

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

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

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number Docket No. FDA-2018-D-1459 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1450.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

November 2018

Table of Contents

I. Introduction

II. Background

III. Questions and Answers

A. Single-Serving Containers

B. Reference Amounts Customarily Consumed (RACCs)

C. Dual-Column Labeling

D. Miscellaneous Topics

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 Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

This guidance is intended for conventional food and dietary supplement manufacturers. It will provide questions and answers on topics related primarily to two final rules: (1) “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”; and (2) “Food Labeling: Revision of the Nutrition and Supplement Facts Labels.” This guidance also discusses formatting issues for dual-column labeling, products that have limited space for nutrition labeling, and additional issues dealing with compliance.

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 FDA guidances means that something is suggested or recommended, but not required.

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.

In this guidance, “you” (or “I”) refers to a manufacturer of conventional food or dietary supplements.

II. Background

In the *Federal Register* of May 27, 2016, we published two final rules related to the Nutrition and Supplement Facts labels, which amended our labeling regulations for foods to provide updated nutrition information to help consumers in maintaining healthy dietary practices. One final rule is 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” (81 FR 34000) (“the serving size final rule”), and the other final rule is entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels,” (81 FR 33742) (“the Nutrition Facts label final rule”). The provisions of the final rules are codified at title 21 of the Code of Federal Regulations, part 101 (21 CFR 101.9 and 101.12). For purposes of this guidance, the following is a summary of the key changes that were codified in 21 CFR 101.9 and 101.12:

- Amending the definition of a single-serving container (21 CFR 101.9(b)(6));
- Requiring that labeling for certain packages bear an additional column of nutrition information regarding the contents of the entire package (21 CFR 101.9(b)(12)(i));
- Requiring that labeling for products in discrete units of certain sizes bear an additional column of nutrition information regarding the contents of the entire unit (21 CFR 101.9(b)(2)(i)(D));
- Allowing manufacturers to provide voluntarily an additional column of nutrition information for single-serving containers of certain sizes that reflects the nutrition information per common household measurement that most closely approximates the reference amount customarily consumed (RACC) (21 CFR 101.9(b)(6));
- Amending a pre-existing provision to allow manufacturers to provide voluntarily an additional column of nutrition information that reflects the nutrition information per unit, regardless of whether the product is a single-serving container or contains multiple servings (21 CFR 101.9(b)(10)(ii)); and
- Amending the requirements for RACCs that are used by manufacturers to determine their label serving size in 101.12(b).

III. Questions and Answers

A. Single-Serving Containers

A.1 How does the serving size final rule define “serving” or “serving size”?

A serving or serving size is the amount of food customarily consumed (*i.e.*, typically eaten) in one eating occasion (section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)(1)(A)(i)) and 21 CFR 101.9(b)(1)). Serving sizes are determined from the RACCs established in 21 CFR 101.12(b) and the procedures described in 21 CFR 101.9(b). A serving size must be written in a common household measure or common household unit (*e.g.*, for a 20-fluid-ounce carbonated beverage, “Serving size 1 bottle”) (21 CFR 101.9(b)(5)).

A.2 What are common household measures or common household units? What are the rules of increments for household units?

For labeling purposes, the term common household measure or common household unit means cup, tablespoon, teaspoon, piece, slice, fraction (*e.g.*, 1/4 pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (*e.g.*, jar, tray) (21 CFR 101.9(b)(5)). To determine the correct household measure for your product, follow the steps listed in 21 CFR 101.9(b)(5), which include, but are not limited to, the following:

1. For all products, except beverages, whenever possible and appropriate the serving size should be expressed as cups, tablespoons, or teaspoons. For beverages, you may use fluid ounces (21 CFR 101.9(b)(5)(i)).
2. If cups, tablespoons, or teaspoons are not applicable, units such as piece, slice, tray, jar, or fraction must be used, as applicable (21 CFR 101.9(b)(5)(ii)).
3. If the above options are not applicable, ounce measurements may be used with the applicable visual unit of measure such as a dimension of a piece (*e.g.*, 1 oz (28 g/about ½ pickle)) (21 CFR 101.9(b)(5)(iii)). Ounce measurements must be expressed in 0.5 oz increments that most closely approximates the RACC (21 CFR 101.9(b)(5)(iii)). Ounces with an appropriate visual unit, as described in step 3 above, can be used for products that naturally vary in size (101.9(b)(5)(vi)).

You must express measurements for cups in 1/4 or 1/3 increments (*e.g.*, 1/4, 1/3, 1/2, 2/3, 3/4, 1, 1 1/4 cups) (21 CFR 101.9(b)(5)(i)). Tablespoons must be expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons (21 CFR 101.9(b)(5)(i)). Amounts of less than one tablespoon can be expressed as teaspoons. Teaspoons shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons (21 CFR 101.9(b)(5)(i)).

For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, 1 fl oz means 30 mL, and 1 oz in weight means 28 grams (g) (21 CFR 101.9(b)(5)(viii)).

A.3 What is the definition of a single-serving container?

A single-serving container is a product that is packaged and sold individually (*i.e.*, that bears a Nutrition Facts panel) and contains less than 200 percent of the applicable RACC for that product (21 CFR 101.9(b)(6)). The entire content of a single-serving container must be labeled as one serving (21 CFR 101.9(b)(6)).

An example of a single-serving container is a 20-oz bottle of soda. The RACC for carbonated beverages is 12 oz (360 mL); a 20-oz bottle of soda contains approximately 167 percent of the RACC and meets the definition of a single-serving container. Therefore, the serving size for a 20-oz bottle of soda would be labeled as “1 bottle.”

A.4 Are there situations in which FDA would not object if products that contain more than 200 percent of the RACC were labeled as a single serving?

Yes. In the serving size final rule, while we declined to define “single-serving container” as containers with 200 percent or more of the RACC, we recognized that some products containing up to and including 300 percent of the RACC could reasonably be consumed by one person in a single eating occasion (see 81 FR 34000 at 34005). Those products are generally required to bear dual-column labeling that includes nutrition information for a serving of the product as well as for the entire container in accordance with 21 CFR 101.9(b)(12). There are certain exceptions to this requirement, including an exception under 21 CFR 101.9(b)(12)(i)(A) for products that meet the requirements to use the tabular format or linear format (see 21 CFR 101.9(j)(13)(ii)(A) for further information about when use of the tabular and linear formats is permissible). Because we acknowledge that some products containing at least 200 percent and up to and including 300 percent of the RACC could reasonably be consumed by one person in a single eating occasion, and we generally require such products to bear dual-column labeling, we agree that nutrition information for the full container for such products can be helpful to consumers. Therefore, we intend to consider the exercise of enforcement discretion to permit products containing at least 200 percent and up to and including 300 percent of the applicable RACC to be labeled as a single serving, provided that it would not be misleading to do so and that the product meets the requirement to use the tabular format or the linear format under 21 CFR 101.9(j)(13)(ii)(A). This would provide flexibility to manufacturers to decide whether to label certain products (*e.g.*, a small brownie) as a single serving when the product does not meet the definition of a single-serving container, contains at least 200 percent and up to and including 300 percent of the RACC, and there is insufficient space to include two columns of information.

A.5 Can I provide a voluntary column of nutrition information per unit when my packaged product is a single-serving container (*i.e.*, contains less than 200 percent of the RACC) and contains more than one individually wrapped unit? For example, would voluntary nutrition information per unit be allowed for a packaged product that contains two individually wrapped sandwiches or two individually wrapped ice cream novelty items for which the entire container contains 180 percent of the RACC?

Yes. In the serving size final rule, we amended 21 CFR 101.9(b)(10)(ii) to allow manufacturers to voluntarily provide an additional column of nutrition information per unit for single-serving containers that contain more than one discrete unit. Before 21 CFR 101.9(b)(10)(ii) was amended, the provision applied only to multiserving containers. This provision of the serving size final rule was intended to provide flexibility for manufacturers that sell these types of products.

B. Reference Amounts Customarily Consumed (RACCs)

B.1 What are RACCs and how are they determined?

RACCs are used to determine serving sizes in accordance with section 403(q)(1)(A)(i) of the FD&C Act, which states that a serving size is an amount of food customarily consumed. RACCs are based, in part, on food consumption, including data derived from the National Health and Nutrition Examination Study (NHANES). NHANES is a population-based survey and program of studies designed to assess the health and nutritional status of adults and children in the United States and to track changes over time. NHANES combines interviews and physical examinations and provides consumption data for the food products regulated by FDA. The list of RACCs is found in Tables 1 and 2 in 21 CFR 101.12(b).

B.2 How do I determine the appropriate RACC for my food product?

The list of RACCs established by FDA is found in Tables 1 and 2 in 21 CFR 101.12(b). Table 1 is for foods for infants and children one through three years of age. Table 2 is for foods for the general population (*i.e.*, aged four years or older). We established RACCs for a variety of food product categories, and these values represent the amount of food customarily consumed at one eating occasion. Most of the RACCs are for foods in a ready-to-eat form.

To determine the appropriate RACC for your food product, locate the appropriate food product category for your product in Table 1 or 2, whichever is applicable. If your product in the form in which it is sold (*i.e.*, “as packaged”) does not have a RACC in either of the tables, you must generate an appropriate RACC for your product considering the following:

- If your product requires further preparation such as cooking or the addition of water or other ingredients (*e.g.*, brownie mix, dried soup), and if only the RACC for the prepared form of the product is listed in 21 CFR 101.12(b), then the RACC for the unprepared

product (*i.e.*, the product as it is packaged and sold) must be the amount of the unprepared product required to make the RACC for the prepared product (21 CFR 101.12(c)).

- If your product is an imitation or substitute food, or altered food, such a “low calorie” version, the RACC must be the same as for the food for which it is offered as a substitute (21 CFR 101.12(d)). For example, a low-calorie cake frosting should use the same 2 tbsp RACC as that for other cake frosting.
- For products that consist of two or more foods packaged and presented to be consumed together (*e.g.*, peanut butter and jelly, cracker and cheese pack, pancakes and syrup), the RACC for the combined product is determined by the following rules (see 21 CFR 101.12(f)):
 - For bulk products (*e.g.*, peanut butter and jelly), the RACC for the combined product shall be the RACC, as established in Tables 1 or 2, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.
 - For products where the ingredient represented as the main ingredient is one or more discrete units (*e.g.*, cracker and cheese pack, pancakes and syrup), the RACC for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the RACC for that ingredient as established in Tables 1 or 2 plus proportioned amounts of all minor ingredients.
 - If the RACCs are in compatible units, they must be summed. If the RACCs are in incompatible units, the weights of the appropriate volumes should be used (*e.g.*, 110 grams (g) pancakes plus the gram weight of the proportioned amount of syrup).
- If your product is an aerated food, there are several technical points that must be considered in determining the appropriate RACC. See 21 CFR 101.12(e) for details.

B.3 How do I determine the appropriate serving size for my food product based on the RACC?

Once you have determined the appropriate RACC for your product, you must determine the correct serving size for your product based on 21 CFR 101.9(b). The first important step in establishing an appropriate serving size is to determine if your product is a single-serving container. If your product is packaged and sold individually and contains less than 200 percent of the applicable RACC, the serving size must be the contents of the entire container (21 CFR 101.9(b)(6)).

For products in discrete units (*e.g.*, muffins, sliced products, such as sliced bread, or individually packaged products within a multiserving package) within a multiserving package and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (*e.g.*, pancakes and syrup), the serving size must be declared as follows (21 CFR 101.9(b)(2)(i)):

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

- If a unit weighs 50 percent or less of the RACC, the serving size shall be the number of whole units that most closely approximates the RACC for the product category (21 CFR 101.9(b)(2)(i)(A));
- If a unit weighs more than 50 percent, but less than 67 percent of the RACC, the manufacturer may declare one unit or two units as the serving size (21 CFR 101.9(b)(2)(i)(B));
- If a unit weighs 67 percent or more, but less than 200 percent of the RACC, the serving size shall be one unit (21 CFR 101.9(b)(2)(i)(C));
- If a unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC, the serving size shall be the amount that most closely approximates the RACC (21 CFR 101.9(b)(2)(i)(D)). Also note that dual-column labeling may be required for such products (21 CFR 101.9(b)(12)(i)). Dual-column labeling as described in 21 CFR 101.9(b)(12)(i) is discussed in section C of this document.

The serving size for maraschino cherries must be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry (21 CFR 101.9(b)(2)(i)(E))².

The serving size for products that naturally vary in size (*e.g.*, pickles, shellfish, whole fish, and fillet of fish) may be the amount in ounces that most closely approximates the RACC for the product category (21 CFR 101.9(b)(2)(i)(F)) (see footnote 2). Ounces with an appropriate visual unit of measure may be used for products that naturally vary in size as provided for in 21 CFR 101.9(b)(2)(i)(F) (see 21 CFR 101.9(b)(5)(iii) and (b)(5)(vi)) (see footnote 2).

For products which consist of two or more foods packaged and presented to be consumed together, where the ingredient represented as the main ingredient is in discrete units (*e.g.*, pancakes and syrup), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the RACC for the combined product determined in 21 CFR 101.12(f) (21 CFR 101.9(b)(2)(i)(G)) (see footnote 2).

For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in 101.9 (that is, are labeled appropriately for individual sale as single-serving containers), the serving size must be 1 unit (21 CFR 101.9(b)(2)(H)) (see footnote 2).

For products in large discrete units that are usually divided for consumption (*e.g.*, cake, pie, pizza, melon, cabbage), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (*e.g.*, cake mix, pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually

² In the serving size final rule, we removed paragraph 101.9(b)(2)(i)(E) and renumbered paragraphs 101.9(b)(2)(i)(F) through 101.9(b)(2)(i)(I) as paragraphs 101.9(b)(2)(i)(E) to 101.9(b)(2)(i)(H), respectively. However, no corresponding change was made to the cross reference to 21 CFR 101.9(b)(2)(i)(G) in 21 CFR 101.9(b)(5)(vi). FDA intends to publish a technical amendment to correct this issue by replacing the cross reference to 21 CFR 101.9(b)(2)(i)(G) with 21 CFR 101.9(b)(2)(i)(F) in 21 CFR 101.9(b)(5)(vi).

divided for consumption (*e.g.*, prepared cake packaged with a can of frosting, a baguette with a jar of jam), the serving size must be the fractional slice of the ready-to-eat product (*e.g.*, 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the RACC for the product category, and may be the fraction of the package used to make the RACC for the unprepared product or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the reference amount for the combined product determined in 21 CFR 101.12(c). In expressing the fractional slice, manufacturers must use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3 (21 CFR 101.9(b)(2)(ii)).

For nondiscrete bulk products (*e.g.*, breakfast cereal, flour, sugar, dry mixes, concentrates, pancake mixes, macaroni and cheese kits), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (*e.g.*, peanut butter and jelly), the serving size must be the amount in household measure that most closely approximates the RACC for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the reference amount for the combined product determined in 21 CFR 101.12(f) (21 CFR 101.9(b)(2)(iii)).

The serving size for meal products and main dish products, as defined in 21 CFR 101.13(l) and (m), that come in single-serving containers as defined in 21 CFR 101.9(b)(6) must be the entire content (edible portion only) of the package (21 CFR 101.9(b)(3)). Serving size for meal products and main dish products in multiserving containers must be based on the RACC applicable to the product in 21 CFR 101.12(b) if the product is listed in 101.12(b) (21 CFR 101.9(b)(3)). The serving size for meal products and main dish products in multiserving containers that are not listed in 21 CFR 101.12(b) must be based on the reference amount according to 21 CFR 101.12(f) (21 CFR 101.9(b)(3)).

B.4 How do I determine the number of servings for my food product?

The number of servings in a single-serving container must be one (21 CFR 101.9(b)(6)) (see also question A.3). For products that do not meet the definition of a single-serving container, the number of servings per container must be based on the serving size of the product (21 CFR 101.9(b)(8)), using the following procedures:

- The number of servings must be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products (21 CFR 101.9(b)(8)(i)). The number of servings between 2 and 5 servings must be rounded to the nearest 0.5 serving (21 CFR 101.9(b)(8)(i)). Rounding should be indicated by the use of the term “about” (*e.g.*, about 2 servings or about 3.5 servings) (21 CFR 101.9(b)(8)(i)).
- For drained solids for which product size varies naturally (*e.g.*, maraschino cherries, pickles), you may state the typical number of servings per container (*e.g.*, usually 5 servings) (21 CFR 101.9(b)(8)(ii)).

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

- For random weight products, you may declare “varied” for the number of servings per container provided the nutrition information is based on the RACC expressed in the appropriate household measure based on the hierarchy described in 21 CFR 101.9(b)(5) (21 CFR 101.9(b)(8)(iii)). Random weight products are foods such as cheeses that are sold as random weights that vary in size, such that the net contents for different containers would vary. You may provide the typical number of servings in parentheses following the statement “varied” (e.g., “varied (usually 5 servings)” or “varied (usually 4 to 6 servings)”) (21 CFR 101.9(b)(8)(iii)).
- For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in 21 CFR 101.9 (that is, are labeled appropriately for individual sale as single-serving containers), the number of servings must be the number of individual packages within the total package (21 CFR 101.9(b)(8)(iv)).
- For packages containing several individually packaged multiserving units, the number of servings must be determined by multiplying the number of individual multiserving units in the total package by the number of servings in each individual unit (21 CFR 101.9(b)(8)(v)).

B.5 The RACC for my product is 50 g; however, a single serving of my product actually weighs 54 g because 54 g is the weight of the 1-cup household measure most closely approximating the RACC. How should the serving size be declared? Is the nutrition information based on the 50-g RACC, or the 1-cup serving size (weighing 54 g)?

The serving size and the nutrition information on the label are based on the household unit closest to the RACC (i.e., 1 cup). The RACC is used as the starting point to determine the serving size for the foods in each product category (see 21 CFR 101.9(b)(2)), but the actual amount of the product per serving (i.e., 54 g) is used to calculate the nutrient amounts for the nutrition information in the Nutrition Facts label.

B.6 What is the RACC for partially cooked, packaged pasta products? Table 2 only gives RACCs for prepared pasta and dry pasta.

The RACC for a partially cooked pasta product is the amount of partially cooked pasta that makes the RACC for cooked pasta (140 g) (see 21 CFR 101.12(c)).

B.7 What is the label serving size for fruitcake?

The label serving size for fruitcake is 1 ½ ounces (see 21 CFR 101.12(b), Table 2, footnote 5).

B.8 What is the label serving size for ice cream cones, eggs, and breath mints of all sizes?

The label serving size for ice cream cones, eggs, and breath mints is one unit (see 21 CFR 101.12(b), Table 2, footnote 8).

B.9 Table 1 in 21 CFR 101.12(b) that provides RACCs for infants and young children one through three years of age lists a RACC of 120 mL (4 fl oz) for “Juices all varieties.” What RACC should I use for beverages that are not juice in this age group?

Table 1 of 21 CFR 101.12(b) does not establish a RACC for beverages that are not juices. However, we recommend that manufacturers of beverages that are not juices, such as milk or water, use a RACC of 120 mL for this age group (4 fl oz).

C. Dual-Column Labeling

C.1 What are the requirements for mandatory dual-column labeling?

The serving size final rule requires that products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable RACC (*e.g.*, a 75-g bag of chips that is 250 percent of the RACC of 30 grams for chips) must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire package, as well as a column listing the quantitative amounts and percent DVs for a serving that is less than the entire package (*i.e.*, the serving size derived from the RACC), unless an exception applies (21 CFR 101.9(b)(12)(i)).

The first column must list nutrition information based on the serving size for the product, and the second column must list the nutrition information based on the entire contents of the package. See Figure 1 (21 CFR 101.9(b)(12)(i)).

The dual-column labeling requirements also apply to products in discrete units. If a discrete unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC, the serving size will be the amount that approximates the RACC, and the product label must provide dual-column labeling for the discrete unit, unless an exemption applies (21 CFR 101.9(b)(2)(i)(D)). The first column would list the nutrition information based on the serving size, while the second column would list the nutrition information for the individual unit (21 CFR 101.9(b)(2)(i)(D)).

Figure 1. Example of a “Dual-Column” label per serving and per container

Nutrition Facts			
2 servings per container			
Serving size		1 cup (255g)	
Calories	Per serving	Per container	
	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.

C.2 What is a discrete unit?

Examples of what constitutes a “discrete unit” are provided in 21 CFR 101.9(b)(2)(i). The examples include muffins, sliced products (such as sliced bread), or individually packaged products within a multiserving package.

C.3 Are products that have limited space for labeling exempt from the dual-column labeling requirement?

Yes. An exemption from the dual-column labeling requirements under 21 CFR 101.9(b)(12)(i) and 21 CFR 101.9(b)(2)(i)(D) is available for products that have: (1) a total surface area available to bear labeling of less than 12 square inches; or (2) a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel (21 CFR 101.9(b)(12)(i)(A)). For the exemption to apply, the product must meet the requirements to use the tabular format for small or intermediate-sized packages (see 21 CFR 101.9(j)(13)(ii)(A)(1) and Figure 2, below) or meet the requirements to use the linear format (see 21 CFR 101.9(j)(13)(ii)(A)(2) and Figure 3, below) (21 CFR 101.9(b)(12)(i)(A)). All products that are eligible for the exemption described in this paragraph are eligible to use the tabular display format (21 CFR 101.9(j)(13)(ii)(A)). Nutrition information can only be given in the linear format if the label cannot accommodate the tabular display as shown in 21 CFR 101.9(j)(13)(ii)(A)(1).

Figure 2. Example of a tabular format for packages with 40 or less square inches

Nutrition Facts	Amount/serving	% DV	Amount/serving	% DV
	Total Fat 2g		3%	Total Carb. 15g
5 servings per container	Sat. Fat 1g	5%	Fiber 0g	0%
Serving size 1/6 cup (28g)	Trans Fat 0.5g		Total Sugars 14g	
Calories per serving 90	Cholesterol 10mg	3%	Incl. 13g Added Sugars	26%
	Sodium 200mg	9%	Protein 3g	
Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%				

Figure 3. Example of a linear format for packages with 40 or less square inches

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. (6% DV).	

C.4 Are there other types of products that are exempt from the dual-column labeling requirements?

Yes. The following products are exempt from the dual-column labeling requirements: (1) raw fruits, vegetables, and seafood for which you provide nutrition labeling voluntarily on the product or in advertising, or are required to provide nutrition labeling when claims are made about the product (see 21 CFR 101.9(b)(12)(i)(B)); (2) products that require further preparation (e.g., pancake mix) and for which you voluntarily provide an additional column of nutrition information for the “as prepared” form of the food (see 21 CFR 101.9(b)(12)(i)(C) and 21 CFR 101.9(e)); (3) products that are commonly consumed in combination with another food (e.g., cereal and milk) and for which you voluntarily provide an additional column of nutrition information for the combination (see 21 CFR 101.9(b)(12)(i)(C) and 21 CFR 101.9(e)); (4) products for which you provide an additional column of nutrition information for two or more groups for which Reference Daily Intakes are established (e.g., both infants and children less than 4 years of age) (see 21 CFR 101.9(b)(12)(i)(C) and 21 CFR 101.9(e)); (5) popcorn products for which you provide an additional column of information per 1 cup popped popcorn (see 21 CFR 101.9(b)(12)(i)(C)); and (6) varied-weight products (see 21 CFR 101.9(b)(12)(i)(C) and 21 CFR 101.9(b)(8)(iii)).

C.5 Can I use voluntary dual-column labeling for products that contain more than 150 percent and less than 200 percent of the RACC to provide consumers with nutrition information per common household measure closest to the RACC to facilitate more direct comparisons of nutrition information between similar products in similar-sized containers?

Yes. If a container or package contains more than 150 percent and less than 200 percent of the applicable RACC, you may voluntarily provide on the Nutrition Facts label a second column of nutrition information, to the left of the column that provides nutrition information per container (i.e., per serving) (21 CFR 101.9(b)(6)). The voluntary column would list the quantitative

*Contains Nonbinding Recommendations
Draft-Not for Implementation*

amounts and the percent Daily Values (percent DVs) per common household measure that most closely approximates the RACC.

This provision allows the nutrition information on products such as a container of ice cream that contains 195 percent of the RACC for ice cream (*i.e.*, a single-serving container) to be compared to an ice cream product that must provide nutrition information per serving and per container, such as a container of ice cream that contains 200 percent of the RACC. In this example, if the container with 195 percent of the RACC voluntarily provides nutrition information for the common household measure closest to the RACC, consumers would be able to compare the nutritional information for the column on each product that provides nutrition information for the common household measure closest to the RACC (*i.e.*, per 2/3 cup).

Note that providing a second column of nutrition information voluntarily under 21 CFR 101.9(b)(6) does not change the serving size of the product. As explained previously in this guidance document, the serving size of a product that is packaged and sold individually that contains less than 200 percent of the applicable RACC must be labeled as one serving. Products that voluntarily provide a second column of nutrition information under 21 CFR 101.9(b)(6) are single-serving containers; however, for such products the amount most closely approximating the RACC is not the serving size.

The following graphic provides an example for a single-serving container that weighs more than 150 percent and less than 200 percent of the RACC that voluntarily adds a second column of nutrition information per household measure that is closest to the RACC (*i.e.*, per ½ cup). The serving size for the product is 1 can (*i.e.*, the full container).

Figure 4. Example of voluntary dual-column labeling for a package containing more than 150 percent and less than 200 percent of the RACC³

Nutrition Facts				
1 serving per container				
Serving size 1 can (about 1 cup) (248g)²				
	Per 1/2 cup³		Per 1 can	
Calories	70		140	
	% DV*		% DV*	
Total Fat	1g	1%	2g	3%
Saturated Fat	0g	0%	0g	0%
Trans Fat	0g		0g	
Cholesterol	0mg	0%	0mg	0%
Sodium	360mg	16%	720mg	31%
Total Carb.	13g	5%	26g	9%
Dietary Fiber	2g	7%	4g	14%
Total Sugars	3g		6g	
Incl. Added Sugars	0g	0%	0g	0%
Protein	1g		2g	
Vitamin D	0mcg	0%	0mcg	2%
Calcium	20mg	2%	40mg	4%
Iron	0.4mg	2%	0.7mg	4%
Potassium	180mg	4%	360mg	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.

D. Miscellaneous Topics

D.1 What is the label serving size for pieces of chewing gum that weigh more than the RACC and can reasonably be consumed at a single-eating occasion?

The label serving size is one unit (see 21 CFR 101.12(b), Table 2, footnote 8).

³ This example presumes that the product is a can of vegetables with liquid, with an applicable RACC of 130 g. The can contains 191% of the RACC, meaning that the package must be labeled as a single-serving container; however, a second column of nutrition information may be provided under 21 CFR 101.9(b)(6). The ½ cup is the common household measure that most closely approximates the RACC of 130 g. Therefore, the nutrition value in the dual columns show as “1/2 cup” (i.e., the household measure most closely approximating the RACC) and “1 can” (i.e., the serving). However, situations may vary depending on the actual products.

D.2 Is the Nutrition Facts Label for packages of sugar-free chewing gum required to list all nutrients that are contained in insignificant amounts?

Products in the general food supply that contain insignificant amounts of eight or more of calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium are eligible to provide a simplified declaration of nutrition information (21 CFR 101.9(f)). Products that qualify for the simplified declaration that bear nutrition claims are required to bear the statement “Not a significant source of _____” (with the blank filled in with the name(s) of any nutrient(s) identified in 21 CFR 101.9(f) that are present in insignificant amounts) and included at the bottom of the nutrition label). However, packages of sugar-free chewing gum are typically sold in small packages that may render it impracticable for the label to display a substantial amount of information. Under 21 CFR 101.9(g)(9), when “circumstance[s] make it impracticable for firms to comply” with Nutrition Facts labeling requirements, “FDA may permit alternative means of compliance or additional exemptions to deal with the situation.”

Given the small package size of certain sugar-free chewing gums and the potentially long statement that would be required if the label had to identify each nutrient that is present in insignificant amounts (see 21 CFR 101.9(f)), we consider 21 CFR 101.9(g)(9) to permit an alternative means of compliance with respect to the nutrition labeling for sugar-free gum products sold in packages for which the addition of such statement would be impracticable. In lieu of providing the “Not a significant source of _____” statement as required in 21 CFR 101.9(f)(4), we recommend that the label for such packages bear a statement such as “Not a significant source of other nutrients” at the bottom of the simplified nutrition label on sugar free chewing gum.

D.3 What are the requirements relating to multiunit retail food packages?

We recognize that many retail food products contain multiple, individually packaged items within the larger container (*i.e.*, multiunit retail food packages). FDA’s labeling requirements provide flexibility for such products, and manufacturers of such products generally have two options. The individual units within the multiunit retail food packages may be “packaged and sold individually,” meaning that each individually packaged item bears a Nutrition Facts label (81 FR 34000 at 34005). Note that, when individual units are packaged and sold individually, the Nutrition Facts label must still be visible at point of sale (see 21 CFR 101.9(h)). FDA regulations provide different requirements for unit containers in a multiunit retail food package when the individual unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale and each unit container is labeled with the statement “This Unit Not Labeled For Retail Sale” or “This Unit Not Labeled for Individual Sale” in type size not less than 1/16-inch in height, except that this statement shall not be required when the inner unit containers bear no labeling at all (see 21 CFR 101.9(j)(15)(iii)). When this option is used, the multiunit retail food package must bear nutrition information in accordance with 21 CFR 101.9.

D.4 Can Nutrition Facts or Supplement Facts labels be placed on the bottom of a food package?

Generally not. The Nutrition Facts label must be placed either on the principal display panel or on the information panel (21 CFR 101.2(b)). The “principal display panel” means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale (21 CFR 101.1). The “information panel” means the part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel, subject to a few exceptions (see 21 CFR 101.2(a)).

The bottom of the package (such as the bottom of boxes, cans, and bottles) does not generally qualify as either a principal display panel or information panel and therefore is generally not a permissible location for the Nutrition Facts label, unless it is visible during normal retail display and consumer handling (as with some frozen food packages or containers of mints and gum).

D.5 Will the increase in RACCs for certain beverages, combined with recent changes to daily values (DVs) and the mandatory declaration of potassium—as updated in the final rule titled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels,” published on the same day as the serving size final rule (81 FR 33742)—require products such as coffee, tea, and bottled water to bear mandatory nutrition labeling when such products were previously exempt under 21 CFR 101.9(j)(4)?

No. As explained in the serving size final rule, we intend to consider the exercise of enforcement discretion with respect to mandatory nutrition labeling on any products currently on the market, or that come on the market in the future, that would have been exempt under 21 CFR 101.9(j)(4) before the effective date of the serving size final rule, until such time as we have the opportunity to consider this issue in a future rulemaking (81 FR 34000 at 34026-34027). Examples of such products include coffee beans (whole or ground), tea leaves, condiment-type dehydrated vegetables, flavor extracts, food colors, and certain bottled water products.

D.6 Does FDA have recommendations or requirements relating to how nutrition information should be formatted if I use the tabular display for small packages as provided in 21 CFR 101.9(j)(13)(ii)? Specifically, are there limitations on the number of columns I can use in the tabular display?

Manufacturers using the tabular display must comply with all applicable requirements in 21 CFR 101.9. With respect to specific requirements that could impact the display of nutrition information using the tabular format, we note that 21 CFR 101.9 includes requirements for which nutrients must be indented under other nutrients (*e.g.*, under 21 CFR 101.9(c)(6)(i)(A), “Soluble fiber content shall be indented under dietary fiber”). Attempting to divide the required nutrition information into more than two columns could result in a violation of such formatting requirements. We recommend that manufacturers follow the sample tabular display for small packages provided in 21 CFR 101.9(j)(13)(ii), which uses two columns of nutrition information.