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Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Guidance for Industry

Small Entity Compliance Guide

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U.S. Department of Health and Human Services
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Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Guidance for Industry[1] Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

In the *Federal Register* of May 27, 2016 (81 FR 33742), FDA (we) published a final rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" ("the final rule"). The final rule amends the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices and set a compliance date of 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. We subsequently extended the compliance dates to January 1, 2020, and January 1, 2021, respectively (83 FR 19619). We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document restates in plain language the revisions made in the final rule and is intended to help small entities comply with the requirements established in 21 CFR 101.9, 101.30, and 101.36.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

In the remainder of this guidance, "you" and "I" refer to food manufacturers that are subject to the rule. Many answers in this guidance are followed by citations to show where a specific requirement can be found in either the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Title 21 of the *Code of Federal Regulations*.

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Who Is Subject to the Rule?

You are subject to the rule if you manufacture food that is subject to our nutrition labeling requirements. The nutrition labeling requirements apply to both conventional foods under 21 CFR 101.9(a) and dietary supplements under 21 CFR 101.9(j)(6).

III. What Foods Are Covered by the Rule?

III.A Does the Rule Cover Foods for the General Food Supply?

Yes. Foods for the general food supply are foods eaten by persons 4 years of age and older.

III.B Does the Rule Cover Foods for Infants and Young Children 1 Through 3 Years of Age?

Yes. 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 are subject to nutrition labeling (21 CFR 101.9(j)(5)(i)). Manufacturers of foods represented or purported to be specifically for infants through 12 months and/or children 1 through 3 years of age must use the Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs) that are specified for this intended group when calculating percent Daily Values (DVs) for labels (21 CFR 101.9(c)(8) and (9)). The previous categories of "infants" (or "infants 7 to 12 months") and "children less than 4 years" have been changed to "infants through 12 months" and "children 1 through 3 years of age" throughout 21 CFR 101.9.

III.C Does the Rule Cover Foods for Pregnant Women and Lactating Women?

Yes. Manufacturers of foods represented or purported to be specifically for pregnant women and lactating women must use the RDIs and DRVs that are specified for this intended group when calculating percent DVs for labels (21 CFR 101.9(c)(8) and (9)).

III.D Does the Rule Cover Dietary Supplements?

Yes. Section 201(f) of the FD&C Act defines "food" as: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Further, section 201(ff) of the FD&C Act explains that dietary supplements are deemed to be foods within the meaning of the FD&C Act except for the purposes of sections 201(g) (definition of "drug") and 417 (reportable food registry) of the FD&C Act. Nutrition labeling information for food must be provided for all products intended for human consumption and offered for sale, unless an exemption is provided (21 CFR 101.9(a)). As dietary supplements fall under the definition of "food," they are therefore subject to nutrition labeling. Specific nutrition labeling requirements and guidelines for dietary supplements can be found in 21 CFR 101.36.

IV. What Foods Are Not Covered by the Rule?

Under 21 CFR 101.9(j), numerous foods are exempt from nutrition labeling requirements or are subject to special labeling requirements. Such products generally include: (1) foods offered for sale by a retailer who has annual gross sales made or business done in sales to consumers that is not more than $500,000; (2) foods offered for sale by a retailer who has annual gross sales made or business done in sales of food to consumers of not more than $50,000; (3) medical foods; and (4) foods that contain insignificant amounts of all nutrients (e.g., coffee beans, tea leaves). For more information on foods not covered by the rule and for further information about exemptions from these requirements, see 21 CFR 101.9(j).

V. Which Nutrients Must Newly be Declared, and What Changes Have Been Made to Nutrients Previously Required or Allowed to be Declared?

V.A Which Nutrients Are Newly Required to be Declared?

V.A.1 Added Sugars

V.A.1.(a) How Are Added Sugars Defined?

Added sugars are defined as sugars that 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" (21 CFR 101.9(c)(6)(iii)). This definition includes single ingredient foods, such as individually packaged table sugar (see Section V.A.1.(a).(i) and Ref. 1).

The following do not fall under the definition of added sugars:

- Sugars in fruit or vegetable juice concentrated from 100 percent juices that are sold to consumers (e.g., frozen 100 percent fruit juice concentrate) (21 CFR 101.9(c)(6)(iii));
- Sugars in fruit juice concentrates that are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standards of identities set forth in 21 CFR 150.140 and 150.160 (21 CFR 101.9(c)(6)(iii));
- Sugars in the fruit component of fruit spreads (21 CFR 101.9(c)(6)(iii));
- Sugar alcohols;
- Sugars in juice concentrates that are counted towards percentage juice label declaration under 21 CFR 101.30 for 100 percent juice or 21 CFR 102.33 for juice beverages (21 CFR 101.9(c)(6)(iii));
- Sugars in juice concentrates that are used to standardize the Brix values of a single species juice consisting of juice directly expressed from a fruit or vegetable in accordance with 21 CFR 102.33(g)(2) (21 CFR 101.9(c)(6)(iii));
- Naturally-occurring sugars found in milk and dairy ingredients, except lactose as defined in 21 CFR 168.122; and

- Naturally-occurring sugars found in whole fruits and vegetables or dried fruits which have not had any sugar added to them.

The amount of added sugars declared on the label should never exceed the amount of total sugars on the label.

V.A.1.(a).(i) Do Honey, Maple Syrup, and Other Single-Ingredient Sugars and Syrups Have to be Declared as Added Sugars?

In the *Federal Register* of June 20, 2019 (84 FR 28726), we announced the availability of a final guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products," which provides clarity on the labeling of added sugars for such products (Ref. 1). In that guidance, we discuss section 12516 of the Agriculture Improvement Act of 2018 (Pub. L. 115-334) ("the Farm Bill"), which states that the food labeling requirements cannot require the declaration "Includes Xg Added Sugars" in a serving of these single-ingredient products. While these products are not required to have this declaration of the gram amount of added sugars, the Farm Bill did not change the requirement under the Nutrition Facts label final rule to include the percent DV for the contribution of sugars from these products to the added sugars in the diet, so the percent DV for added sugars must still be included consistent with 21 CFR 101.9(d)(7)(ii). We stated that we intend to exercise enforcement discretion by permitting the use of the "†" symbol immediately following the percent DV declaration for added sugars on packages and containers of single-ingredient sugars and syrups. This symbol would lead to a footnote inside the Nutrition Facts label, explaining the amount of added sugars that one serving of the product contributes to the diet, as well as the contribution of a serving of the product toward the percent DV for added sugars. This symbol and footnote are not required; however, we encourage you to use them.

V.A.1.(a).(ii) Do Added Sugars in Dried Cranberry Products and Cranberry Beverage Products Have to be Declared as Added Sugars?

You must still declare added sugars in grams and the corresponding percent DV on labels for all dried cranberry products and cranberry beverage products (21 CFR 101.9(c)(6)(iii)). In the Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products guidance, we said that we intend to exercise enforcement discretion for these cranberry products to allow the use of a symbol immediately following the added sugars percent DV declaration which would lead to a truthful and not misleading statement outside the Nutrition Facts label explaining that sugars are added to improve the palatability of naturally tart cranberries (see Ref. 1). This symbol can be used for cranberry products that are sweetened with added sugars and that contain total sugars per serving at levels no greater than comparable products with no added sugars (i.e. unsweetened grape juice) (Ref. 1).

V.A.1.(a).(iii) Does Allulose Count as an Added Sugar?

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. We stated that, as a monosaccharide, it

must be included in the declaration of each, pending any future rulemaking that would otherwise exclude it from the declaration (81 FR 33742 at 33796; 21 CFR 101.9(c)(i) through (iii)).

In the *Federal Register* of April 18, 2019 (84 FR 16272), we announced the availability of a draft guidance for industry entitled "The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels." This guidance, when finalized, would advise manufacturers of our intent to exercise enforcement discretion for the exclusion of allulose from the amount of "Total Sugars" and "Added Sugars" declared on the label and the use of a general factor of 0.4 calories per gram for allulose when determining "Calories" on the Nutrition and Supplement Facts labels, pending review of the issues in a rulemaking (Ref. 2).

V.A.1.(b) How Do I Calculate Added Sugars?

In the *Federal Register* of November 5, 2018 (83 FR 55266), we announced the availability of a final guidance for industry entitled "Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals." This guidance provides questions and answers (Q&A) on topics related to compliance with the labeling of added sugars. The Q&A discusses how you should determine the amount of added sugars in a serving of a product, as well as which ingredients need to be taken into consideration when calculating the added sugars declaration for a serving of a product (Ref. 3).

This guidance also provides a detailed discussion on the calculation of added sugars for ingredients and products such as concentrated fruit and vegetable purees, fruit and vegetable pastes, fruit and vegetable powders, juice cocktails, or juice blends, which often contain juice concentrates (Q&A IV. 7-12), products for which manufacturers employ a hydrolysis step (Q&A IV. 14-16), and products that undergo non-enzymatic browning or fermentation (Q&A IV. 18–21) (Ref. 3). Please refer to this guidance for questions you may have regarding the calculation and declaration of added sugars for a serving of your product.

V.A.2 Vitamin D

Vitamin D is now considered a nutrient of "public health significance" for the general population, and its declaration is now mandatory (81 FR 33742 at 33884). Both the gram amount and the percent DV for Vitamin D must be declared at the bottom of the label, directly preceding the calcium declaration (21 CFR 101.9(c)(8)(ii)). While only the term "vitamin D" can be used on the food labels (21 CFR 101.9(c)(8)(iv)), the specific form that is added to a food must be listed in the ingredient list statement (21 CFR 101.4). For Supplement Facts labels, the source ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from" (21 CFR 101.36(d)). When you do not identify a source ingredient within the nutrition label, you must list it in an ingredient statement (21 CFR 101.4(g)). You should not list it in both places (81 FR 33742 at 33891).

V.A.3 Potassium

Potassium is also now considered a nutrient of "public health significance" for the general population (81 FR 33742 at 33884). It has been assigned an RDI, instead of a DRV (21 CFR 101.9(8)(iv)). We now require the declaration of both the gram amount and the percent DV for potassium at the bottom of the label, directly following the iron declaration. Potassium is now covered under the term "mineral" that appears in each section of 21 CFR 101.9. Any listing of potassium on the Nutrition Facts label must meet the specific nutrient declaration requirements for minerals under 21 CFR 101.9(g)(4), 101.9(g)(4)(i), 101.9(g)(4)(ii), and 101.9(g)(6). These requirements are discussed further in section VII.E "Has Nutrient Compliance or the Level of Variance Allowed Changed?" below.

V.B Have There Been Any Changes to the Definition or Presentation of Nutrients That Were Already Required to Be Declared?

V.B.1 Dietary Fiber

Any dietary fiber declared on the label must meet the new definition of dietary fiber (21 CFR 101.9(c) and (c)(6)(i)), which is discussed in the following section. This definition includes a listing of dietary fiber that FDA has determined should be in the calculation of dietary fiber for declaration on Nutrition Facts labels. The new definition and process to amend the listing of dietary fiber is discussed in this section.

V.B.1.(a) How Is Dietary Fiber Defined?

Dietary fiber is now 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" (21 CFR 101.9(c)(6)(i)). Soluble fiber and insoluble fiber both must meet this new definition of dietary fiber (21 CFR 101.9(c)(6)(i)(A) and (B)).

V.B.1.(a).(i) Which Isolated or Synthetic Non-Digestible Carbohydrate(s) Qualify as Dietary Fiber?

The following isolated or synthetic non-digestible carbohydrate(s) should be included in the calculation of the amount of dietary fiber, as FDA has determined that they have physiological effects that are beneficial to human health:

- Beta-glucan soluble fiber (as described in 21 CFR 101.81(c)(2)(ii)(A));
- Psyllium husk (as described in 21 CFR 101.81(c)(2)(ii)(A)(6));
- Cellulose;
- Guar gum;
- Pectin;
- Locust bean gum; and
- Hydroxypropylmethylcellulose. (21 CFR 101.9(c)(6)(i)).

In the *Federal Register* of June 15, 2018 (83 FR 27894), we announced the availability of a final guidance for industry entitled "The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels," where we stated that we intend to propose that the following eight non-digestible carbohydrates be added to the definition of dietary fiber, as well:

- Mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber and apple fiber, among many others);
- Arabinoxylan;
- Alginate;
- Inulin and inulin-type fructans;
- High amylose starch (resistant starch 2);
- Galactooligosaccharide;
- Polydextrose; and
- Resistant maltodextrin/dextrin (see Ref. 4).

Until we complete rulemaking to add any additional non-digestible carbohydrates to the regulatory definition of dietary fiber, we intend to exercise enforcement discretion to allow manufacturers to include the eight recognized fibers when calculating the amount of dietary fiber to declare on the Nutrition and Supplement Facts labels.

Additionally, in March of 2019 and January of 2020, we granted citizen petition requests and announced our intent to propose that "cross-linked phosphorylated RS4" and glucomannan, respectively, be added to the definition of dietary fiber (Refs. 5 and 6). For up-to-date information on the additional non-digestible carbohydrates that FDA intends to propose to be added to the definition of dietary fiber, see "Questions and Answers on Dietary Fiber," available at http://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber#synthetic_fibers.

V.B.1.(a).(ii) What If There is an Additional Isolated or Synthetic Non-Digestible Carbohydrate I Want to be Included in the List of Dietary Fibers?

There are two ways that the list of dietary fiber can be amended to include additional isolated or synthetic non-digestible carbohydrates in the definition. The first way is by submitting a citizen petition to request an amendment to the dietary fiber definition (see 21 CFR 10.30(b)). The second way involves the petition process for the authorization of a health claim. For further information regarding the petition process for the authorization of a health claim, refer to 21 CFR 101.70. Once an isolated or synthetic non-digestible carbohydrate is added to the dietary fiber definition, all manufacturers must include it as part of the total dietary fiber declaration if it is present in their product (21 CFR 101.9(c)(6)(i)).

In the *Federal Register* of March 2, 2018 (83 FR 8997), we announced the availability of a final guidance entitled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)" (Ref. 7). For further information on this topic, please refer to that final guidance, as it

goes further in explaining FDA's current thinking on information needed when submitting a citizen petition and the scientific review approach we plan to use for evaluating scientific evidence to determine whether an isolated or synthetic non-digestible carbohydrate that is added to food has a physiological effect that is beneficial to human health.

V.B.1.(b) How Do I Calculate Dietary Fiber?

Compliance with any declaration of dietary fiber is determined using the appropriate "Official Methods of Analysis of the AOAC International" (21 CFR 101.9(g)(2)). AOAC 2009.01, AOAC 2011.25, or an equivalent AOAC method of analysis may be used to measure the amount of dietary fiber in a serving of a product. 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 (see 21 CFR 101.9(c)(6)(i)). 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. AOAC 2011.25 is a newer method that can measure low molecular weight non-digestible carbohydrates and is considered a reliable and appropriate method to measure the amount of soluble and insoluble fiber in a serving of a product, if declared separately (81 FR 33742 at 33960).

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 dietary fiber content, then you must make and keep records to verify the amount of non-digestible carbohydrates that do not meet the proposed definition of dietary fiber that have been added to the food (21 CFR 101.9(g)(10)(i) through (iii); see also section VI. "How Do I Comply with the Recordkeeping Requirements?").

V.B.2 Total Sugars

"Sugars" has changed to "Total Sugars," which includes both "Added Sugars" and sugars that are naturally occurring in food. The label declaration of "Total Sugars" is not required if the product contains less than one gram of sugars per serving and no claims are made about sugars, sweeteners, or sugar alcohol content. If the total sugars content is not required and therefore not declared, the statement "Not a significant source of total sugars" must be placed at the bottom of the table of nutrient values (see 21 CFR 101.9(c)(6)(ii)).

V.B.3 Sugar Alcohol

In addition to preexisting regulations, sugar alcohol content must now also be declared when a claim is made on the label or in labeling about added sugars when sugar alcohols are present in the food (21 CFR 101.9(c)(6)(iv)).

V.C Which Nutrients Can I Still Voluntarily Declare, Even Though They Are No Longer Mandatory?

While the declarations of vitamins A and C are no longer mandatory, you can declare this information voluntarily. Declaration of vitamins A and C can be provided for foods for adults

and children 4 years or more of age, as well as 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. However, vitamin A and vitamin C declaration is mandatory when the respective nutrient is added as a nutrient supplement or claims are made about it on the label or in the labeling of foods (21 CFR 101.9(c)(8)(ii)). There have been no changes to the prior provision that allowed for voluntary declaration of the percent of vitamin A that is present as β-carotene (101.9(c)(8)(vi)).

V.D Which Nutrients Are Newly Allowed to be Voluntarily Declared?

Declaration of fluoride is voluntary whether it is intentionally added or naturally present, unless a claim is made about fluoride content, which would trigger mandatory declaration. When fluoride content is declared, it must be expressed as zero when a serving contains less than 0.1mg of fluoride, to the nearest 0.1mg increment when a serving contains less than or equal to 0.8mg of fluoride, and the nearest 0.2mg when a serving contains more than 0.8mg of fluoride (21 CFR 101.9(c)(5)).

For bottled water that bears a statement about added fluoride, as permitted under 21 CFR 101.13(q)(8), nutrition labeling that complies with the simplified format requirements (21 CFR 101.9(f)) is required (21 CFR 101.9(c)(5)).

V.E Which Nutrients Can I No Longer Declare?

V.E.1 "Calories From Fat"

While the declaration of "Calories from fat" used to be required, it is no longer required nor is it allowed to be declared voluntarily (81 FR 33742 at 33780). Any reference to this declaration has been removed from the updated regulations (81 FR 33742 at 33780).

V.E.2 "Other Carbohydrate"

The voluntary declaration of "Other Carbohydrate" is also no longer allowed. Any reference to this declaration has been removed from the updated regulations (81 FR 33742 at 33868).

VI. How Do I Comply with the Recordkeeping Requirements?

VI.A When Are Records Necessary?

For certain nutrients, there are no AOAC official methods of analysis or other reliable or appropriate analytical procedures available to verify the amount of the declared nutrient on the Nutrition Facts or Supplement Facts label. Verification is important because it ensures that the declared nutrient amount is truthful, accurate, and complies with all applicable labeling requirements. In such situations, we require you to make and keep records that are necessary to verify the declaration of these nutrients, as you are in the best position to verify how you arrived at this determination and to know which of your records provide the necessary documentation for us to determine compliance.

Records are needed to verify the declaration of the following:

- The amount of added sugars added to the food during processing, when both naturally occurring and added sugars are present in a food (21 CFR 101.9(g)(10)(iv));
- The amount of added sugars, 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) when both naturally occurring and added sugars are present in a food (21 CFR 101.9(g)(10)(iv));
- The amount of added non-digestible carbohydrate(s) that does not meet the 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 (21 CFR 101.9(g)(10)(i));
- The amount of added soluble non-digestible carbohydrate(s) that does not meet the definition of dietary fiber when the soluble dietary fiber present in a food is mixture of soluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (21 CFR 101.9(g)(10)(ii));
- The amount of added insoluble non-digestible carbohydrate(s) that does not meet the 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 (21 CFR 101.9(g)(10)(iii));
- The amount of all rac-α-tocopherol 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 (21 CFR 101.9(g)(10)(vi)); and
- The amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food when a mixture of both forms is present in a food (21 CFR 101.9(g)(10)(vii)).

For example, if you manufacture products containing fruit and vegetable juice concentrates as an ingredient that have not been reconstituted to 100 percent juice in the finished food, you must provide documentation that shows how you determined how much of the sugars provided by the juice concentrate should be declared as added sugars in the finished product (21 CFR 101.9(g)(10)(iv)).

Similar verification is needed regarding the 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. In such situations, you must:

1. make and keep records of all relevant scientific data and information relied upon to demonstrate 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
2. 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 will the amount of added sugars declared exceed the amount of total sugars on the label; or

3. submit a citizen petition requesting 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 is a reduction in added sugars after non-enzymatic browning and/or fermentation that 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 101.9(g)(6). You must include the reason that you are unable to determine a reasonable approximation of the amount of added sugars in a serving of your finished product and a description of the process that you used to come to that conclusion.

(See 21 CFR 101.9(g)(10)(v)(A) through (C).)

VI.B What Counts as a Record?

Records can include, for example, analyses of databases, recipes or formulations, or batch records (21 CFR 101.9(g)(10)). They can be kept either as original records, true copies (e.g. photocopies, pictures, scanned copies), or electronic records in accordance with 21 CFR part 11 (21 CFR 101.9(g)(11)). The records requirements provide flexibility in what records you make available to FDA to verify the declared amounts of these nutrients. As 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, you should mark the information as such before providing the records to FDA (81 FR 33742 at 33962).

VI.C How Long Must Records be Kept?

Records must be kept for a period of two years after introduction or delivery for introduction of the food into interstate commerce, and they must be provided to FDA upon request during an inspection for official review and copying (or other means of reproduction) (21 CFR 101.9(g)(11)). Records need to be reasonably accessible to FDA during an inspection at each manufacturing facility, even if not stored onsite, to determine compliance with labeling requirements (81 FR 33742 at 33963). These recordkeeping requirements are the same for foreign and domestic firms.

VII. How Have the Values of Nutrients Been Updated?

VII.A How Have the Calculations of Caloric Content Changed?

While the final rule still allows for the calculation of caloric content using a variety of methods, there has been an update to the prior method of using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively. Now, as stated in 21 CFR 101.9(c)(1)(i)(C), calories from carbohydrate are required to be calculated using a general factor of 4 kcal/gram of total carbohydrate less the

amount of non-digestible carbohydrates, which includes soluble and insoluble non-digestible carbohydrates that do and do not meet the definition of dietary fiber, and sugar alcohols. A general factor of 2 calories per gram is to be used for soluble non-digestible carbohydrates, but insoluble non-digestible carbohydrates (0 calories per gram) are not included in the caloric calculation. The calorie contribution of soluble non-digestible carbohydrate would be added to that sum to determine the total carbohydrate calorie contribution (81 FR 33742 at 33867). The following general factors are to be used for the 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 (21 CR 101.9(c)(1)(i)(F)).

VII.B How Have the Daily Reference Values (DRVs) Changed?

The following table (Figure 1) reflects the updated DRVs for each population group that have been established for fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, protein, and added sugars (see also 21 CFR 101.9(c)(9)).

Figure 1: Table 1 – Daily Reference Values Used to Calculate Percent DV

Nutrient	**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)	78[1]	30	39[2]	78[1]
Saturated Fat	Grams (g)	20[1]	N/A	10[2]	20[1]
Cholesterol	Milligrams (mg)	300	N/A	300	300
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Total Carbohydrate	Grams (g)	275[1]	95	150[2]	275[1]
Dietary Fiber	Grams (g)	28[1]	N/A	14[2]	28[1]
Protein	Grams (g)	50[1]	N/A	13[2]	N/A
Added Sugars	Grams (g)	50[1]	N/A	25[2]	50[1]

[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.

We did not establish a reference calorie intake for infants through 12 months of age. We also did not establish DRVs for trans fat, polyunsaturated fat, monounsaturated fat, insoluble fiber, total sugars, or sugar alcohol for any population group.

VII.C How Have the Reference Daily Intakes (RDIs) Changed?

Certain RDIs used in the declaration of the percent DV of nutrients on Nutrition and Supplement Facts labels have been updated, which may affect the percent DV declared on such labels.[2] Figure 2 below reflects the list of ordered nutrients and their RDIs, which are used to calculate the percent DVs (see also 21 CFR 101.9(c)(8)(iv)). RDIs have now been established for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women for the following nutrients: vitamin A, vitamin D, vitamin E, vitamin C, vitamin K, vitamin B12, vitamin B6, folate, choline, riboflavin, niacin, calcium, iron, thiamin, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, potassium (21 CFR 101.9(c)(8)(i) through (iv)). While we have not established a DRV for protein for infants through 12 months or for pregnant women and lactating women, we have established an RDI for protein of 11 grams and 71 grams, respectively, for these groups (see Figure 2). We did not establish 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 (81 FR 33742 at 33917).

Figure 2: Table 2 – Reference Daily Intakes Used to Calculate Percent DV

Nutrient	Unit of Measure	Adults and Children ≥ 4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin D	Micrograms (mcg)	20	10	15	15
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Vitamin A	Micrograms RAE[2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Vitamin E	Milligrams (mg)[3]	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[4] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2
Folate[5]	Micrograms DFE[6] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8

[2] We updated the RDIs for the following nutrients and minerals based on their RDAs: calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, and zinc (81 FR 33742 at 33897 through 33901). Updated RDIs based on AIs are available for the following nutrients and minerals: biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K (81 FR 33742 at 33926).

Nutrient	Unit of Measure	Adults and Children ≥ 4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
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
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	n/a	11	n/a	71[7]

[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 micrograms supplemental β-carotene, 12 micrograms dietary β-carotene, 24 micrograms dietary α-carotene, or 24 micrograms dietary β-cryptoxanthin.
[3] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*- α-tocopherol.
[4] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.
[5] "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.
[6] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid.
[7] 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.

VII.C.1 Which Units of Measure Have Changed?

The units of measure have changed for vitamin A, vitamin D, vitamin E, folate, and niacin. Where previously "international units," or "IU," was used for vitamin A, vitamin D, and vitamin E, we now require the use of a metric unit of measure (mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E). The declarations of vitamin A and vitamin D will be expressed in mcg on the nutrition and supplement facts labels, and vitamin E will be expressed in mg (21 CFR 101.9(c)(8)(iv)). The amount of vitamin D may also be expressed in IU, in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after its declaration in mcg (21 CFR 101.9(c)(8)(iv)). This is allowed because vitamin D is a nutrient of public health significance, the National Academy of Medicine (formerly the Institute of Medicine (IOM)) uses IU for vitamin D, and voluntary labeling in IU will assist consumers in maintaining healthy dietary practices (81 FR 33742 at 33912). For

vitamin E, the use of this new unit of measure would account for the difference in activity between naturally occurring and synthetic vitamin E (81 FR 33742 at 33913).

Changes regarding the labeling of folate have been made so that there is now consistency between conventional foods and dietary supplements. When the amount of folate is declared in the labeling of a conventional food or a dietary supplement, the name "folate" is to be listed for products containing folate (both natural and synthetic), folic acid, or a mixture of folate and folic acid. Folate is to be declared in mcg Dietary Folate Equivalents (DFE). The terms folic acid or folacin are no longer allowed to be used as synonyms for folate. They cannot be listed without parentheses in place of folate, and they cannot be added in parentheses immediately following folate, unless synthetic folic acid is added as a nutrient supplement to a product or a claim is made about it. In that case, the declaration of folic acid must be included, in parentheses after the declaration of folate, as a quantitative amount by weight (21 CFR 101.9(c)(8)(ii)).

The unit of measure has changed for niacin, from "mg" to "milligrams NE," where "NE" stands for "niacin equivalents" (21 CFR 101.9(c)(8)(iv)). However, only the amount will continue to be declared on the Nutrition and Supplement Facts labels. The declaration of niacin content requires products to include both preformed niacin (from nicotinic acid and nicotinamide in the diet or niacin) and tryptophan, including those that may not contain preformed niacin. Compliance can be determined by measuring niacin and tryptophan separately; AOAC methods exist for both niacin and tryptophan (81 FR 33742 at 33915).

VII.C.2 How Do I Know if the Declaration of Vitamins and Minerals is Mandatory or Voluntary?

Declaration is mandatory for the vitamins and minerals of public health significance, which have been updated and now are vitamin D, calcium, iron, and potassium. They must be listed in that order, and their declaration is mandatory on foods for adults and children 4 years of age and older, as well as on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women (21 CFR 101.9(c)(8)(ii)).

Voluntary declaration is allowed for any other essential nutrient presented in Figure 2. However, if any of these nutrients is added to food as a nutrient supplement or if a claim is made about it on the label or in the labeling of foods, then mandatory declaration is required (21 CFR 101.9(c)(8)(ii)).

VII.C.3 What Information Has to be Declared for Vitamins and Minerals?

For the vitamins and minerals of public health significance (vitamin D, calcium, iron, and potassium), the inclusion of both absolute amounts (quantitative amount by weight) and percent DV are required (except as described for labels in 21 CFR 101.9(j)(13)). However, if these nutrients are present at an amount less than 2 percent of the RDI, then the quantitative amounts and percentages of these nutrients are not required to be declared. They 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 Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided in 21 CFR 101.9(f), 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 (21 CFR 101.9(c)(8)(iii)).

When any other nutrient listed in Figure 2 is added to a food as a nutrient supplement or when a claim is made about it (therefore triggering mandatory declaration), the declaration must include the amount per serving, expressed as percent DV, unless otherwise stated as both the quantitative amount by weight and percent DV (21 CFR 101.9(c)(8)(ii)). Any nutrient (except folic acid) that is voluntarily declared must be declared as a percent of the RDI (21 CFR 101.9(c)(8)(ii)) but declaring the quantitative amount by weight is voluntary (81 FR 33742 at 33947-48). The quantitative amount of folic acid must always be declared (21 CFR 101.9(c)(8)(ii)). You must use the appropriate RDI, depending on which population group your food is represented or purported to be for (21 CFR 101.9(c)(8)(i)).

Zeros following the 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) (21 CFR 101.9(c)(8)(iii)). The phrase "levels of significance" refers to the degree of accuracy when rounding nutrients for purposes of declaring quantitative amounts of vitamins and minerals on the label. For example, the RDIs for some vitamins and minerals are small numerical values, and nutrients with an RDI of less than 5 (i.e. thiamin, riboflavin, vitamin B_6, vitamin B_{12}, copper, and manganese) would not be able to be declared on the Supplement Facts label if they contain less than 2 percent of the RDI and the amount is declared to the nearest mg or mcg. In such situations, manufacturers could declare the quantitative amounts to the nearest hundredth of a mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than can be scientifically supported. These rounding recommendations are explained in further detail in FDA's guidance for industry entitled "Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals" (Ref. 3).

VII.D How Do the Nutrient Requirements for Supplement Facts Labels Differ?

Both the content and format of the Supplement Facts label have been updated to correspond to the Nutrition Facts label, wherever possible. However, there are still some differences between the two. On the Supplement Facts label, information on calories and serving size was not made more prominent through increased type size, as it has been on the Nutrition Facts label. While the percentage of the RDI for protein for foods purported to be for infants through 12 months of age is allowed on Nutrition Facts labels, this declaration must be omitted for Supplement Facts labels (21 CFR 101.36(b)(2)(iii)).

In addition, the new ordering for vitamins and minerals on the Supplement Facts label is as follows: vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate and folic acid, vitamin B12, biotin, pantothenic acid, choline, calcium, iron,

phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and fluoride (21 CFR 101.36(b)(2)(B)).

VII.E Has Nutrient Compliance or the Level of Variance Allowed Changed?

There are still two classes of nutrients for compliance purposes. Class I covers those added nutrients in fortified or fabricated foods (21 CFR 101.9(g)(3)(i)), and Class II nutrients are those that are naturally occurring, or indigenous, nutrients (21 CFR 101.9(g)(3)(ii)). For compliance purposes, if both Class I and Class II nutrients are present in the final food product, then the total amount of the nutrient (both indigenous and exogenous) is subject to class I requirements.

The updated rule does not change the level of variances allowed in 21 CFR 101.9(g)(4) and 101.9(g)(5), but the rule also now includes soluble fiber and insoluble fiber in 21 CFR 101.9(g)(4) and added sugars in 21 CFR 101.9(g)(5). Therefore, 21 CFR 101.9(g)(4) now states that a food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat will be deemed to be misbranded under section 403(a) of the FD&C Act, unless the nutrient content of the composite is formulated to be at least equal to the declared value for the vitamin, mineral, protein, or dietary fiber meeting the definition of a Class I nutrient (potassium has been removed), or the nutrient content of the composite is at least equal to 80 percent of the declared value for the vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, or dietary fiber meeting the definition of a Class II nutrient (potassium and "other carbohydrate" have been removed). Our regulations, at 21 CFR 101.9(g)(5), state that a food with a label declaration of calories, sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, trans fat, cholesterol, or sodium will 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. Reasonable excesses of soluble fiber, insoluble fiber and sugar alcohols, and reasonable deficiencies of added sugars are also now acceptable within current good manufacturing practices.

VII.F Which Version of the Official Methods of Analysis of the AOAC International Should be Used?

The final rule now incorporates by reference the Official Methods of Analysis of the AOAC International, 19th edition (2012) (21 CFR 101.9(l)(1)(i)).

VIII. How Do I Comply with the Formatting Requirements?

There are required formats for Nutrition and Supplement Facts labels. We strongly recommend that the nutrition information be presented using the graphic specifications below (see also Appendix B to 21 CFR part 101 and Ref. 8).

VIII.A How Do I Comply with the Standard Version of the Nutrition Facts Label?

Figures 3 through 5 reflect what a standard vertical Nutrition Facts label must look like (see 21 CFR 101.9(d)(12)). This format is to be used except on foods where the tabular display is

permitted, where dual columns are required or voluntarily used, where the simplified format is used, where the aggregate display is used, and on foods in small or intermediate-sized packages. These formats, except for the aggregate display, as no changes to this format were made, are discussed in detail below.

Figures 3 and 4 show a Nutrition Facts label including only those nutrient declarations which are mandatory. Figure 5 shows a Nutrition Facts label that includes both mandatory and voluntary nutrient declarations.

Figure 3: Standard Vertical with Mandatory Nutrients

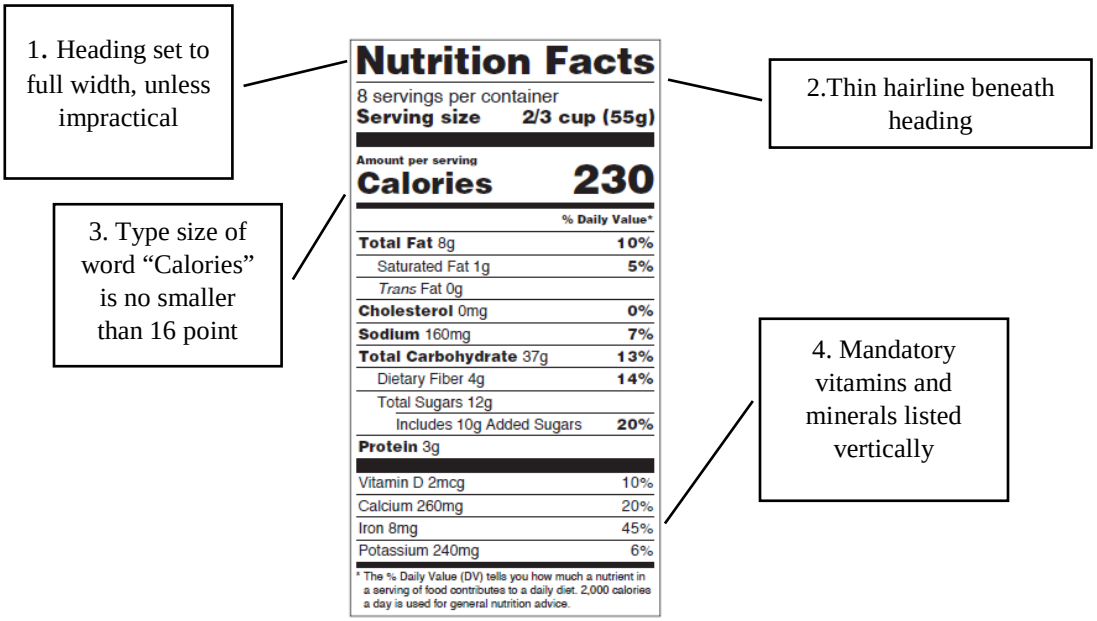


Figure 4: Standard vertical, Side-by-side

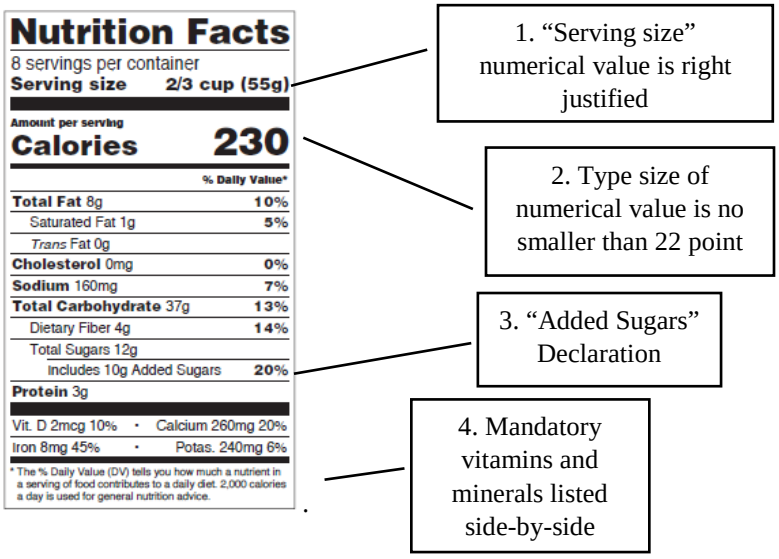
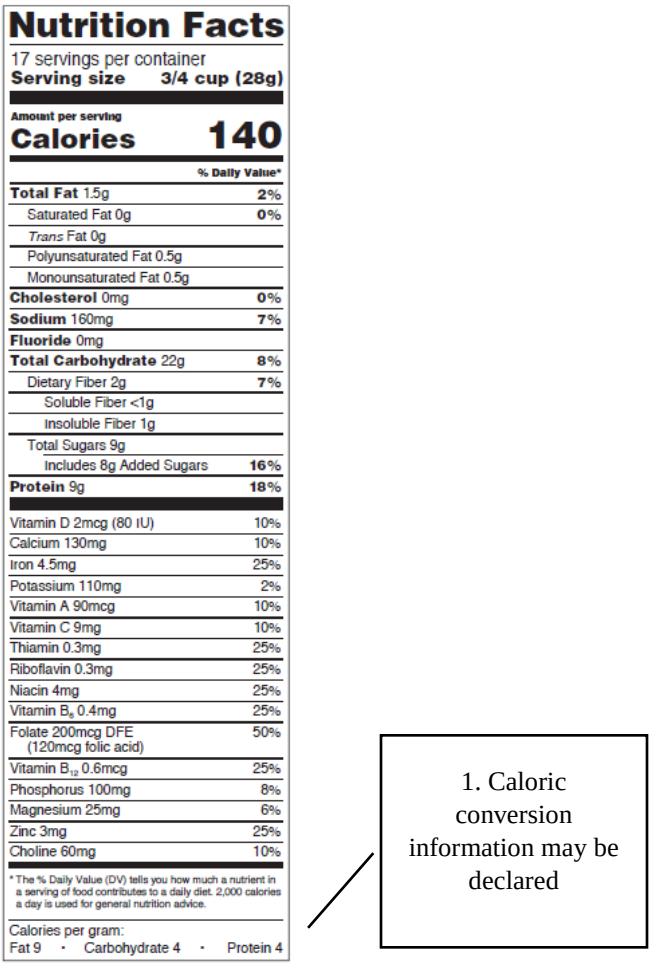


Figure 5: Standard Vertical, Mandatory and Voluntary Nutrients



VIII.A.1 How Has the Formatting Changed for the "Nutrition Facts" Header on a Standard Vertical Label?

The "Nutrition Facts" heading must be in a type size no smaller than all other print size in the nutrition label, except for the numerical information for "Calories," which according to 21 CFR 101.9(d)(1)(iii) must be in a type size no smaller than 22 point for the standard label (21 CFR 101.9(d)(2)). It must be set the full width of the nutrient information, unless impractical (21 CFR 101.9(d)(2)). It is not required to be set the full width of the nutrient information for labels presented according to the following formats: tabular display, aggregate display, tabular dual column display, tabular display for small or intermediate-sized packages, and linear display for small or intermediate-sized packages (21 CFR 101.9(d)(2)).

A thin horizontal line (i.e., a hairline rule) is to be inserted directly beneath the Nutrition Facts heading, before the servings per container statement (except on the linear display discussed below) (21 CFR 101.9(d)(1)(v)).

VIII.A.2 How Has the Formatting Changed for the Declaration of Calories on a Standard Vertical Label?

The type size has increased for "Calories" and the numeric value of "Calories." On the standard vertical display of the Nutrition Facts label, the numeric value of "Calories" must be listed in a type size no smaller than 22 point, as well as in bold or extra bold type highlighting (21 CFR 101.9(d)(1)(iii)). The word "Calories" must be listed in a type size no smaller than 16 point, as well as in bold or extra bold type highlighting (21 CFR 101.9(d)(1)(iii)). See Figures 3 through 5.

VIII.A.3 How Has the Formatting Changed for the Declarations of Serving Size and Servings Per Container on a Standard Vertical Label?

The "___ servings per container" declaration now immediately follows the "Nutrition Facts" heading and must be in a type size no smaller than 10 point (21 CFR 101.9(d)(3)(i)).

Below "___ servings per container" is the declaration of "Serving size." "Serving size" is to be highlighted in bold or extra bold and in a type size no smaller than 10 point (21 CFR 101.9(d)(3)(ii)). While the "Serving size" declaration is still left-justified, the corresponding numerical value is now right-justified on Nutrition Facts labels only (not on Supplement Facts labels), provided that adequate space is available (21 CFR 101.9(d)(3)(ii)). If the "Serving size" declaration does not fit in the allocated space, then a type size no smaller than 8 point may be used on packages of any size.

For further information on the updates made to the Reference Amounts Customarily Consumed and Serving Size regulations, please reference the Small Entity Compliance Guide 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: Guidance for Industry" (Ref. 9), as well as the final guidance entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics" (Ref. 10).

VIII.A.4 How Has the Formatting Changed for the Declaration of Vitamins and Minerals on a Standard Vertical Label?

Nutrient information for vitamins and minerals (except sodium) are to be separated from information regarding other nutrients by a bar (21 CFR 101.9(d)(8)). They may be listed vertically (Figures 3 and 5) or horizontally (Figure 4). If listed horizontally in two columns, then vitamin D and calcium should be listed on the first line, and iron and potassium should be listed on the second line (21 CFR 101.9(d)(8)). Nutrient information must be in a type size no smaller than 8 point (21 CFR 101.9(d)(1)(iii)).

VIII.A.5 Where Can I Declare "Calories from Saturated Fat" on a Standard Vertical Label?

While "Calories from fat" can no longer be declared, "Calories from saturated fat" is still allowed (21 CFR 101.9(c)(1)(ii)). When declared, it is to be indented under the statement of calories and must be in a type size no smaller than 8 point (21 CFR 101.9(d)(5)).

VIII.A.6 Where, and How, Do I Declare "Added Sugars" on a Standard Vertical Label?

The statement "Includes 'X' g Added Sugars" must be used to declare added sugars content (except on packages of single ingredient sugars), and this statement must be indented directly beneath the listing for "Total Sugars" on the Nutrition Facts label (21 CFR 101.9(c)(6)(iii)). The 'X' will be filled in with the respective added sugar content (21 CFR 101.9(c)(6)(iii)). In Appendix B to 21 CFR 101, we illustrate our recommendation to shorten the length of the hairline requirement between total sugars and added sugars to help denote that "added sugars" are a subcomponent of "total sugars." As mentioned above, a DRV has been established for added sugars for most population groups, and the % Daily Value declaration is required as well (21 CFR 101.9(d)(7)(ii)). Added sugars must also be declared on the Supplement Facts label (21 CFR 101.36(b)(2)(i)).

Added sugars content must be expressed to the nearest gram, except in the following circumstances:

- The statement "Contains less than 1 gram" or, alternatively, "less than 1 gram" may be used if a serving contains less than 1 gram added sugars; or
- The added sugars content may be expressed as zero if the serving contains less than 0.5 gram.

See 21 CFR 101.9(c)(6)(iii).

If a product contains less than 1 gram of added sugars per serving and no claims are made about sweeteners, sugars, or sugar alcohol content, then the declaration of the amount of added sugars is not required. If the added sugars content is therefore not declared, you must place the statement "Not a significant source of added sugars" at the bottom of the table of nutrient values (except as provided for in 101.9(f)) (21 CFR 101.9(c)(6)(iii)).

VIII.A.7 How Has the "% Daily Value*" Footnote Been Changed?

The final rule modified the footnote that refers to the "% Daily Value*" column heading to provide clarity and a better explanation. The modified footnote now states 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" on all Nutrition Facts label formats on foods for the general population (21 CFR 101.9(d)(9)), with the exception of foods having minimal calories and with certain formats (i.e., the simplified display, infants through 12 months of age, children 1-3 years, and the linear and tabular displays for small or intermediate-sized packages), as described below. The footnote table listing DRVs for total fat, saturated fat, cholesterol,

sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets is no longer included as part of this footnote (81 FR 33742 at 33950).

The footnote may be omitted for 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. However, the voluntary use of the first part of the footnote ("*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet.") is allowed for these foods (21 CFR 101.9(d)(9)).

VIII.A.8 What Changes Need to be Made on Labels for Foods Represented or Purported to be Specifically for Infants Through 12 Months of Age or for Children 1 Through 3 Years of Age?

The next two figures reflect the Nutrition Facts labels for foods represented or purported to be specifically for infants through 12 months of age (Figure 6) and for children 1 through 3 years of age (Figure 7). The nutrients declared for these subgroups must include calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium (21 CFR 101.9(j)(5)(i)). Calories from saturated fat, polyunsaturated fat, and monounsaturated fat can now be voluntarily declared, if desired (see 21 CFR 101.9(c)).

Percent DVs for total fat and potassium on the labeling of foods, other than infant formula, represented or purported to be for infants through 12 months of age are now required (see 21 CFR 101.9(d)(7) and (j)(5)). However, a percent DV declaration for saturated fat, cholesterol, sodium, dietary fiber, and added sugars is not allowed on such foods. In addition, as with foods for all other populations, a percent DV declaration for trans fat and total sugars is not allowed, as no DRVs have been established for those nutrients (21 CFR 101.9(j)(5)(ii)(A)). No "% Daily Value*" footnote is to be declared either (21 CFR 101.9(j)(5)(ii)(A)).

On labels of foods, other than infant formula, represented or purported to be for children 1 through 3 years of age, the "% Daily Value*" footnote statement must 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" (21 CFR 101.9(d)(9)), and a type size no smaller than 6 point must be used for the footnote (21 CFR 101.9(d)(1)(iii)).

Figure 6: Infants through 12 Months of Age (21 CFR 101.9(j)(5)(ii)(B))

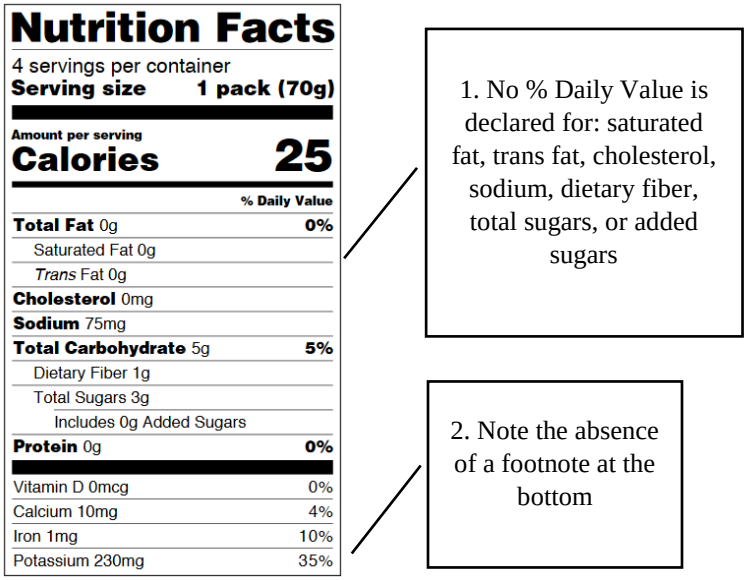
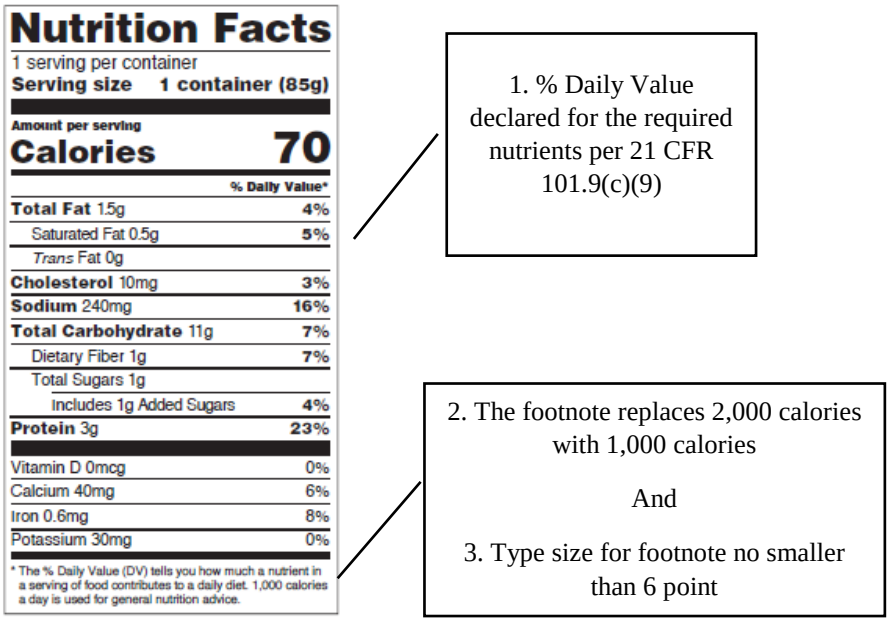


Figure 7: Children 1 through 3 Years (21 CFR 101.9(j)(5)(ii)(B))

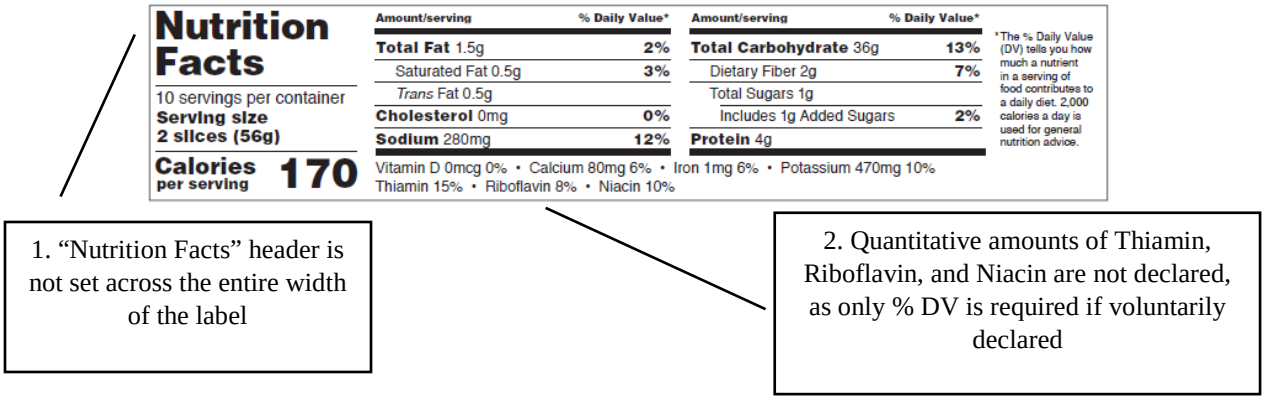


VIII.B When Can I Use the Tabular Format?

The tabular format can be used when there is not sufficient continuous vertical space to accommodate the required components of the nutrition label, up to and including the mandatory declaration of potassium (21 CFR 101.9(d)(11)(iii)). This is different than the tabular format for

small or intermediate-sized packages (see Section VIII.C below). Figure 8 reflects the tabular format.

Figure 8: Tabular Display



VIII.B.1 How Does the Declaration of Calories in the Tabular Format Differ from that of the Standard Vertical Label Version?

In the tabular format, the word "Calories" must be in a type size no smaller than 10 point, instead of 16 point as required for the standard vertical label (21 CFR 101.9(d)(1)(iii)). The 10-point type size for calories is also required for the tabular display for small and intermediate-sized packages (see section VIII.C) and the tabular dual column display (see section VIII.D) (21 CFR 101.9(d)(1)(iii)).

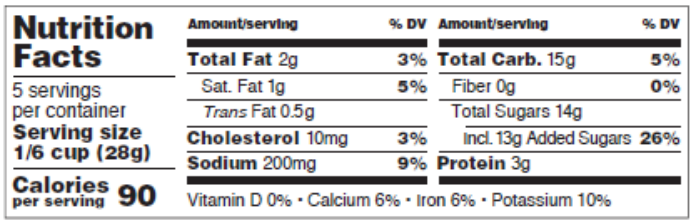
VIII.B.2 How Do the Declarations of Serving Size and Servings Per Container in the Tabular Format Differ from the Standard Vertical Label Version?

The "___ servings per container" declaration is the same as required for the standard vertical label version. However, the declaration of "Serving size," which is listed below the "___ servings per container" declaration, must be highlighted in bold or extra bold and in a type size no smaller than 9 point (21 CFR 101.9(d)(3)(i)). This format is also the same for the tabular display for small and intermediate-sized packages (see section VIII.C) and the tabular dual column display (see section VIII.D) (21 CFR 101.9(d)(3)(i)).

VIII.C How Do I Comply with These Requirements if My Food Packaging Only Has a Total Surface Area Available to Bear Labeling of 40 or Less Square Inches?

We allow modifications of the Nutrition Facts label for foods in packages with a total surface area available to bear labeling of 40 or less square inches. One modification is allowing the use of the tabular display for small packages or intermediate-sized packages if the product has a total surface area available to bear labeling of 40 or less square inches and neither the standard vertical display (see Figures 3-5) nor the tabular display (see Figure 8) can be accommodated (21 CFR 101.9(j)(13)(ii)(A)). See Figure 9.

Figure 9: Tabular Display for Small Packages



Nutrition Facts

5 servings per container
Serving size 1/6 cup (28g)

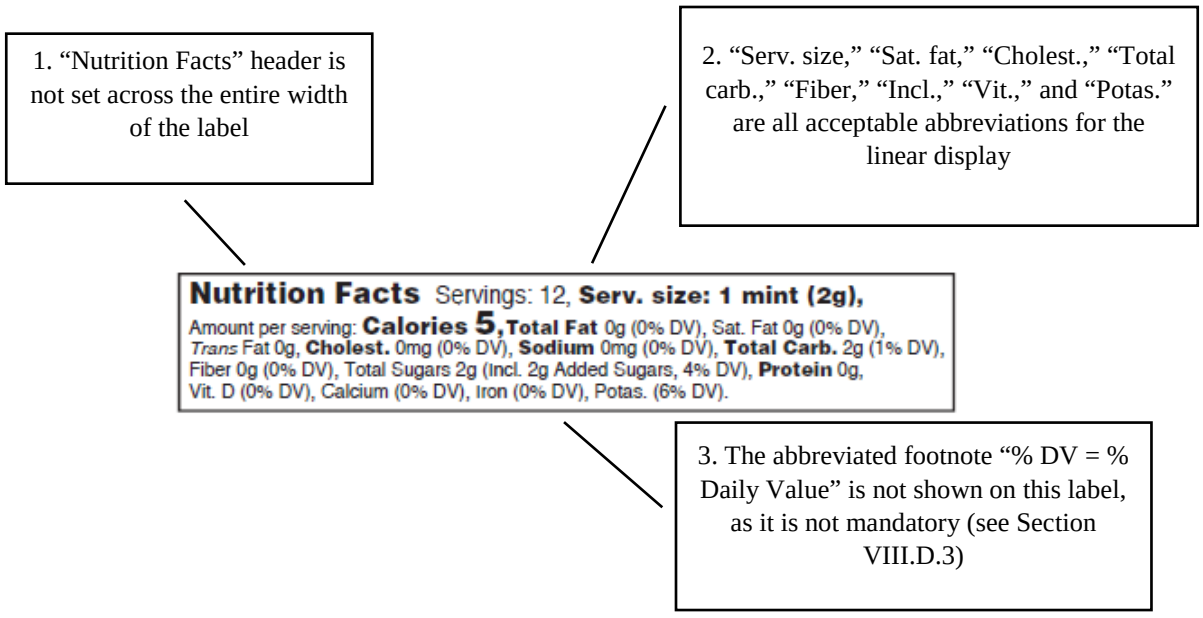
Calories per serving 90

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%

Another modification is the use of a linear display. For products with a total surface area available to bear labeling of 40 or less square inches, nutrition information can be presented in a linear format, but only if the label will not accommodate a tabular display (21 CFR 101.9(j)(13)(ii)(A)). However, when there is less than 12 square inches of available labeling space, either the small tabular or linear display can be used (21 CFR 101.9(j)(13)(ii)(A)). We retained the preexisting linear label format to provide flexibility for labels on small packages with various shapes and sizes. However, we adapted it to maintain consistency with the other formatting changes that have been finalized. As discussed in detail below, the "Calories" information has increased in type size (see Section VIII.C.1) and the serving size and serving per container declarations have been updated (see Section VIII.C.2). In addition, "Sugars" has changed to "Total Sugars" (21 CFR 101.9(d)(6)(ii)), "Added Sugars" declaration is now mandatory (21 CFR 101.9(d)(6)(iii)), and the abbreviated footnote "% DV = % Daily Value" is optional on some formats (see Section VIII.C.3). Note that the hairline that separates the "Nutrition Facts" header from the rest of the label is not present on the linear display. Figure 10 shows the updated linear format.

Figure 10: Linear Display for Small and Intermediate-Sized Packages (101.9(j)(13)(ii)(A)(*2*))



The third modification is the use of abbreviations, as listed in 21 CFR 101.9(j)(13)(ii)(B). We now allow for the following additional abbreviations on labels for small and intermediate-sized packages: "vitamin" may be abbreviated as "Vit.," "potassium" may be abbreviated as "Potas.," and "Includes" may be abbreviated as "Incl." These abbreviations will further conserve label space. In addition, we allow the abbreviations of "Total carb." and "Incl." to be used on dual-column display labels (see section VIII.D).

VIII.C.1 What Type Size Must be Used for the Declaration of Calories on the Tabular or Linear Displays for Small or Intermediate-Sized Packages?

The numeric value for "Calories" must be in a type size no smaller than 14 point, and the word "Calories" must be in a type size no smaller than 10 point (21 CFR 101.9(d)(1)(iii)). See Figures 9 and 10.

VIII.C.2 How Do the Declarations of Serving Size and Servings Per Container on the Tabular or Linear Displays for Small or Intermediate-Sized Packages Differ from the Standard Label Version?

The "___ servings per container" declaration immediately follows the "Nutrition Facts" heading, as in the standard label version; however, it must be in a type size no smaller than 9 point on the tabular or linear display for small packages (21 CFR 101.9(d)(3)(i)). If a linear display is used, then the actual number of servings (i.e., "Servings" as shown in Fig 10) may be listed instead of the servings per container declaration.

The declaration of "Serving size," which follows below the "___ servings per container" or "servings" declaration, is to be highlighted in bold or extra bold and in a type size no smaller than 9 point on the tabular or linear display for small or intermediate-sized packages. See Figures 9 and 10.

VIII.C.3 Is the "% Daily Value*" Footnote Required on Foods in Small and Intermediate-Sized Packages?

For products in small and intermediate-sized packages that qualify for the use of the tabular or linear format as specified in 21 CFR 101.9(j)(13)(ii)(A)(*1*) and (*2*), there is no longer a requirement to place an asterisk, followed by the statement "Percent Daily Values are based on a 2,000 calorie diet," at the bottom of the label if the footnote corresponding to "% Daily Value" is omitted. If "Daily Value" is not spelled out in the heading, then an asterisk can be placed at the bottom of the label followed by the statement "% DV = % Daily Value" in a type size no smaller than 6 point (21 CFR 101.9(d)(1)(iii)). See Figures 9 and 10.

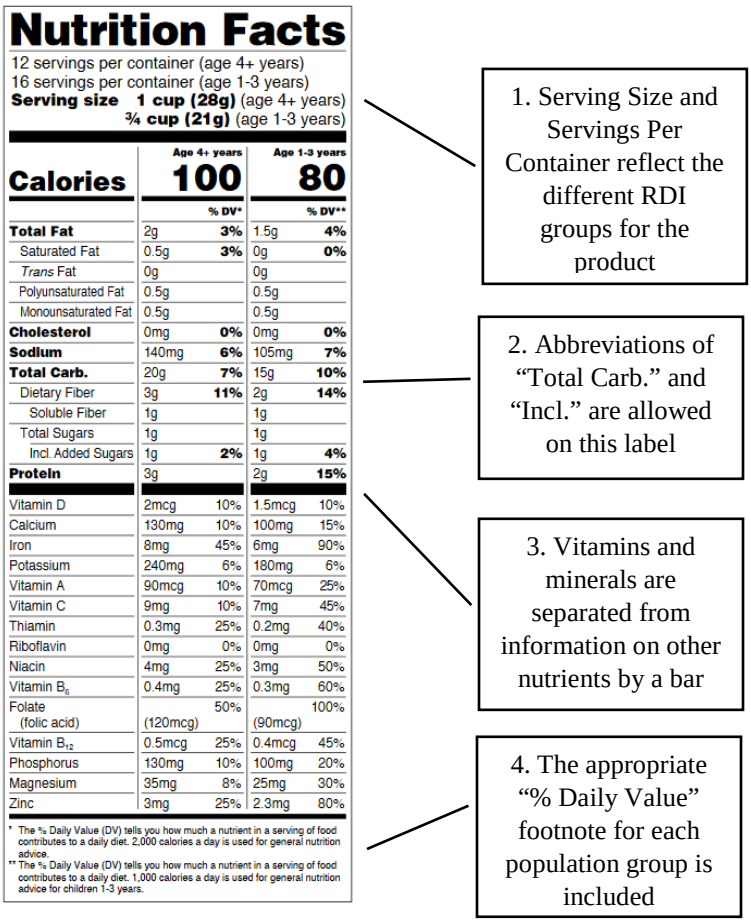
VIII.D How Do I Comply with the Nutrition Labeling Formatting Requirements when Dual Column Labeling is Required or Provided Voluntarily?

Dual column labeling is required under certain conditions, and can be used in other situations. In the *Federal Register* of March 2, 2018 (83 FR 9003), we announced the availability of a separate Small Entity Compliance Guide 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: Guidance for Industry," which, among other topics, discusses a new requirement regarding the use of dual-column labeling (Ref. 9). In the *Federal Register* of December 31, 2019 (84 FR 72230), we announced the availability of a final guidance for industry entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics." This final guidance also discusses formatting issues for dual-column labeling (Ref. 10).

Regarding specific formatting for dual column labeling, the final rule updates certain requirements. Directly following the serving size declarations, each column of nutrition information must contain a heading that accurately describes why a dual column is being utilized. For example, a product may provide nutrition information for two different RDI groups, like in Figure 11 below. A product may also provide nutrition information for two different forms of the same food (e.g., "Per ¼ cup mix" and "Per prepared portion"), as in Figure 12 below (21 CFR 101.9(e)). The quantitative information by weight and percent DV must be presented for each column, and the columns are to be separated by vertical lines (21 CFR 101.9(e)(3)). Nutrient information for vitamins and minerals must be separated from the information on other nutrients by a bar and be arrayed vertically in the required order (21 CFR 101.9(e)(4)). Note that the "Amount per serving" statement is not required for the dual column formats (21 CFR 101.9(d)(4)). See Figures 11 through 15 (see also 21 CFR 101.9(e)(5) and (e)(6)(i)).

Figure 11: Dual Column Display for 2 different RDI Groups (101.9(e)(5))



Nutrition Facts

12 servings per container (age 4+ years)
16 servings per container (age 1-3 years)
Serving size **1 cup (28g)** (age 4+ years)
¾ cup (21g) (age 1-3 years)

	Age 4+ years		Age 1-3 years	
Calories	**100**		**80**	
		% DV*		% DV**
Total Fat	2g	**3%**	1.5g	**4%**
Saturated Fat	0.5g	**3%**	0g	**0%**
Trans Fat	0g		0g	
Polyunsaturated Fat	0.5g		0.5g	
Monounsaturated Fat	0.5g		0.5g	
Cholesterol	0mg	**0%**	0mg	**0%**
Sodium	140mg	**6%**	105mg	**7%**
Total Carb.	20g	**7%**	15g	**10%**
Dietary Fiber	3g	**11%**	2g	**14%**
Soluble Fiber	1g		1g	
Total Sugars	1g		1g	
Incl. Added Sugars	1g	**2%**	1g	**4%**
Protein	3g		2g	**15%**
Vitamin D	2mcg	10%	1.5mcg	10%
Calcium	130mg	10%	100mg	15%
Iron	8mg	45%	6mg	90%
Potassium	240mg	6%	180mg	6%
Vitamin A	90mcg	10%	70mcg	25%
Vitamin C	9mg	10%	7mg	45%
Thiamin	0.3mg	25%	0.2mg	40%
Riboflavin	0mg	0%	0mg	0%
Niacin	4mg	25%	3mg	50%
Vitamin B_6	0.4mg	25%	0.3mg	60%
Folate (folic acid)	(120mcg)	50%	(90mcg)	100%
Vitamin B_{12}	0.5mcg	25%	0.4mcg	45%
Phosphorus	130mg	10%	100mg	20%
Magnesium	35mg	8%	25mg	30%
Zinc	3mg	25%	2.3mg	80%

* 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.
** 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 for children 1-3 years.

1. Serving Size and Servings Per Container reflect the different RDI groups for the product

2. Abbreviations of "Total Carb." and "Incl." are allowed on this label

3. Vitamins and minerals are separated from information on other nutrients by a bar

4. The appropriate "% Daily Value" footnote for each population group is included

Figure 12: Dual Columns, Two Forms of the Same Food (101.9(e)(5))

1. "Amount per serving" declaration is not required

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	40mg	0%	40mg	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.

Figure 13: Dual Column Display, Per Serving and Per Container (101.9(e)(6)(i))

Nutrition Facts

2 servings per container

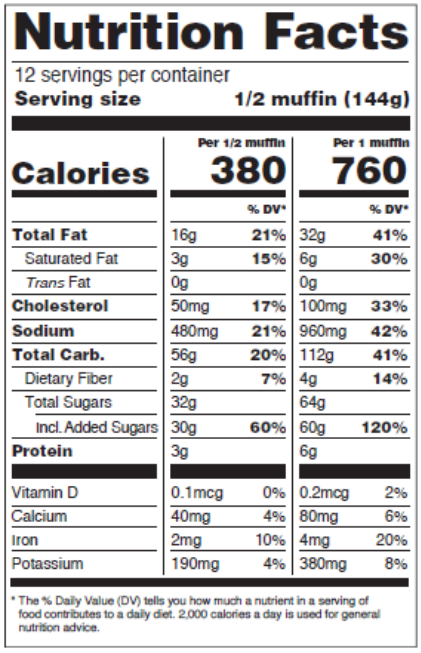
Serving size **1 cup (255g)**

	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.

1. Two column headings describing why the dual column display is being used

Figure 14: Dual Column Display, Per Serving and Per Unit (101.9(e)(6)(i))



Nutrition Facts

12 servings per container

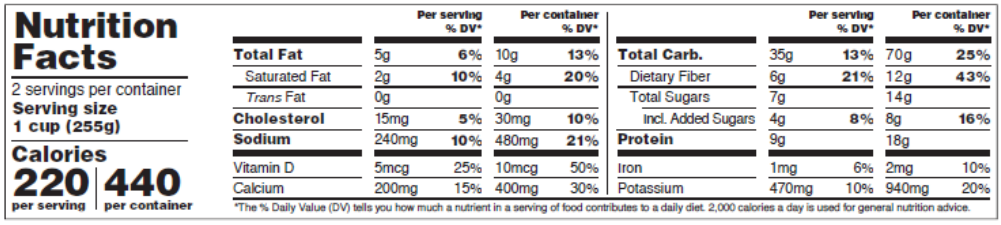
Serving size **1/2 muffin (144g)**

	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.

Figure 15 shows the use of dual columns in a tabular display format for products. As mentioned above, "Calories" must be in a type size no smaller than 10 point, and the numeric amount for "Calories" must be in a type size no smaller than 22 point (21 CFR 101.9(d)(1)(iii)). "Serving size" declaration must be in a type size no smaller than 9 point; however, the "___ servings per container" declaration must be in a type size no smaller than 10 point, as with the standard label version (21 CFR 101.9(d)(3)(i) and (ii)). "Amount per serving" is not required (21 CFR 101.9(d)(4)).

Figure 15: Tabular Dual Column Display (101.9(e)(6)(ii))



Nutrition Facts

2 servings per container

Serving size
1 cup (255g)

Calories

220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*		Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**	**Total Carb.**	35g	**13%**	70g	**25%**
Saturated Fat	2g	**10%**	4g	**20%**	Dietary Fiber	6g	**21%**	12g	**43%**
Trans Fat	0g		0g		Total Sugars	7g		14g	
Cholesterol	15mg	**5%**	30mg	**10%**	Incl. Added Sugars	4g	**8%**	8g	**16%**
Sodium	240mg	**10%**	480mg	**21%**	**Protein**	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%	Iron	1mg	6%	2mg	10%
Calcium	200mg	15%	400mg	30%	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.

VIII.E When Can the Simplified Format Be Used?

You can use the simplified format 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 (21 CFR 101.9(f)). For foods intended for infants through 12 months of age and children 1 through 3 years of age, you can use 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, or potassium (21 CFR 101.9(f)). The definition of "insignificant amount" has not changed.

The footnote requirement which states, "Not a significant source of ___" (listing the name(s) of any nutrients listed in this paragraph that are present in insignificant amounts) still exists (21 CFR 101.9(f)(4)). While the full "% Daily Value" footnote (see 21 CFR 101.9(d)(9)) is not required for the simplified format, the column header "% Daily Value" can be abbreviated as "% DV." If this abbreviation is used, then an asterisk must be placed at the end of the abbreviation and the corresponding footnote must read, "% DV = % Daily Value" (21 CFR 101.9(f)(5)). No footnote is required if "Daily Value" is spelled out in the column header (21 CFR 101.9(f)(5)). Figure 16 displays an example of a simplified format label.

Figure 16: Simplified Format Label *(*101.9(f))

VIII.F Are Foods in Small Packages with a Total Surface Area Available to Bear Labeling of Less than 12 Square Inches Exempt from the Nutrition Facts Labeling Requirements?

Not always. Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches are not exempt from bearing a Nutrition Facts label if a nutrition claim or other nutrition information in any context on the label or in labeling or advertising (21 CFR 101.9(j)(13)(i)) is used or as outlined for covered vending machine food (see 21 CFR 101.8(c)). However, as previously allowed, if your product qualifies for and uses the exemption (i.e., claims or other nutrition information are not presented on the label or in labeling or advertising), then you must list an address or telephone number that a consumer can use to obtain the required nutrition information (21 CFR 101.9(j)(13)(i)(A)).

VIII.G How Do These New Formatting Rules Affect the Percentage Juice Declaration?

With the changes to some type size requirements on the Nutrition Facts label, it is permissible if the percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice is smaller in height than the declaration of "Serving size," "Calories," and the numerical value for "Calories," in addition to already being permitted to be smaller in height than the brand name, product name, logo, universal product code, and "Nutrition Facts" heading (21 CFR 101.30(e)(2)).

VIII.H Are There Specific Formatting Requirements for Supplement Facts Labels?

Information other than the title, headings, and footnotes must be in uniform type size no smaller than 8 point (21 CFR 101.36(e)). Column headings (e.g., "Amount Per Serving" and "% Daily Value") and footnotes (e.g., "Percent Daily Values are based on a 2,000 calorie diet") must be in a type size no smaller than 6 point (21 CFR 101.36(e)). Because many dietary supplement products may contribute a negligible amount of calories, we do not require information about calories to be displayed in a larger type size or highlighted on Supplement Facts labels (81 FR 33742 at 33939).

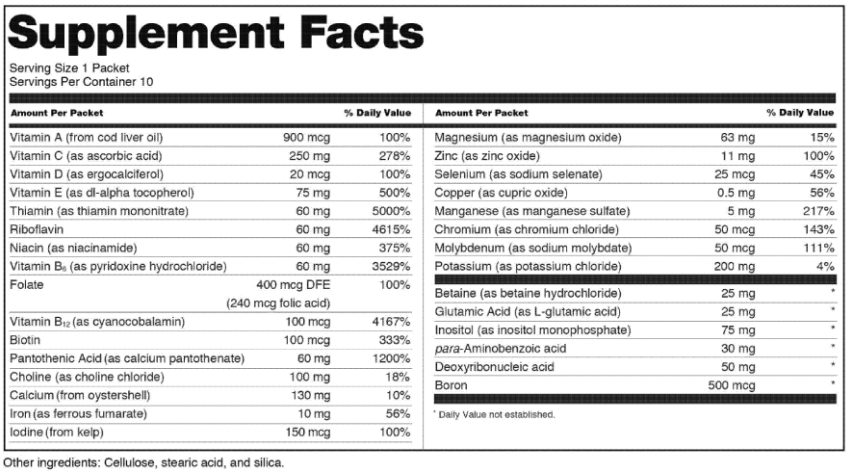
For small packages which have a total surface area available to bear labeling of less than 12 square inches, all information within the nutrition label must be in type size no smaller than 4.5 point (21 CFR 101.36(i)(2)(i)).

Intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, have different type size requirements. All information within the nutrition label must be in a type size no smaller than 6 point (21 CFR 101.36(i)(2)(ii)). However, type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than eight dietary ingredients to be listed (21 CFR 101.36(i)(2)(ii)). Similarly, type size no smaller than 4.5 point may be used on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed (21 CFR 101.36(i)(2)(ii)).

The footnote stating that the "Percent Daily Values are based on a 2,000 calorie diet" is required if the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars (21 CFR 101.36(b)(2)(iii)(D)). On labels of products represented or purported to be for use by children 1 through 3 years of age, the footnote statement must read: "Percent Daily Values are based on a 1,000 calorie diet" if the % Daily Value is declared for total fat, total carbohydrate, dietary fiber, protein, or added sugars (21 CFR 101.36(b)(2)(iii)(D)).

If there is inadequate space to list the required information vertically, the list may be split. 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 DV information given to the left (21 CFR 101.36(e)(12)). The column headings are also repeated (21 CFR 101.36(e)(12)). Figure 17 reflects this label formatting.

Figure 17: Supplement Facts Label – Split List (101.36(e)(12))



Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	900 mcg	100%
Vitamin C (as ascorbic acid)	250 mg	278%
Vitamin D (as ergocalciferol)	20 mcg	100%
Vitamin E (as dl-alpha tocopherol)	75 mg	500%
Thiamin (as thiamin mononitrate)	60 mg	5000%
Riboflavin	60 mg	4615%
Niacin (as niacinamide)	60 mg	375%
Vitamin B_6 (as pyridoxine hydrochloride)	60 mg	3529%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	100 mcg	4167%
Biotin	100 mcg	333%
Pantothenic Acid (as calcium pantothenate)	60 mg	1200%
Choline (as choline chloride)	100 mg	18%
Calcium (from oystershell)	130 mg	10%
Iron (as ferrous fumarate)	10 mg	56%
Iodine (from kelp)	150 mcg	100%

Amount Per Packet		% Daily Value
Magnesium (as magnesium oxide)	63 mg	15%
Zinc (as zinc oxide)	11 mg	100%
Selenium (as sodium selenate)	25 mcg	45%
Copper (as cupric oxide)	0.5 mg	56%
Manganese (as manganese sulfate)	5 mg	217%
Chromium (as chromium chloride)	50 mcg	143%
Molybdenum (as sodium molybdate)	50 mcg	111%
Potassium (as potassium chloride)	200 mg	4%
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established.

Other ingredients: Cellulose, stearic acid, and silica.

IX. When Must I Comply with the Rule?

If you have $10 million or more in annual food sales, your compliance date is January 1, 2020. If you have less than $10 million in annual food sales, your compliance date is January 1, 2021.

If you manufacture single-ingredient packages and/or containers of pure honey, pure maple syrup, or other pure sugars and syrups, as well as the cranberry products discussed in the Final Guidance (Ref. 1), we intend to exercise enforcement discretion until July 1, 2021, for compliance with the labeling changes outlined in the Nutrition Facts label rule and the Serving Size rule.

If you manufacture certain dried cranberry products with added flavorings (Ref. 11), we intend to exercise enforcement discretion until July 1, 2020, for compliance with the labeling changes outlined in the Nutrition Facts label final rule and the Serving Size final rule.

X. Why Must I Comply with the Rule?

Failure to comply with the final rule will render the covered food misbranded under section 403(q) of the FD&C Act and potentially other sections as well. The introduction or delivery for introduction into interstate commerce of any food that is misbranded constitutes a prohibited act under section 301(a) of the FD&C Act. Among potential consequences, committing a prohibited act can result in injunction and/or seizure (see sections 302 and 304 of the FD&C Act (21 U.S.C. 332 and 334)).

XI. References

The following references are on display at the Dockets Management Staff ((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 https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. U.S. Food and Drug Administration. 2019. The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products: Guidance for Industry. Accessed online at https://www.fda.gov/media/127928/download.

2. U.S. Food and Drug Administration. 2019. The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels: Guidance for Industry. Accessed online at https://www.fda.gov/media/123342/download.

3. U.S. Food and Drug Administration. 2019. Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry. Accessed online at https://www.fda.gov/media/117402/download.

4. U.S. Food and Drug Administration. 2018. The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry. Accessed online at https://www.fda.gov/media/113663/download.

5. U.S. Food and Drug Administration. 2019. "FDA Grants Citizen Petition for Dietary Fiber." Accessed online at https://www.fda.gov/food/cfsan-constituent-updates/fda-grants-citizen-petition-dietary-fiber.

6. U.S. Food and Drug Administration. 2020. "FDA Grants Citizen Petition on Glucomannan as a Dietary Fiber." Accessed online at https://www.fda.gov/food/cfsan-constituent-updates/fda-grants-citizen-petition-glucomannan-dietary-fiber.

7. U.S. Food and Drug Administration. 2018. Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30): Guidance for Industry. Accessed online at https://www.fda.gov/media/101183/download.

8. U.S. Food and Drug Administration. 2019. The New Nutrition Facts Label: Examples of Different Label Formats. Accessed online at https://www.fda.gov/media/99151/download.

9. U.S. Food and Drug Administration. 2018. 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; Service

Size for Breath Mints; and Technical Amendments: Guidance for Industry. Accessed online at https://www.fda.gov/media/111144/download.

10. U.S. Food and Drug Administration. 2019. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics: Guidance for Industry. Accessed online at https://www.fda.gov/media/133699/download.

11. U.S. Food and Drug Administration. 2019. Policy Related to Cranberry Products with Added Flavorings: Guidance for Industry. Accessed online at https://www.fda.gov/media/130373/download.