) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-

dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B_1), riboflavin (vitamin B_2), and calories (energy). Energy content per serving may be expressed in kilojoule units, added in parentheses immediately following the statement of caloric content.

(*3*) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (*e.g.,* ''Vitamin A (90% as beta-carotene)''). The amount of beta-carotene in terms of micrograms (mcg) may be included in the parentheses following the percent statement (*e.g.,* ''Vitamin A (90% (810 mcg) as beta-carotene)'').

(ii) * * *

(A) The amounts shall be expressed in the increments specified in § 101.9(c)(1) through (7), which includes increments for sodium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg). The amount of vitamin D may, but is not required to, be expressed in IUs, in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IUs must appear in parentheses after the declaration of the amount of vitamin D in mcg.

* * * * *

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent Daily Value for protein, when present, shall be calculated using the corrected amount of protein as specified in § 101.9(c)(7)(ii); no percent of the Daily Value shall be given for subcomponents for which DRVs or RDIs have not been established (*e.g.,* total sugars). Additionally, the percentage of the RDI for protein shall be omitted when a food is purported to be for infants through 12 months of age.

* * * * *

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet.'' If the product is represented or purported to be for use by children 1 through 3 years of age, and if the percent of Daily Value is declared for total fat, total carbohydrate, dietary fiber, or protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement ''Percent Daily Values are based on a 1,000 calorie diet.''

(E) The percent of Daily Value shall be based on RDI or DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(11)(ii) of this section.

(F) For declared subcomponents that have no DRVs or RDIs, a symbol (*e.g.,* an asterisk) shall be placed in the ''Percent Daily Value'' column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by a statement ''Daily Value not established.''

(G) When calories or calories from saturated fat are declared, the space under the ''% DV'' column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the ''% DV'' column, the column may be omitted as shown in paragraph (e)(11)(vii) of this section. When the ''% DV'' column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under ''Amount Per Serving.''

(3) * * *

(ii) * * *

(A) These amounts shall be expressed using metric measures in appropriate units.

* * * * *

(c) * * *

(4) The sample label shown in paragraph (e)(11)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

* * * * *

(e) Except as provided for small and intermediate sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. A font size at least two points greater shall be used for ''Calories'' and the heading ''Calories'' and the actual number of calories per serving shall be highlighted in bold or extra bold type. Type size no smaller than 6 point may be used for column headings (*e.g.,* ''Amount Per Serving'' and ''% Daily Value'') and for footnotes (*e.g.,* ''Percent Daily Values are based on a 2,000 calorie diet).

* * * * *

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (*e.g.,* the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(11)(iii) of this section.

* * * * *

(11) * * *

BILLING CODE 4164–01–P

(i) Multiple vitamins (Includes voluntary listing of vitamin D in IUs)

Supplement Facts

Serving Size 1 Gelcap
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

(ii) Multiple vitamins for children and adults (excludes Servings Per Container which is stated in the net quantity of contents declaration)

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children 1 through 3 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	<1%**	<1%*
Total Sugars	1 g	†	†
Includes 1g Added Sugars		4%**	2%*
Vitamin A (50% as beta-carotene)	450 mcg	150%	50%
Vitamin C	60 mg	400%	67%
Vitamin D	20 mcg	133%	100%
Vitamin E	8 mg	133%	53%
Thiamin	0.9 mg	180%	75%
Riboflavin	0.9 mg	180%	69%
Niacin	11.2 mg	187%	70%
Vitamin B_6	0.9 mg	180%	53%
Folate	300 mcg DFE (180 mcg folic acid)	200%	75%
Vitamin B_{12}	2.0 mcg	222%	83%

*Percent Daily Values are based on a 2,000 calorie diet.
**Percent Daily Values are based on a 1,000 calorie diet.
†Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, gelatin, maltodextrin, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, artificial flavors, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, cholecalciferol, and cyanocobalamin.

(iii) Multiple vitamins in packets (Includes voluntary listing of vitamin D in IUs)

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		**% Daily Value**		**% Daily Value**
Vitamin A	450 mcg	50%	450 mcg	50%
Vitamin C	90 mg	100%	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%		
Vitamin E	15 mg	100%		
Thiamin	1.2 mg	100%	1.2 mg	100%
Riboflavin	1.3 mg	100%	1.3 mg	100%
Niacin	16 mg	100%	16 mg	100%
Vitamin B_6	1.7 mg	100%	1.7 mg	100%
Folate	200 mcg DFE (120 mcg folic acid)	50%	200 mcg DFE (120 mcg folic acid)	50%
Vitamin B_{12}	1.2 mcg	50%	1.2 mcg	50%
Biotin			3 mcg	10%
Pantothenic Acid	2.5 mg	50%	2.5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid (preservative), tricalcium phosphate, sodium benzoate (preservative), sodium caseinate, preservatives (methylparaben, potassium sorbate, BHA, BHT), ergocalciferol, cyanocobalamin, and artificial flavors.

(iv) Dietary supplement containing dietary ingredient with and without RDIs and DRVs

Supplement Facts

Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	**% Daily Value**
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Trans Fat 0 g	†
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients

Supplement Facts

Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

Supplement Facts

Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids

Supplement Facts

Serving Size 1 Tablet
Servings Per Container 50

Amount Per Tablet	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*

* Daily Value not established.

Other ingredients: Cellulose, lactose, and magnesium stearate.

(viii) Dietary supplement illustrating "per serving" and "per day" information (Includes voluntary listing of vitamin D in IUs)

Supplement Facts

Serving Size 1 Caplet
Servings Per Container 100

	Per Caplet		Per Day (3 Caplets)	
	Amount	% Daily Value	Amount	% Daily Value
Vitamin D (as cholecalciferol)	7 mcg (280 IU)	35%	21 mcg (840 IU)	105%
Calcium (as calcium citrate)	650 mg	50%	1950 mg	150%

Other ingredients: Hydroxypropylmethylcellulose (HPMC), microcrystalline cellulose, maltodextrin, and magnesium stearate.

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

Amount Per Packet		% Daily Value	Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	900 mcg	100%	Zinc (as zinc oxide)	11 mg	100%
Vitamin C (as ascorbic acid)	250 mg	278%	Selenium (as sodium selenate)	25 mcg	45%
Vitamin D (as ergocalciferol)	20 mcg	100%	Copper (as cupric oxide)	0.5 mg	56%
Vitamin E (as dl-alpha tocopherol)	75 mg	500%	Manganese (as manganese sulfate)	5 mg	217%
Thiamin (as thiamin mononitrate)	60 mg	5000%	Chromium (as chromium chloride)	50 mcg	143%
Riboflavin	60 mg	4615%	Molybdenum (as sodium molybdate)	50 mcg	111%
Niacin (as niacinamide)	60 mg	375%	Potassium (as potassium chloride)	10 mg	<1%
Vitamin B_6 (as pyridoxine hydrochloride)	60 mg	3529%	Choline (as choline chloride)	100 mg	18%
Folate	400 mcg DFE (240 mcg folic acid)	100%	Betaine (as betaine hydrochloride)	25 mg	*
Vitamin B_{12} (as cyanocobalamin)	100 mcg	4167%	Glutamic Acid (as L-glutamic acid)	25 mg	*
Biotin	100 mcg	333%	Inositol (as inositol monophosphate)	75 mg	*
Pantothenic Acid (as calcium pantothenate)	60 mg	1200%	*para*-Aminobenzoic acid	30 mg	*
Calcium (from oystershell)	130 mg	10%	Deoxyribonucleic acid	50 mg	*
Iron (as ferrous fumarate)	10 mg	56%	Boron	500 mcg	*
Iodine (from kelp)	150 mcg	100%			
Magnesium (as magnesium oxide)	63 mg	15%			

* Daily Value not established

Other ingredients: Cellulose, stearic acid, and silica.

(f)(1) Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Nutrition and Food Labeling (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

* * * * *

(i)(1) Dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(5)(i) for foods other than infant formula, represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age.

* * * * *

Dated: May 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11867 Filed 5–20–16; 8:45 am]

BILLING CODE 4164–01–P